# INTERIM REPORT - Q3 2008



- Breast cancer test, BCtect™, approved by Super Religare Laboratories Ltd (SRL) following extensive internal testing.
- Commercial launch of BCtect™ in India scheduled for 8 November 2008
- Research grant awarded by the EU Commission
- → New patents in Japan, New Zealand and Hong Kong

## HIGHLIGHTS FOLLOWING QUARTER END:



DiaGenic designated DNA Vision as the European clinical reference laboratory





#### BREAST CANCER

DiaGenic's first commercial test will be launched in India on 8 November 2008.

BCtect™ has been chosen as the product name of the breast cancer test:



The positive results from the comprehensive clinical multi-centre study to document the diagnostic value of BCtect™ in India have formed the basis for the commercial launch by Super Religare Laboratories Ltd (formerly SRL Ranbaxy Ltd). SRL has completed the quality audit of the reference laboratory Labindia, received feedback from doctors in the target group and tested its own logistical processes. BCtect™ gave correct predictions in this important study by SRL with blinded samples that documented the entire process from taking blood samples and transportation of samples through to processing at Labindia.

Comprehensive marketing material has been prepared by SRL, from general information folders for women to detailed documents for doctors to support the correct use of the test.

The commercial launch of BCtect™ will take place on 8 November 2008 in New Delhi. The initial launch will be followed by a subsequent roll-out to the 10 largest cities in India. By early 2009 it is expected that the test will be available across India.

The introductory positioning of the test in Europe will primarily focus on the younger (pre-menopausal) women with higher radiological density in their breasts and women with symptoms such as multiple tumors in their breasts.

Studies to document the use of BCtect™ as a first line test for screening familiar high risk younger women are under preparation. These studies should provide the required documentation for the test to be reimbursed in many countries.

DiaGenic gave a oral lecture and a poster presentation at the "International Society of Oncology and Biomarkers" conference in Tokyo from 5 to 9 October. The results presented showed a sensitivity of 75 % among Indian premenopausal women. Mammography has significantly lower sensitivity among women with high radiological breast density.

#### ALZHEIMER'S DISEASE

DiaGenic has chosen the name ADtect™ for the Alzheimer's disease test:



To support CE marking of ADtect™ DiaGenic has increased the number of collaborating partners, research programmes and hospitals in Europe. An extensive review of study locations, with presentations of procedures and training, has been carried out to ensure high standards.

The early stage of Alzheimer's disease, mild cognitive impairment (MCI), continues to have a high priority through the FUGE-supported multi-centre study in Norway and DiaGenic's own multi-centre study in Sweden. Cooperation with EDAR and other EU supported projects has given access to several study locations and centres of expertise. The development of a diagnostic test to detect patients with MCI who will progress into Alzheimer's disease is of key importance in all our discussions with pharmaceutical companies.

#### PARKINSON'S DISEASE

The joint project to develop a biomarker together with Harvard Medical School, financed by the Michael J. Fox Foundation, is now in an active phase - the first gene selections have been made using the probes selected by Harvard and DiaGenic. These are now being analysed using blood samples received from Harvard and gene cards delivered by Applied Biosystems. Several Norwegian and Swedish university hospitals have been enrolled in a DiaGenic led multi-centre study for clinical verification and validation of the Parkinson's test. On completion of this project, further external finance will be pursued for the development of an approved diagnostic marker.

#### RESEARCH GRANTS

DiaGenic is participating in an extensive EU supported research programme called "Standardisation and improvement of generic pre-analytical tools and procedures for in vitro diagnostics" (SPIDIA). In SPIDIA, 4 biotech companies, 6 universities and research organisations and the official European Standardisation organisation (CEN) are involved. The project is an integrated cooperative project to improve, standardise and quality assure the molecular biological techniques used in blood and tissue based diagnostic testing. As a participant in the programme DiaGenic will receive a grant of appro-

ximately EUR 580,000 distributed over 4 years. The grant will be used to develop further the pre-analytical process for the analysis of blood based gene expression and to be implemented in the Alzheimer test.

#### **PATENTS**

DiaGenic has been informed that patent applications for Japan, New Zealand and Hong Kong will be approved. The patent in Japan and New Zealand covers both Alzheimer's disease and breast cancer, while the patent in Hong Kong is an extension of the European Alzheimer's patent.

### REGULATORY

Preparations for ISO certification from Det Norske Veritas and for CE mark of the BCtect™ and ADtect™ tests under the IVD directive are proceeding in parallel. The plan is to have both tests CE marked by early 2009 in order to secure the first revenues from Europe in the first half of 2009.

#### PARTNER STRATEGY

In order to ensure quality and easy access to the tests from launch, DiaGenic has chosen similar strategy in Europe as in India. The analytical work will be performed at a central reference laboratory and several distributors will market and sell the tests. Blood samples will be taken at collection centres and sent to the central laboratory.

expression analysis supplier by Applied Biosystems. DNA Vision is currently carrying out a number of studies for leading pharmaceutical companies and diagnostic firms.

