Interim Report 2011

DiaGenic ASA

DiaGenic

Highlights

MCItect®: The first blood based test for early Alzheimer disease (AD)

- *DiaGenic is leading the development with an early Alzheimer test (MCItect®) that can predict Mild Cognitive Impairment (MCI) patients converting to AD within 2 years with prediction accuracy of 74% enabling early disease intervention.*
  - *MCItect® is ready for use in phase II clinical trials*
  - *US FDA pre IDE (Investigational Device Exempt) submission of MCItect® after verification and validation studies (Investigational use only).*
  - *This documentation will also provide European CE labeling for MCItect®*
  - *Upon approval, MCItect® can be used to develop companion diagnostics.*
  - *MCItect® US FDA PMA (Pre-Market Approval) submission for regular clinical use, thereby also supporting Alzheimer drug sales, after performance of EU/US prospective trial.*

Gene expression test for 18F PET imaging in Alzheimer disease

- *DiaGenic continue discussions with world leading imaging companies to develop a test that correlates with brain deposits of amyloid in the brain detected by PET (Positron Emission Tomography) imaging. Discussions are progressing.*
  - *Combining imaging and blood based tests improves quality of AD management through optimal use of PET imaging.*

Parkinson disease: New R&D progress, data presentation in China and interest from Pharma

- *A DiaGenic whole genome study identifying gene signatures that can detect Parkinson disease with improved accuracy in the important early disease state was presented at the XIX World Congress on Parkinson's Disease and Related Disorders in November 2011.*
  - *Total accuracy of 88%, Sensitivity of denovo PD is increased to 85%, while previously only 70% was reported. Expands the potential clinical utility*
  - *Substantial pharma interests in an early disease biomarker for clinical PD trials*

Financial review

- *2011 pre-tax earnings, NOK -34.8 million, improved by NOK 7.1 million compared with 2010.*
- *Cash balance of NOK 59 million at the end of the year.*

CNS BIOMARKERS FOR DRUG DEVELOPMENT AND COMPANION DIAGNOSTICS

The main focus area of DiaGenic is to provide biomarkers for drug development and companion diagnostics first within Alzheimer's disease (AD) followed by Parkinson's disease (PD).

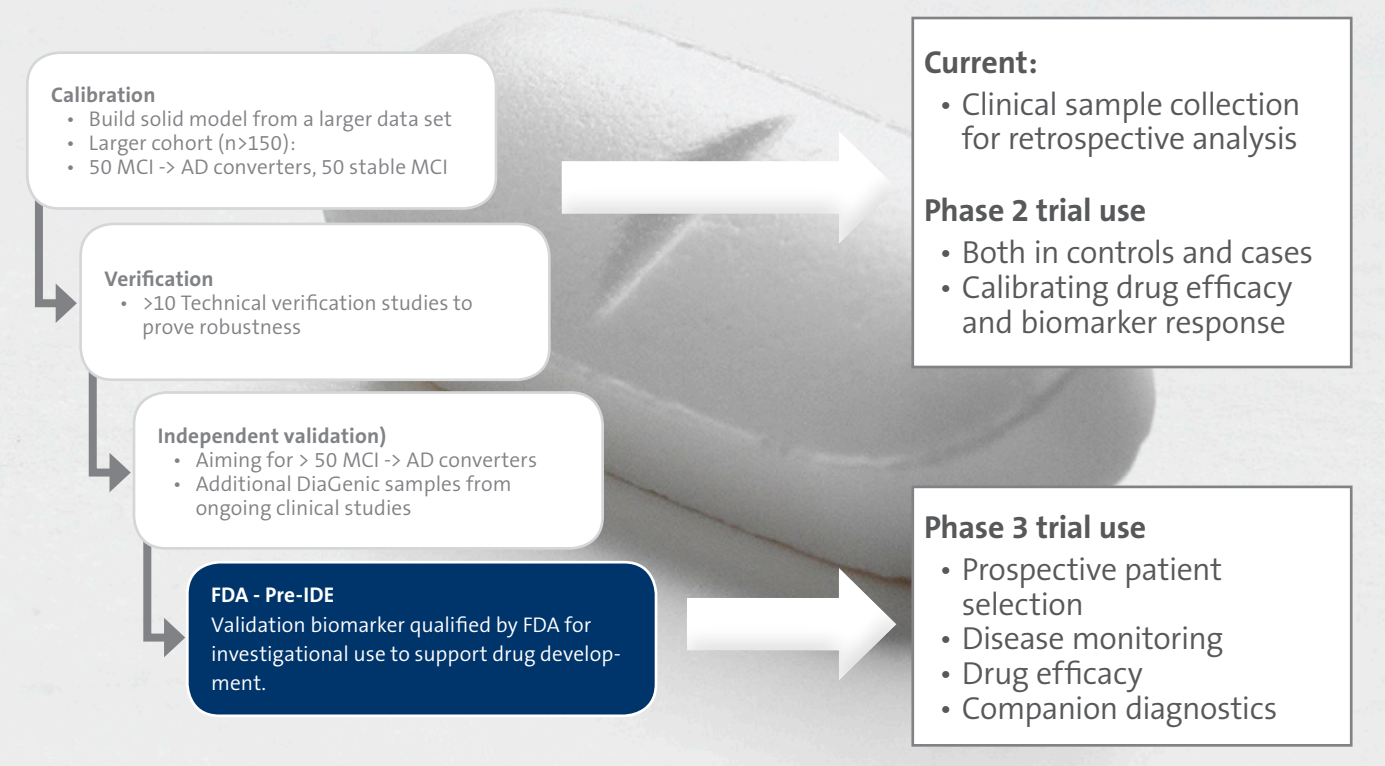
The number of AD patients and associated medical expense will grow exponentially between 2010 and 2050. Forecasts by the Alzheimer Association in the US indicate that Medicare and Medicaid alone will spend $ 130 billion in 2011, growing by more than 20% each year if no advances are made. A treatment that delays disease onset by only 5 years will reduce the overall cost of AD by 40%.

