

A quarter dedicated
to progress on CE
marking

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1st Quarter 2009

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Chief Executive Officer

TM

DiAGENiC

FOR EARLIER DISEASE DETECTION



1st Quarter 2009 Highlights

A quarter dedicated to progress on CE marking

- Finalized the necessary analytical work for CE marking of both BCtect® and ADtect®
- Awarded 6.5 mill NOK research grant for development of Parkinson's Disease test
- Signed term sheet with a pharmaceutical company on development of a new biomarker
- Presented the ADtect® and the company at the ADPD congress in Prague

Post quarter end

- Signed distributor contracts for several European countries
- CE Invitro Diagnostics compliance achieved for ADtect®

Agenda:

1st Quarter
2009
Presentation

- 1st Quarter Highlights
- Product in the market
- 1st Quarter Finance
- Product Development and Clinical Studies
- Commercial Strategies
- Outlook

India

-

Continues
to be a
slow
rollout

- Our distributor continues their work on establishing BCtect[®] among key opinion leaders in New Delhi using seeding kits.
 - Several visits to customers by DiaGenic and consultants were performed in the quarter
 - To support our distributor, SRL Diagnostics, in their scientific marketing to opinion leaders in New Delhi.
 - First a scientific meeting is planned in New Delhi in June for communication to current users of BCtect[®], thereafter a national rollout is planned
 - Increased promotion activities is needed to increase the market uptake.

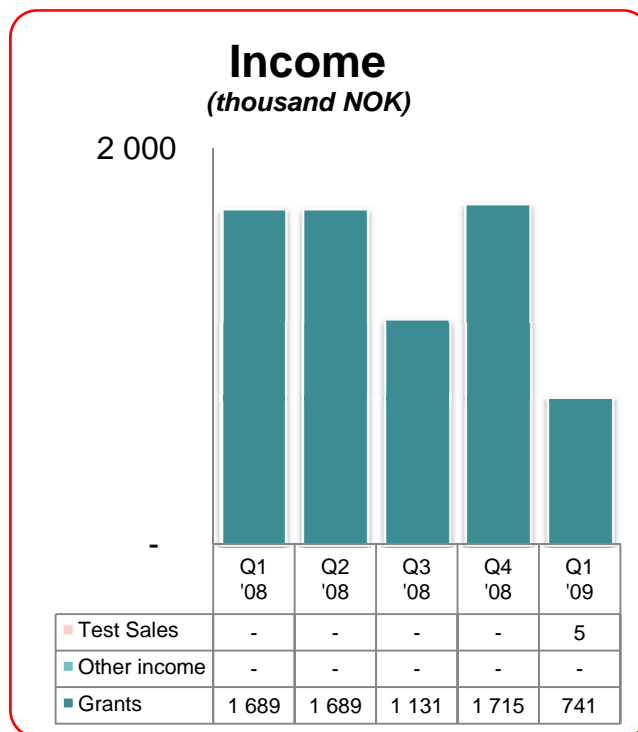


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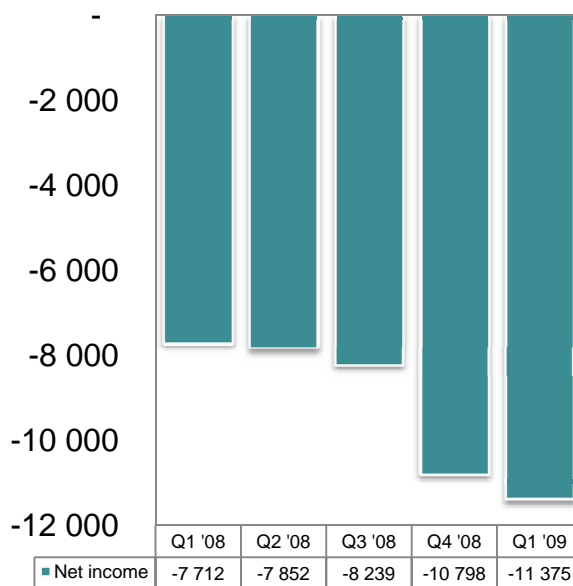
Finance, Income



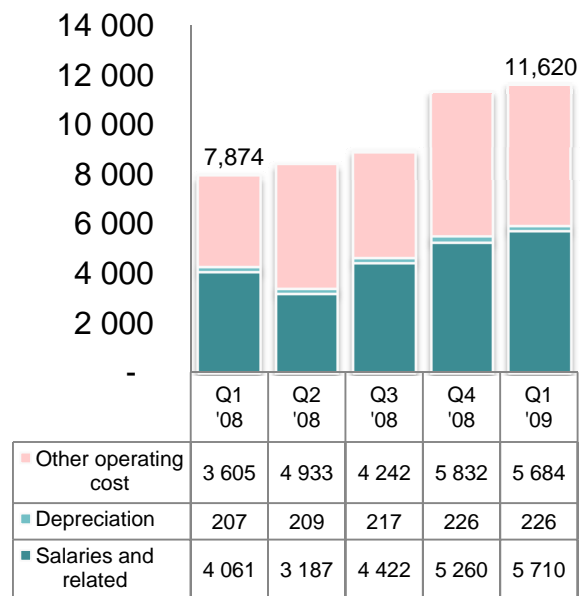
- Research grants in Q1 '09 consist of support from:
 - Michael J. Fox Foundation
 - Innovation Norway
 - EU Commission
- The FUGE Alzheimer's project ended in 2008 and is the main driver for reduced research grants.

Finance, Profit & Loss

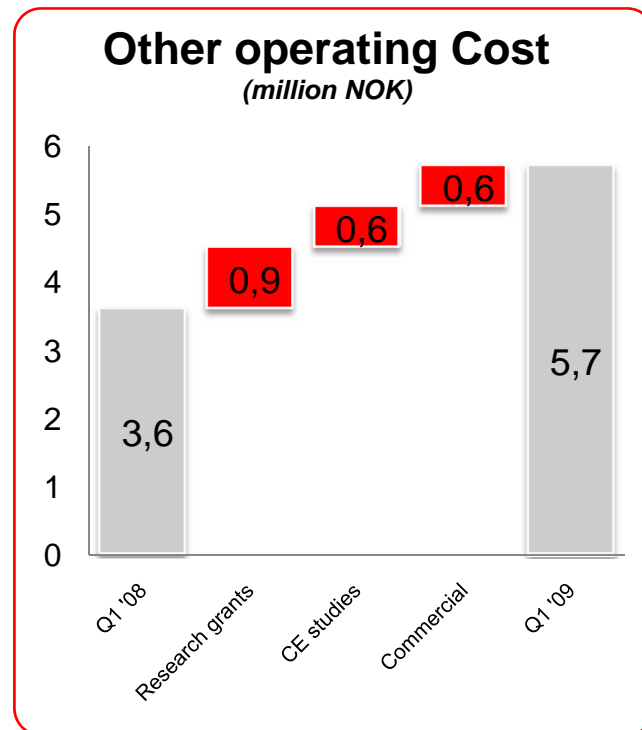
Net Income (thousand NOK)



Operating Cost (thousand NOK)



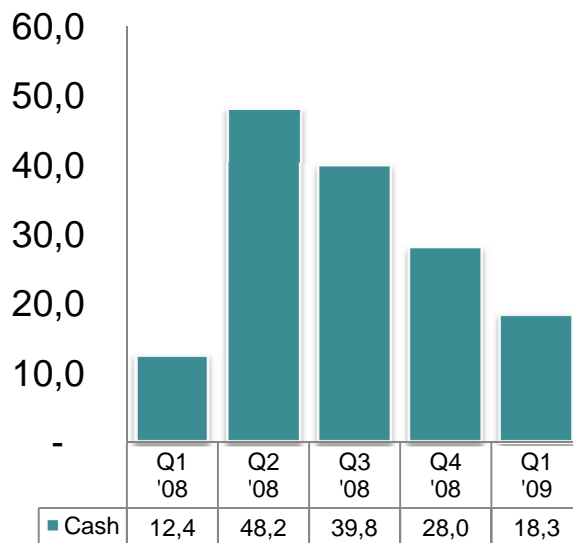
Finance, Operating cost details



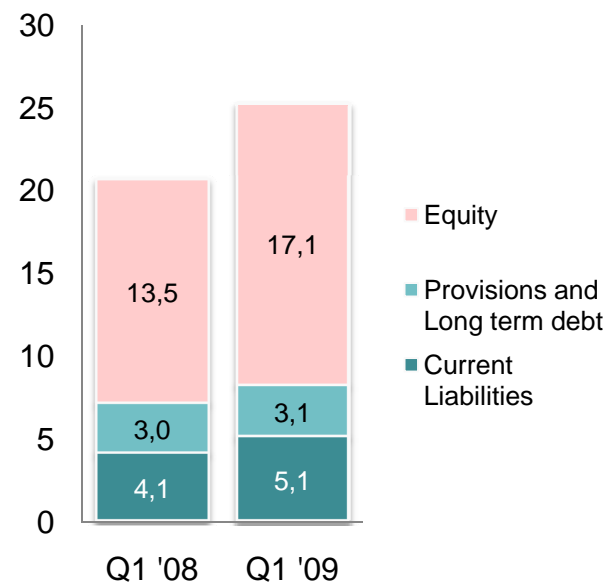
- **Salaries and related costs**
 - No. of employees at the end of first quarter:
 - 2008: 17 employees
 - 2009: 22 employees

Balance sheet

Cash and Cash equivalents (million NOK)



Equity and Liabilities (million NOK)



Finance, 2009 Outlook

- Burn rate for second quarter '09 expected to be in the same territory as first quarter '09.
- Search for external funding such as debt finance, equity finance and research grants continues.

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- The Norwegian Research Council's BIA grant
 - 6 mill NOK over 4 years initially
 - New funds supporting 2009 activities awarded.
 - Multicentre trials with university hospitals in Norway (The National Hospital and St Olav), Sweden and other European countries
 - Aims to develop a diagnostic test
 - Multicentre trial already started by DiaGenic's own means, excellent compliance from the hospitals.



Research
grants
awarded



Compliance
Studies
nearly
finished



✓ Documenting clinical utility:

- 580 patient samples tested
- Follows a strict model
 - Calibration set first, then an independent test set validation

✓ Documenting technical robustness

- 15 different studies
 - Variability across the whole process
 - Stability upon different conditions

• Data management and software implementation ongoing

- Finalised the calibration model and technical studies
 - More than 57.000 data points to be reviewed!
 - Through bioinformatic work substantial improvements on stability achieved
- Software implementation
- Report compilation before registration

CE marking within shortly



Compliance
studies
finalized



- ✓ **Documenting clinical utility:**
 - 470 patient samples tested
 - All samples reviewed by an external review board
 - Follows a strict model
 - Calibration set first, then an independent test set validation
- ✓ **Documenting technical robustness**
 - Variability across the whole process
 - Stability upon different conditions
- ✓ **Completed analysis of the studies, including the independent test set**
 - ✓ 50.000 data points reviewed and results implemented into our diagnostic software
- ✓ **CE compliance achieved**
 - Overall 72% accuracy achieved across sites.
 - Some sites have a substantial higher accuracy.
 - Additional studies ongoing with Swedish University hospitals

CE compliance to the IVD directive achieved!

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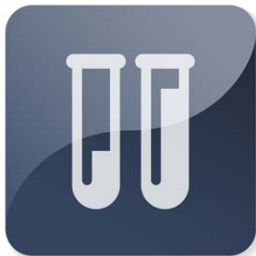
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DiaGenic
-
Business
segments



Rx- business

Biomarker for Prescription drug use



MDX-business

Molecular Diagnostics

Rx– Business

Biomarker for Prescription drug use

**Rx–
Business
Biomarker for
Prescription
drug use**



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

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, reducing entry barriers for others
- Documented and regulatory (Europe) registered tests
 - Big pharma are already collecting dedicated samples in clinical studies for the potential use on gene expression tests (Alzheimer's Disease)
- Developing a Parkinson's Disease Biomarker
 - Michael J Fox Foundation and the Norwegian Research Council
 - Collaboration with Harvard Medical School and university hospitals in Norway and Sweden
- Initiated studies needed for new diagnostic assays
 - Multicentre studies across Europe on MCI (mild cognitive impairment)
 - US sites to be added pending financing



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
- CE marked tests
 - ADtect® CE compliant
 - BCtect® soon to be CE-marked
- PDtect® in development to a diagnostic test
- Building a distributor network in Europe

Distributor agreements

- ✓ **Algol Pharma**
 - ✓ Distributor for Norway, Sweden, Denmark and Finland
- ✓ **Access Health Care**
 - ✓ Distributor for Switzerland and Austria
- ✓ **Genekor**
 - ✓ Distributor for Greece and Cyprus
- ✓ **Data Diş Ticaret (a division of the Reysas Group)**
 - ✓ Distributor for Turkey
- **Ongoing dialogue with multinational companies for other countries**
 - Pending CE documentation and local market research

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Outlook

- Once the CE mark has been achieved DiaGenic will launch BCtect® and the ADtect® in Europe.
 - Experience from opinion leaders' initial reception of BCtect® in India has been very useful for planning the launch of the test in European countries.
 - DiaGenic will now allocate resources so that the company's expertise can support distributors actively in Europe.
- In Parkinson's disease a diagnostic test PDtect® is under development.
 - The test is to be further developed into a biomarker for use in pharmaceuticals development.
- In biomarkers the company states a targeted commitment towards the pharmaceutical industry particularly within neurodegenerative diseases:
 - MCI (mild cognitive impairment, the early stages of dementia)
 - Alzheimer's disease
 - Parkinson's disease.

Outlook (Cont.)

- DiaGenic has chosen the very robust, but also relatively expensive gene card Taqman® as the basis for our first generation of diagnostic tests.
 - The next generation of tests will use technology that is significantly cheaper in operation and is automated for high volume loads. DiaGenic will start evaluation of the available technologies as soon as capacity is released in the organisation following the CE-marking of BCtect® and ADtect®.
- DiaGenic seeks partners and external financing as conditions prior to commencing clinical studies in the USA.
 - Such studies would form the basis for a subsequent application to the FDA for approval of ADtect®

Conclusion Q1 2009

- **DiaGenic's first CE compliance achieved**
 - ADtect® to be registered by the authorities.
 - Major progress on the BCtect® towards CE marking
 - Calibration and verification studies done, analysis of the independent test set ongoing
- **Distributor contracts signed**
 - 8 European countries finalized
 - Progress in dialogue with multinational companies responsible for several countries
- **The company prepares for supporting the European market**
 - Enthusiastic and hardworking employees



DiAGENiC

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20 Largest Share Holders

May 8th

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'
2 025 000	3.91	SHARMA PRAVEEN
1 914 000	3.70	A/S SKARV
1 444 870	2.79	HOLBERG NORDEN V/HOLBERG FONDSFORVA
1 400 000	2.71	SKAGEN VEKST
1 391 928	2.69	JPMORGAN CHASE BANK NORDEA TREATY ACCOUN
1 097 387	2.12	HOLBERG NORGE V/HOLBERG FONDSFORVA
1 003 100	1.94	LIVSFORSIKRINGSSELSK STRATEGISK
880 000	1.70	HAAVIND KARL WILHELM
868 478	1.68	SÆTERØY HÅKON
835 000	1.61	DnB NOR MARKETS, AKS MARKET-MAKING DERIVA
813 300	1.57	VERDIPAPIRFONDET NOR V/NORDEA FONDENE AS
708 000	1.37	AMFIBIEN AS V/ JOHN HESTAD
656 378	1.27	STORHAUG DAG
476 100	0.92	SANDEN A/S C/O JAN PETTER COLLI
432 000	0.84	BRYNILDSEN KJELL-IVAR
410 000	0.79	SEB ENSKILDA ASA EGENHANDELSKONTO
28 591 541	55.26	Sum top 20

Breast cancer

- Breast cancer is the most common for of cancers among women with more 600,000 new cases and 150,000 deaths in Europe and the US alone. Early diagnosis and treatments holds the key to survival. This has lead most western countries to establish a screening program for BC. However, the current testing methods - mammography, ultrasound and MRI - all have increasingly recognized limitations. The too low accuracy of mammography especially in women below the age of 50 and in women with dense breasts results in too many missed cancers. There is a clear need for additional and better diagnostic tools, both to improve the detection rate when using conventional mammography, and to select the appropriate patients for the new and costly MRI method. DiaGenic's concept is ideal – peripheral blood is a convenient and easily accessible clinical sample



Parkinson's disease

- Parkinson's disease (PD) is a chronic, degenerative neurological disorder and belongs to a group of conditions called motor system disorders. There is no objective test, or biomarker, for Parkinson's, so the rate of misdiagnosis can be relatively high, especially when the diagnosis is made by a non-specialist. Estimates regarding the number of people in the United States with Parkinson's range from 500,000 to 1,500,000 with 50,000 new cases reported annually. Since Parkinson's is more common in people 60 years old and older, it is expected that the incidence of Parkinson's will increase with the ageing of the baby boomers. Although PD is more common in older persons, some people begin to show symptoms before reach the age of 40. The diagnostic accuracy is only 47% in a community setting, 74% in standard geriatric and neurological practice. Experts in neurological movements disorders achieve 92-98% accuracy.
- The MJ Fox Foundation is funding a DiaGenic study together with Dr Clemens R Scherzer, Assistant Professor of Neurology at Brigham and Womens Hospital and Harvard Medical School to develop the first blood test for Parkinson's disease. This involves identification of, and independent validation of a unique gene expression signature for Parkinson using peripheral blood. Since blood samples have already been collected, the immediate start of the analytical and bioinformatics studies will ensure a rapid development of a prototype of the blood test preceding an approved diagnostic test

Alzheimer's disease



- Alzheimer's disease is the leading cause of dementia and a recent update estimates that more than 20 million people currently have the disease. Even more threatening is that these figures expect to triple in the next 30-40 years. Diagnosis of AD involves a large battery of assessments, including clinical interviews, cognitive function, and, sometimes, also functional imaging and measurements of neuro-physiological function. However, with all these tests it is still difficult to make an accurate diagnosis, especially at an early stage of the disease. There are today more than 14 disease modifying drugs in clinical phase III and it is expected that several of them will be on the market in 2 - 4 years time. Efficacy of the new drugs will depend on early diagnosis and thus boost the diagnostic market.