In addition to the central laboratory DiaGenic intend to have an operational distribution network in place once the first tests are CE marked. This will enable sale as soon as the tests are CE marked. Dia-Genic is currently negotiating with relevant distributors and will give priority to companies with sales networks in several countries, and complementary products in their portfolio. DiaGenic's objective is to have a distribution network for the most important markets in Europe ready when the tests are CE marked.

#### FINANCE

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

#### **INCOME AND RESEARCH GRANTS**

DiaGenic had no operating income in the first nine months of the year. Research grants are entered net in the accounts. In the 3rd quarter of 2008 DiaGenic





posted NOK 1,131k (1,879k) in research grants. For the first nine months of the year research support amounted to NOK 4,510k (5,294k).

#### **OPERATING COSTS**

Total operating costs for the 3rd quarter of 2008 after deducting government grants amounted to NOK 8,881k (6,937k). Salaries and personnel costs represented NOK 4,422k (4,123k) of total operating costs in the 3rd quarter of 2008. Other operating costs totalled NOK 4,242k (2,629k). The increase in other operating costs net of grants for the 3rd quarter of 2008 compared with the corresponding period in 2007 is due to greater activity in product development and lower research grants.

For the first nine months of the year total operating costs after deducting government grants amounted to NOK 25,084k (21,202k). Salaries and personnel costs represented NOK 11,670k (10,671k). The rise mainly relates to an increase in staffing to cover the expansion in product development activity. Other operating costs represented NOK 12,781k (9,982k) of total operating costs in first nine months of the year. The main reason for the increase in other operating costs is the higher level of activity relating to commercialisation and costs in connection the expansion in product development activity.

#### **BALANCE SHEET**

Total Assets at 30th September 2008 was NOK 47,912k (36,034k), of which Current Assets amounted to NOK 44,499k (32,377k). During the third quarter inventory for consumables in India has been established. Inventory amounted to NOK 1,424k (0) at the end of the third quarter.

Equity capital at 30th September 2008 was NOK 39,121k (28,452k). Short-term debt at 30 September 2008 was NOK 5,680k (4,894k). Long-term debt at the end of the 3rd quarter of 2008 was NOK 1,117k (1,418k) and relates to the leasing of equipment for the company's laboratory.

#### **CASHFLOW AND FINANCING**

The net change in liquidity in the 3rd quarter of 2008 amounted to NOK -8,360k (-4,436k). The main driver for the change in cashflow from the 3rd quarter of 2007 to the 3rd quarter of 2008 is the change in cashflow from operating activities. In the 3rd quarter of 2008 cashflow from operating activities amounted to NOK -7,925k (-3,940k). The main

factors in the change in cashflow from operating activities between the two quarters are changes in net profit (loss), receivables and inventory.

For the first nine months of the year the net change in liquidity was NOK 20,147k (2,317k). The main reason for the increase in net cashflow is a higher cashflow from financing, which amounted to NOK 41,209k (24,005k) for the first nine months of the year. The cashflow from financing is mainly linked to the size of share issues, as the issue carried out in 2008 raised NOK 41,509k in net proceeds (after deduction of issue expenses), while the issue carried out in 2007 raised NOK 24,257k in net proceeds. The company's liquid assets are held in bank deposits and at 30 September 2008 amounted to NOK 39,812k (27,884k). The deposits will be distributed with 3 different Norwegian banks with high credit ratings.

The quarterly report has been prepared in accordance with IAS 34. The accounting principles used in this quarterly report correspond to those used in the accounts for the year 2007.

#### FUTURE PROSPECTS

DiaGenic will launch the BCtect™ test in New Delhi in collaboration with our partners Super Religare Laboratories and Labindia on 8 November 2008. The other major cities in India will follow in early 2009. DiaGenic will actively contribute to support the launch and marketing of the test.

In light of the global financial turbulence DiaGenic has chosen to give priority to activities that are necessary to bring forward products for sale. In addition to the launch in India these are activities that are necessary to obtain the CE mark in Europe for BCtect™ and ADtect™. The company is in process to establish a distribution network for Europe and expects that such a network will be in place for the most important countries when CE marking of the products is obtained. When the tests have been launched in Europe the company will have diagnostic tests on sale in two important geographic regions.

DiaGenic will continue to seek external funding (research grants, partner deals and non dilutive financing) of costly clinical studies for development of new products and for entry into new geographic markets.

FINACIAL STATEMENT- Q3/2008

FINACIAL STATEMENT- QE PROFIT & LOSS ACCOUNT	2008		2007		2008	2007	2007
(figures NOK thousands)	Q3		Q3	П	1 Jan-30 Sept	1 Jan-30 Sept	1 Jan-30 Dec
Operating Income							
Other income	0		0		0	0	-50
Total operating revenue	0		0		0	0	-50
Operating costs							
Wages and social costs	4,422		4,123		11,670	10,671	13,86
Depreciation	217		185		633	550	76
Other operating costs	4,242		2,629		12,781	9,982	14,44
Total operating costs	8,881		6,937		25,084	21,202	29,07
Operating profit (loss)	-8,881		-6,937		-25,084	-21,202	-29,01
Financial income	686		330		1,399	793	1,08
Financial expenses	44		54		118	151	19
Pre-tax profit (loss)	-8,239		-6,662		-23,803	-20,561	-28,12
Income tax costs (benefits)	0		0		0	0	
NET PROFIT (LOSS)	-8,239		-6,662		-23,803	-20,561	-28,12
	-,	_	5,552	T			
Net profit per share (figures in NOK)	-0.16		-0.14		-0.34	-0.47	-0.6
Net profit per share after delution	-0.16		-0.14		-0.34	-0.47	-0.6
BALANCE SHEET					2008	2007	200
(figures NOK thousands)					30 Sept	9/30/2008	31 D
ASSETS							
Fixed assets							
Goodwill					572	572	57
Fixed assets					2,840	3,085	3,02
Total non-current assets		_		-	3,412	3,657	3,59
Current assets Inventories					1 424	0	
Other receivables					1,424 3,263	4,493	6,88
Cash and cash equivalents					39,812	27,884	19,66
Total current assets					44,499	32,377	26,54
TOTAL ASSETS					47,912	36,034	30,14
EQUITY AND LIABILITIES							
Equity					62.025	40.013	40.1
Paid in equity					62,925	49,013	49,17
Other equity Total equity					-23,803 39,121	-20,561 28,452	-28,12 21,0!
iotal equity					33,121	20,432	21,0.
Provisions							
Pension liabilities					1,994	1,270	1,60
Total provisions					1,994	1,270	1,60
Other long term liabilities							
Other long term liabilities					1,117	1,418	1,4
Total other long term liabilities					1,117	1,418	1,4:
Liabilities							
Accounts payable					3,421	2,114	1,7
Social security, VAT etc. payable					694	643	1,0
Other current liabilities Total current liabilities					1,565 5,680	2,137 4,894	3,30 6,00
		Г			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	,== ,	
TOTAL EQUITY AND LIABILITIES					47,912	36,034	30,14



FINACIAL STATEMENT- Q3/2008											
CASH FLOW STATEMENTS	2008		2007		2008		2007		2007		
(figures NOK thousands)	Q3		Q3		1 Jan-30 Sept		1 Jan-30 Sept		1 Jan-30 Dec		
Cash flow from operating activities											
Pre-tax profit (loss)	-8,239		-6,662		-23,803		-20,561		-28,125		
Income taxes paid	0		0		0		0		0		
Ordinary depreciation	217		185		633		550		767		
Impairment of fixed assets	0		0		0		0		0		
Fair value granted option rights	110		165		363		489		126		
Loss on sale of fixed assets	0		0		0		0		0		
Change in pension scheme liabilities	129		-195		387		-101		235		
Change in inventories, accounts receiveable and accounts payable	-205		1,479		260		-2,122		-2,499		
Change in other short-term receivables and other short-term liabilities	64		1,087		1,547		577		-262		
Net cash flow from operating activities	-7,925		-3,940		-20,612		-21,169		-29,758		
Cash flow from investment activities											
Proceeds from sale of fixed assets	0		0		0		0		0		
Acquisitions of fixed assets	-266		-384		-450		-519		-675		
Net cash flow from investing activities	-266		-384		-450		-519		-675		
								П			
Cash flow from financing activities											
Contribution of share capital	-76		0		41,509		24,257		24,257		
Payment of long term liabilities	-93		-112		-300		-252		-254		
Net cash flow from financing activities	-169		-112		41,209		24,005		24,003		
Net change in cash and cash equivalents	-8,360		-4,436		20,147		2,317		-6,430		
Cash and cash equivalents	39,812		27,884		39,812		27,884		19,666		
Changes in Equity and Number of Shares:			Share prem.		Other		Other		Total		Number
(figures in NOK/numbers)	Share capital		reserve		reserves		equity		equity		of shares
As at 1st January 2007	1,988,326		22,279,144		0		0		24,267,470		39,766,520
Fair value granted subscription rights	0		0		654,236		0		654,236	П	0
Increase of capital - 11th May 2007	198,500		24,058,200		0		0		24,256,700		3,970,000
Net loss 1st January - 31st December 2007	0		0		0		-28,125,039		-28,125,039		0
Allocation of net loss	0		-27,470,803		-654,236		28,125,039		-0		0
As at 31st December 2007	2,186,826		18,866,541		0		0		21,053,367		43,736,520
Fair value granted subscription rights	0		0		362,993		0		362,993		0
Increase of capital - 7 May 2007	400,000		41,108,221		0		0		41,508,221		8,000,000
Net loss 01 Jan 30 September 2008	0		0		0		-23,803,112		-23,803,112		0
Allocation of net loss	0		0		0		0		0		0
As at 30th September 2008	2,586,826		59,974,762		362,993		-23,803,112		39,121,470		51,736,520



DIAGENIC ASA GRENSEVEIEN 92 N-0663 OSLO TLF: 23 24 89 50 FAX: 23 24 89 59

E-MAIL: DIAGENIC ADIAGENIC.COM