In the last decade a number of clinical trials have failed to demonstrate clinical effects of tentative new drugs. Currently several phase III clinical studies are ongoing, and results from the first three (Solanezumab, Bapineuzumab and Gammagard) are expected later in 2012. Treatment of Alzheimer's disease is currently a 5.8 billion USD market, with an annual growth of 11%, increasing to 14.5 billion USD in 2020 upon successful development of new disease modifying drugs targeting the early stages of the disease.

As the world's first blood-based prodromal AD gene expression markers, DiaGenic has demonstrated that MCI patients converting to AD within two years can be identified in an MCI population with a prediction accuracy of 74 %. Identification of patients converting to AD within 2 years is key for short (18-24 months) clinical trials. The performance of the biomarker is also similar to spinal fluid (CSF) biomarkers (current only available biochemical test for R&D) in a smaller cohort within the study. Blood tests are preferred by clinicians and pharma companies due to cost effective ease of use.

These results, as world's first in blood, have created encouraging attention among our potential pharma partners seeing the potential expansion of their addressable markets, and been a valuable tool to move our dialogues forward. The multiple dialogues and negotiations during Q4 have been intensive, constructive and progressive. The potential partners express a clear motivation and need for having a blood based biomarker such as the one DiaGenic is developing. Pharma companies express two needs:

- To have access to a non-invasive blood-based prodromal AD biomarker to support drug development in Phase II and Phase III. Using a blood based tool to identify AD at an early stage has the potential to substantial reduce the expensive clinical trial costs, decrease noise and thereby increase the success rate. DiaGenic aim to develop a FDA qualified biomarker for use in pharmaceutical clinical studies ("investigational use only" label), planning for FDA PreIDE submission after verification and validation studies.
- An FDA approved diagnostic test for clinical use which supports their sales of both existing and potential new drugs. In their view, DiaGenic's blood based test is easy accessible and can be used in a non-specialized setting. Currently there are no FDA approved diagnostic tests for AD. Immunoassays for spinal



fluid testing are available in selected laboratories as a lab developed test (LDT). These tests are invasive (spinal fluid tap) with inherent risks and have a high procedural cost in addition to the assays. Blood based testing is clearly preferred and may increase the potential for an early diagnosis and therapeutic intervention resulting in increased quality of managing the disease and thereby delaying the costly end-phase of the disease.

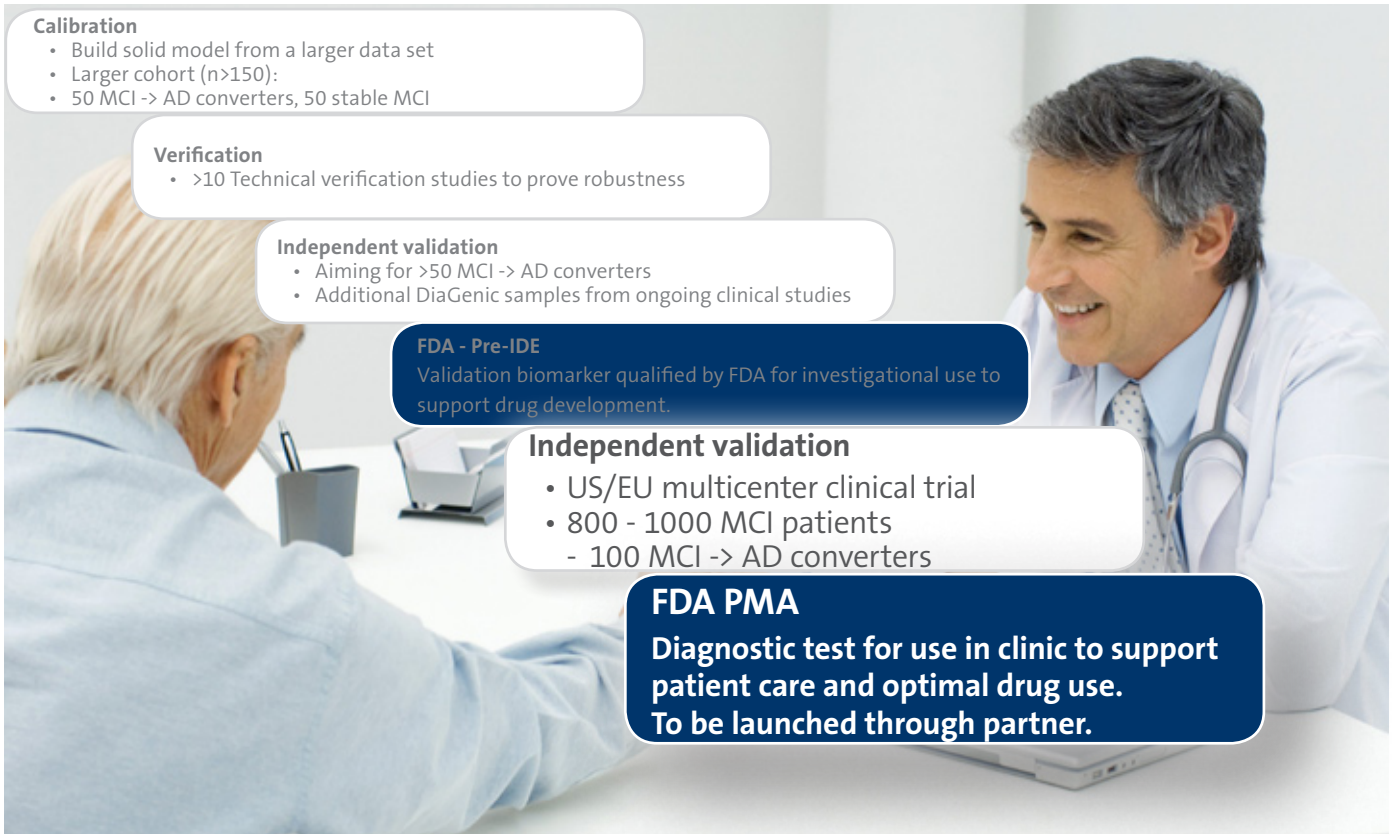
We continue to develop our novel prodromal AD test (MCItect) through new rigorous studies to demonstrate both robustness (verification studies) and performance (validation studies) in independent clinical cohorts. These studies aim for an FDA PreIDE (Investigational Device Exempt) application for use in clinical trials. Until then our test can be applied in phase II trials, and in phase III trials for retrospective analysis. These studies will also provide the necessary documentation for European CE marking for regular clinical use in patients. Upon approval from FDA this biomarker can be used in pivotal phase III trials to support registration.

The use of blood based gene expression biomarkers together with high cost PET imaging as part of a multimodal diagnostic approach will be a valuable tool that contribute to reduced costs, increased access and improved quality in the diagnostic work-up of patients with AD and especially in the pre dementia stages. PET imaging is proposed as an imaging biomarker to detect brain deposits of beta amyloid and this PET market is expected to reach above 1 billion USD in 2020. Our discussion and negotiation with one of the leading producers of amyloid PET tracers is also progressing, including public funding options. Through this collaborative agreement DiaGenic intends to develop a specific gene expression signature test that correlates with brain deposits of amyloid as detected by PET imaging. A multi modal diagnostic approach combining biochemical and neuroimaging methods has also recently been defined in the recent issued "Dubois criteria" for Alzheimer's disease R&D accepted both in Europe and in the US, and has also gained support within EMA.

MOLECULAR DIAGNOSTICS – ALZHEIMER'S DISEASE

DiaGenic has recently performed two independent surveys of the US blood based diagnostic market for our Alzheimer's tests. These studies used different methodologies to better describe the current US market needs for a blood based diagnostic test with specifications similar to ADtect®. One of the surveys gave a market forecast based on a survey amongst 104 clinicians subsequent to in depth discussions with key opinion leaders. With the current market, existing treatment options, reimbursement policy and test accuracy of 80% one could project peak sales in US of in the range of 200 million USD within 5 years for a blood based test. With the arrival of new effective therapeutic options (including Companion Diagnostics) one could, depending on the effectiveness of the drugs, expect peak sales of a pre-dementia stage AD test like MCItect® and ADtect® to multiply several times.

Prerequisites for a successful entry into this promising market include successful development of an FDA approved diagnostic test and the availability of a commercial partner (laboratory chain or diagnostic company) with sufficient market outreach. The development of an FDA approved biomarker builds upon the studies from the PreIDE (Investigational Device Exempt) application as described above. A subsequent PMA (Pre Market Approval) application to FDA contains a clinical validation from a prospective study following MCI patients over 18-24 months. This US multicentre study will be built on top of ongoing clinical studies in Europa.



FURTHER PROGRESSION IN DIAGENIC DEVELOPMENT ACTIVITIES IN THE LAST QUARTER OF 2011

A unique gene signature for prodromal Alzheimer's disease identified and presented

As previously described, DiaGenic successfully completed a pilot study in Mild cognitive impairment (i.e. the pre-dementia stage of AD) in 3Q 2011, a study which was built on our collaboration with Pfizer. The result of this study was presented in November 2011 at the Clinical Trials Conference in Alzheimer's disease which was held in San Diego under the title "Development of a blood-based gene expression test for identification of Prodromal AD and rate of progression in AD". For the first time, a gene signature in blood that detects pre-dementia stage (or prodromal) AD was presented. In addition, a gene signature for progression rate in AD was also identified. Such tests may enable an earlier detection of AD in a stage when the disorder has yet only had a limited degenerative effect on the brain. Furthermore, a progression test would also enable monitoring of treatment effects in AD and may serve as a decision making biomarker for Pharmaceutical companies.

Parkinson's disease

Parkinson's disease (PD) is the second most common neurodegenerative disorder after Alzheimer's disease. No cure has been launched but at least 26 pharmaceutical companies are currently developing medicines many of which target disease modification in PD.

In the 4th quarter of 2011 we presented results from our whole genome study which, with high accuracy, identified gene signatures in blood in Parkinson's disease patients. These results created substantial interest from several pharmaceutical companies developing medicines for PD. Furthermore, these companies state that DiaGenic is in the forefront of this new field and that our biobank with serial samples from PD patients is unique. The results of our preliminary bioinformatic explorations were presented both as an oral lecture with the title "Gene expression profiling of peripheral blood for detection of Parkinson's disease" and the bioinformatic work as a poster at the XIX World Congress on Parkinson's Disease and Related Disorders, 11th-14th of December, Shanghai, China. The research is done as part of collaboration with Norwegian University of Life Sciences.

Further analysis of gene expression data from the whole genome study has demonstrated a model accuracy of 88% (89% sensitivity and 87% specificity) using a set of around 700 probes. This study contained 79 PD patients, including 27 denovo PD, 109 controls and technical samples. We used the Illumina platform for the whole genome screening to identify disease related probes (gene transcripts) and to develop disease specific diagnostic models. In total more than 11.000 genes were expressed in blood and around 2.000 were impacted by PD. Early diagnosis of PD is challenging and a clinical accuracy of below 60% by non specialists is often reported, in this group of patients we reported 85% sensitivity. However accurate identification is needed for developing new disease modifying drugs.

PATENTS

In the fourth quarter 2012, a new patent application (family 5) was filed. The invention describes a broad range of gene probes and their functional equivalents to identify and diagnose different stages of Alzheimer's disease (AD), particularly pre-dementia (or prodromal) AD. Furthermore, gene probes to monitor disease progression in patients with AD are also described in the application. The probes and their functional equivalents are provided in a kit form.

The new application strengthens our patent portfolio and ensures protection for our future AD- related product pipeline. The increasing patent portfolio makes DiaGenic a leader in the field of blood- based molecular diagnostics.

The decision to grant the previous communicated US breast cancer patent USPTO 8105773 (11,628300) has now been issued.

POST QUARTER OUTLOOK

- Execute on the companion diagnostic strategy, closing R&D agreements with pharmaceutical and imaging companies within the CNS field.
- Initiating new US collaborations to expand our Alzheimer biobank supporting the development of an early (Prodromal) AD test
- DiaGenic's current strategy for entry into the US Alzheimer diagnostic market is through a FDA PMA application.
  - Execution and readout of calibration, verification and validation studies

Financial review

2011 pre-tax earnings of NOK -34.8 million, improved by NOK 7.1 million compared with 2010. Cash balance of NOK 59 million at the end of the year.

In the fourth quarter DiaGenic had NOK operating revenues of NOK 0.1 million from sales of ADtect® and collection kits, and NOK 1.6 million in research grants. The corresponding figures for fourth quarter 2010 are NOK 1,078k in operating revenues and NOK 1,338k in research grants. Following the positive findings from the Pfizer pilot study, the main business activities during the quarter have been focused on driving potential pharma partner agreements forward and continue the ongoing clinical studies within the fields of Alzheimer's disease.

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

Comprehensive income

Revenues and research grants

DiaGenic had NOK 60k (NOK 1,078k) in operating revenues in the fourth quarter and NOK 3,095k (NOK 1,093k) for the full year 2011. Operating revenues in the quarter relates to sales of ADtect® and collection kits (a kit that contains components used to collect patient blood samples). Fourth quarter 2010 revenue relates to income from collaborative agreements with pharma based on milestones achieved. Operating revenues for the full year are mainly revenue from collaborative agreements with pharma based on milestones achieved, which will vary quarter on quarter. Research grants are entered net into the accounts (reducing other operating costs). Research grants for the fourth quarter 2011 were NOK 1,570k (NOK 1,338k) and NOK 4,587k for full year 2011 (NOK 4,117k).

Operating costs

Total operating costs after deducting research grants were NOK 9,375k (NOK 11,605k) for the fourth quarter and NOK 40,116k (NOK 43,625k) for the full year. Salaries and personnel expenses amounted to NOK 6,872k (NOK 5,944k) for the fourth quarter and NOK 23,643k (NOK 22,129k) the full year. Other operating costs less salaries and personnel expenses were NOK 2,036k (NOK 4,019k) for the fourth quarter and NOK 13,372k (NOK 18,768k) for the twelve month period. The main driver behind the increase in Salaries and personnel expenses from fourth quarter 2010 to fourth quarter 2011 is pension costs. The reduction in other operating costs is mainly due to lower blood sample expense in the quarter compared with the corresponding period in 2010.

Financial position

Total assets at 31 December 2011 were NOK 68,603k (NOK 111,700k), of which current assets amounted to NOK 65,010k (NOK 107,291k). Cash and cash equivalents accounted for the largest share of current assets at the end of December 2011 with a balance of NOK 58,859k (NOK 98,838k). Total value of inventory was NOK 915k (NOK 978k) at 31 December 2011.

Equity at 31 December 2011 amounted to NOK 54,975k (NOK 89,596k). