



DiaGenic ASA – Interim Report Q1 2010

# for early disease detection





# Growing market attention; Molecular diagnostics and biomarkers for Pharma

## 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 HIGHLIGHTS

- More clinics in UK and Finland promote BCtect®

## SALES AND MARKETING

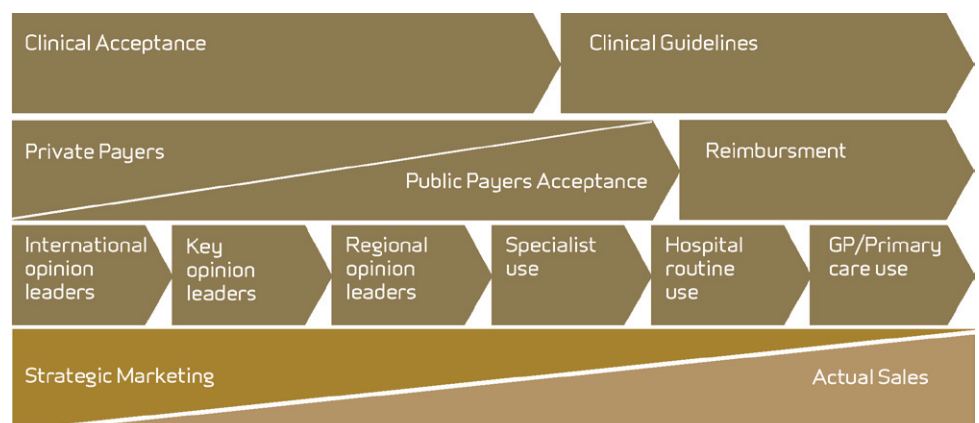
### Europe - Building the market

In the quarter DiaGenic and Ferrer inCode signed a distribution agreement for the blood-based ADtect® test for early diagnosis of Alzheimer's disease. The agreement gives Ferrer inCode, the biotech subsidiary of Grupo Ferrer Internacional, the exclusive right to sell and market ADtect® initially in Germany, Belgium, the Netherlands, Luxemburg, France, Italy, Spain and Portugal followed by Latin America.

The core teams in Spain and Germany have received product training and start promoting ADtect® in their countries from June 2010, followed by BeNeLux and France late 2010, and launch in Italy in 2011. The launch will follow the traditional principles of scientific marketing, and local scientific advisory boards are being prepared with key opinion leaders.

Quest Diagnostics, the distributor in UK and Ireland, is actively promoting BCtect® to private clinics, and in late March the London Breast Clinic ([www.thelondonbreastclinic.com](http://www.thelondonbreastclinic.com)) officially opened for testing. They offer both BCtect® as a stand-alone test and in a discounted package with mammography and clinical consultation. This activity has created substantial interest from other clinics and media. This agreement has not materialised in any sales in the first quarter. After the quarter, two hospitals in the larger Nuffield Health hospital group ([www.nuffieldhealth.com](http://www.nuffieldhealth.com)), the Bristol and Glasgow Hospitals, publicly announced the future availability of BCtect®. Algol Pharma has signed the first private clinic in Finland as customer for BCtect®.

In accordance with our plan for scientific marketing, DiaGenic's distributors together with representatives from DiaGenic targeted several Key Opinion Leaders (KOL's) across Europe to gain clinical acceptance. This has resulted in local clinical studies ongoing or awaiting local review board approval in Norway, Switzerland and Greece. With these studies the KOL's gain experience with the test on their own patients and aim for local presentations in scientific meetings.





## BIOMARKERS FOR DRUG DEVELOPMENT AND COMPANION DIAGNOSTICS

*Providing biomarkers for drug development and companion diagnostics is a key strategic focus area for DiaGenic.*

During the quarter readout of clinical trials in the Alzheimer's area strengthens the need for improved and uniform clinical diagnosis of AD patients. DiaGenic has registered an increasing interest from larger Pharma and imaging companies on the use of gene expression within this challenging field, supporting the relevance of our technology. DiaGenic continues discussions with leading pharmaceutical companies on the use of ADtect® and on MCItect co-development.

To support this strategy DiaGenic participated after the quarter end at the annual BIO International Convention 2010 in Chicago, USA, with a booth at the Scandinavia Pavilion. During the meeting DiaGenic's presentation to large Pharma companies received positive interest.





## RESEARCH AND PRODUCT DEVELOPMENT

### Alzheimer's disease

The development of ADtect® was based on a multi-centre clinical study with patients recruited from memory clinics and hospitals. The independent validation within the CE-study had a limited number of patients included. To expand the dataset DiaGenic has conducted an extensive study including 130 new patients and controls, making the combined study to one of the largest within this area.

In a subset of patients recruited from Swedish hospitals a much higher accuracy was observed (>85%). This reflects the true accuracy of the test when compared to patients with a higher accuracy of the clinical diagnosis by using CSF biomarkers.

Future Alzheimer's disease drugs will most likely target the disease stage before full clinical presentation, the Mild Cognitive Impairment (MCI) stage. To enhance development of our MCItect, DiaGenic has entered into collaboration with several university hospitals in the Netherlands, Germany and Denmark, in addition to our ongoing collaboration with University of California, Davis.

An oral presentation titled "Validation of a novel blood test for the early detection of Alzheimer's disease - Challenges with an 'imperfect gold standard'" by Research Director Anders Lönneborg was held at the 25th International Conference of Alzheimer's disease. The DiaGenic sales exhibition was well attended and presented in a national television report from the congress.

The article "Identifying a gene expression pattern in peripheral blood for the early detection of Alzheimer's disease" by B Boij et al and "A validated blood test for early detection of Alzheimer's disease" by P Rye et al were submitted for publications. These articles describe the gene selection studies and the final development of our ADtect® test.

### Breast Cancer

The CE studies support the claim for aid in diagnosis of breast cancer in patients on diagnostic workup of suspected cancer and with a competitive advantage in premenopausal females.

In the quarter BCtect and its use were presented at the following international congresses:

2nd Asian Breast Cancer Congress (ABCC). DiaGenic hosted a symposium titled: "*Gene expression profiling – a novel tool for prognosis and early detection of breast cancer*".

7th European Breast Cancer Conference, EBCC 2010. DiaGenic presented a poster "*Early breast cancer detection: Validation of a commercially available blood-based gene expression test*" and a sales exhibition.

IMPAKT 2009 Breast Cancer Conference. DiaGenic presented a poster "*Validation of a blood based gene expression test, BCtect®, for the detection of breast cancer.*"

The article: "*Gene expression profiling of peripheral blood cells for early detection of breast cancer*" by J Aaroe et al was published in Breast Cancer Research 2010. This article discusses our probe selection based on whole genome screening of breast cancer patients and is the reference for coming publications on BCtect®.

### Parkinson's disease

The development of a test for early detection of Parkinson's disease is supported by a research grant from the Norwegian Research Council, through their user directed innovation programme (BIA). The ongoing sample collection studies in Europe are progressing, and have reached the gene identification and selection phase. DiaGenic intends to perform a whole genome analysis of a subset of samples to ensure optimal test accuracy.

### PATENTS

During the first quarter DiaGenic received a "Notice of Allowance" for its family 3 patent application in New Zealand, which is the second patent in family 3. The patent when granted will cover a set of gene sequences and gene families for diagnosis of breast cancer.

The company also filed a new patent application having a short title "Diagnostic gene expression platform" (earliest priority date 10th January, 2010). The invention here relates to oligonucleotide probes, provided in kit form, which may be used to prepare gene expression patterns and identify, diagnose or monitor breast cancer or stages thereof.

## FINANCIAL REVIEW

*Costs in Q1 2010 flat from Q4 2009. NOK 33 million in cash at quarter end.*

Comparative figures from the corresponding period last year are shown in parentheses.

### Comprehensive income

#### Revenues and research grants

DiaGenic had no operating revenues in first quarter 2010 (NOK 5k). Research grants are entered net into the accounts (reducing operating costs). Research grants for the first quarter 2010 were NOK 863k (NOK 741k).

#### Operating costs

Total operating costs after deducting research grants were NOK 11,933k (NOK 11,624k) for the first quarter. Salaries and personnel expenses amounted to NOK 6,374k (NOK 5,710k) and all other operating costs were NOK 5,366k (NOK 5,910k) for the first quarter. The increase in salaries and personnel expenses in first quarter 2010 compared with the corresponding period in 2009 is mainly due to an increase in pension costs. Cost of Goods Sold for first quarter 2010 totalled NOK 194k (NOK 4k) and relates in principal to a provision for obsolescence in inventory.

### Financial position

Total assets at 31 March 2010 were NOK 42,146k (NOK 25,338k), of which current assets amounted to NOK 38,566k (NOK 21,624k). Cash and cash equivalents

accounted for the largest share of current assets at the end of March 2010 with a balance of NOK 32,921k (NOK 18,250k). Total value of inventory was NOK 2,425k (NOK 1,430k) at 31 March 2010.

Equity at 31 March 2010 amounted to NOK 26,352k (NOK 17,140k). Current liabilities at the end of March 2010 was NOK 7,448k (NOK 5,128k) and pension liabilities totalled NOK 2,774k (NOK 2,132k). Other long term liabilities at 31 March 2010 totals NOK 5,572k (NOK 938k) and includes lease of laboratory equipment and 4 year loan from Innovation Norway in the amount of NOK 5 million. Current interest rate on the loan is 5.75% p.a.

### Cash flows

Net cash flow from operating activities for first quarter 2010 was NOK -10,995k (NOK -9,282k). The main driver for the year over year variances in operating cash flow is changes in accounts receivable balances. Financing activities for first quarter 2010 includes a completed share offering for total net proceeds (after deducting issue expenses) in the amount of NOK 8,747k. The company's cash and cash equivalents are held in bank deposits and amounted to NOK 32,921k (NOK 18,250) on 31 March 2010.

### Equity and Financing

In the quarter the Company issued 3.5 million shares for total gross proceeds of NOK 9.6 million and consequently increased share capital by NOK 175k to NOK 3,512k. As resolved by the general meeting on 18

December 2009 participants in the private placement on 26 November 2009 and the share issue on 22 December 2010 were allotted 1 warrant for each share allotted in the share issues. Subscription price for the warrants are set to NOK 3.25 per share and the warrants may be exercised up to 30 September 2010.

## RISK FACTORS

The information contained in this report includes certain forward looking statements that address activities, events or developments that the company expects, projects, believes in or anticipates will occur in the future. These statements are based on various assumptions made by the Company which are beyond the Company's control and subject to risk factors and uncertainties. The Company is exposed to a large number of risk factors including, but not limited to, market acceptance of the company's products, necessary approvals from the authorities and the clinical effectiveness of the company's products. Reference is made to the annual report for 2009 and Prospectus dated 21 January 2010 for further information relating to risk factors. As a result of the above-mentioned or other risk factors actual events and the actual result may differ significantly from that indicated in the forward looking statements. For 2010 key risks are considered to evolve around product launch and sales progression of the tests in addition to liquidity risk related to need for sufficient capital for future operations until revenues from operations can cover operating costs.

## Future prospects

- 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 to the pharmaceutical industry.

# FINANCIAL STATEMENTS- Q1/2010

STATEMENT OF COMPREHENSIVE INCOME	Note	2010	2009	2009
<i>(figures NOK thousands)</i>		<i>Q1</i>	<i>Q1</i>	<i>1 Jan-31 Dec.</i>
Operating Income				
Other income		0	5	131
<b>Total operating revenue</b>		<b>0</b>	<b>5</b>	<b>131</b>
Operating expenses				
Cost of goods sold	4	194	4	372
<b>Total cost of goods sold</b>		<b>194</b>	<b>4</b>	<b>372</b>
Operating costs				
Wages and social costs		6,374	5,710	21,275
Depreciation		235	226	966
Writedown		0	0	352
Other operating costs		5,131	5,684	17,021
<b>Total other operating costs</b>		<b>11,739</b>	<b>11,620</b>	<b>39,614</b>
<b>Total operating costs</b>		<b>11,933</b>	<b>11,624</b>	<b>39,986</b>
<b>Operating profit (loss)</b>		<b>-11,933</b>	<b>-11,619</b>	<b>-39,856</b>
Financial income		224	289	738
Financial expenses		106	45	214
<b>Net financial income/expense</b>		<b>117</b>	<b>244</b>	<b>524</b>
<b>Pre-tax profit (loss)</b>		<b>-11,816</b>	<b>-11,375</b>	<b>-39,332</b>
Income tax costs (benefits)		0	0	0
<b>Net profit (loss)</b>		<b>-11,816</b>	<b>-11,375</b>	<b>-39,332</b>
Other comprehensive income		0	0	0
<b>Comprehensive income</b>		<b>-11,816</b>	<b>-11,375</b>	<b>-39,332</b>
<b>Net profit per share (figures in NOK)</b>		<b>-0.17</b>	<b>-0.22</b>	<b>-0.73</b>
<b>Net profit per share after dilution</b>		<b>-0.17</b>	<b>-0.22</b>	<b>-0.73</b>

# STATEMENT OF FINANCIAL POSITION

	Note	2010	2009	2009
<i>(figures NOK thousands)</i>		<i>31 March</i>	<i>31 March</i>	<i>31 Dec</i>
<b>ASSETS</b>				
Fixed assets				
Goodwill		572	572	572
Software		1,475	761	1,559
Fixed assets		1,533	2,381	1,576
<b>Total non-current assets</b>		<b>3,580</b>	<b>3,714</b>	<b>3,707</b>
Current assets				
Inventory	4	2,425	1,430	2,127
Trade receivables		0	0	141
Other receivables		3,220	1,943	5,105
Cash and cash equivalents		32,921	18,250	35,404
<b>Total current assets</b>		<b>38,566</b>	<b>21,624</b>	<b>42,777</b>
<b>Total assets</b>		<b>42,146</b>	<b>25,338</b>	<b>46,484</b>
<b>EQUITY AND LIABILITIES</b>				
Equity				
Share capital	2	3,512	2,587	3,337
Paid in equity	2	34,656	25,927	65,368
Other equity		-11,816	-11,375	-39,332
<b>Total equity</b>		<b>26,352</b>	<b>17,140</b>	<b>29,373</b>
Provisions				
Pension liabilities		2,774	2,132	2,571
<b>Total provisions</b>		<b>2,774</b>	<b>2,132</b>	<b>2,571</b>
Other long term liabilities				
Other long term liabilities		5,572	938	5,698
<b>Total other long term liabilities</b>		<b>5,572</b>	<b>938</b>	<b>5,698</b>
Current liabilities				
Accounts payable		2,310	1,433	3,307
Social security, VAT etc. payable		931	874	1,950
Other current liabilities		4,207	2,822	3,586
<b>Total current liabilities</b>		<b>7,448</b>	<b>5,128</b>	<b>8,842</b>
<b>Total equity and liabilities</b>		<b>42,146</b>	<b>25,338</b>	<b>46,484</b>



CASH FLOW STATEMENT	Note	2010	2009	2009
<i>(figures NOK thousands)</i>		<i>Q1</i>	<i>Q1</i>	<i>1 Jan-31 Dec.</i>
<b>Cash flow from operating activities</b>				
Pre-tax profit (loss)		-11,816	-11,375	-39,332
Income taxes paid		0	0	0
Ordinary depreciation		235	226	966
Impairment of fixed assets		0	0	352
Fair value granted option rights		48	102	409
Loss on sale of fixed assets		0	0	0
Change in pension scheme liabilities		203	170	609
Change in inventories, accounts receivable and accounts payable		-1,153	-2,024	-988
Change in other short-term receivables and other short-term liabilities		1,488	3,619	2,296
<i>Net cash flow from operating activities</i>		<i>-10,995</i>	<i>-9,282</i>	<i>-35,687</i>
<b>Cash flow from investment activities</b>				
Proceeds from sale of fixed assets		0	0	0
Acquisitions of fixed assets		-108	-310	-1,394
<i>Net cash flow from investing activities</i>		<i>-108</i>	<i>-310</i>	<i>-1,394</i>
<b>Cash flow from financing activities</b>				
Proceeds from share issue		8,747	0	39,883
Proceeds from new loan		0	0	5,000
Payment of long term liabilities		-126	-116	-356
<i>Net cash flow from financing activities</i>		<i>8,621</i>	<i>-116</i>	<i>44,527</i>
<i>Net change in cash and cash equivalents</i>		<i>-2,483</i>	<i>-9,708</i>	<i>7,446</i>
<b>Cash and cash equivalents</b>		<b>32,921</b>	<b>18,250</b>	<b>35,404</b>

STATEMENT OF CHANGES IN EQUITY AND NUMBER OF SHARES:

<i>(figures in NOK/numbers)</i>	<i>Note</i>	<i>Share capital</i>	<i>Share prem. reserve</i>	<i>Other reserves</i>	<i>Other equity</i>	<i>Total equity</i>	<i>Number of shares</i>
<b>As at 1st January 2009</b>		<b>2,586,826</b>	<b>25,825,158</b>	<b>0</b>	<b>0</b>	<b>28,411,984</b>	<b>51,736,520</b>
Fair value granted subscription rights		0	0	409,322	0	409,322	0
Increase of capital - 8th July 2009		125,000	9,225,000	0	0	9,350,000	2,500,000
Transaction cost		0	-702,115	0	0	-702,115	0
Increase of capital - 26th November 2009		625,000	33,750,000	0	0	34,375,000	12,500,000
Transaction cost		0	-3,139,705	0	0	-3,139,705	0
Comprehensive income 01.01.-31.12.2009		0	0	0	-39,331,572	-39,331,572	0
Allocation of comprehensive loss		0	-38,922,250	-409,322	39,331,572	0	0
<b>As at 31st December 2009</b>		<b>3,336,826</b>	<b>26,036,088</b>	<b>0</b>	<b>0</b>	<b>29,372,916</b>	<b>66,736,520</b>
Fair value granted subscription rights		0	0	47,964	0	47,964	0
Increase of capital - 22nd February 2010	2	175,000	9,450,000	0	0	9,625,000	3,500,000
Transaction cost		0	-878,105	0	0	-878,105	0
Comprehensive income 01.01.-31.03.2010		0	0	0	-11,815,847	-11,815,847	0
<b>As at 31st March 2010</b>		<b>3,511,826</b>	<b>34,607,983</b>	<b>47,964</b>	<b>-11,815,847</b>	<b>26,351,928</b>	<b>70,236,520</b>

## Note 1: Presentation

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The financial information is prepared in accordance with International Accounting Standard 34 "Interim Financial Reporting" ("IAS 34"). This financial information should be read together with the financial statements for the year ended 31st of December 2009 prepared in accordance with International Financial Reporting Standards ("IFRS").

The accounting policies used and the presentation of the Interim Financial Statements are consistent with those used in the latest Annual Financial Statements.

The preparation of the Interim Financial Statements requires management to make estimates and assumptions that affect the reported amounts of revenues, expenses, assets, liabilities and disclosure of contingent liabilities at the date of the Interim Financial Statements. If in the future such estimates and assumptions, which are based on management's best judgment at the date of the Interim Financial Statements, deviate from the actual circumstances, the original estimates and assumptions will be modified as appropriate in the period in which the circumstances change.

## Note 2: Going concern

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The financial statement is presented on the going concern assumption under International Financial Reporting Standards. Accordingly, the financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts, the amounts and classification of liabilities, or any other adjustments that might result should the Company be unable to continue as going concern.

As per the date of this report the Company does not have sufficient working capital for its planned business activities over the next twelve month period. Proceeds from sales revenue is not expected to be adequate in order to cover necessary funding requirement for the coming twelve month period. In February 2010 the Company carried out a share issue with gross proceeds of NOK 9.6 million. In accordance with the resolution at the Extraordinary General Meeting on 18th of December 2009, the Company issued a total of 16 million warrants in February 2010. Each warrant holds the right to subscribe for one new share in the Company at a subscription price of NOK 3.25. The warrants may be exercised up to and including 30th of September 2010. Upon full exercise of the warrants as mentioned above, the company will have sufficient working capital for the next 12 months at today's cost. Targeted efforts are pursued in order for the warrants to be exercised. If the warrants are not exercised it might lead to needs for further refinancing of the Company. Sources of funding include loans, equity financing and research funding. The Board of Directors and the management team are positive that efforts to secure further funding can be completed. The Board of Directors confirmed on this basis that the going concern assumption is valid, and that financial statements are prepared in accordance with this assumption.

## Note 3: Related parties

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Transactions with related parties by way of consultancy services took place in the quarter. The transactions are considered to be immaterial in the quarter. All transactions and agreements are made on commercial terms from the market for goods and services.

### Other transactions

Transactions with companies that have connections to related parties are conducted at market terms, based on the principle of arm's length.

## Note 4: Inventory – figures in TNOK

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	Q1 - 2010	Q1 - 2009
Inventory	2.425	1.430

Inventory is valued at lower of cost and net selling price. Inventory is valued to cost. A provision for obsolescence resulted in a TNOK 107 reduction in inventory value and increased Cost of Goods Sold in Q1 2010.

## Note 5: Events after the balance sheet date

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At the date of this report, there are no events after the balance sheet date which will affect the company's position on the balance sheet date, or which are essential for the company's future financial position.



DiaGenic ASA

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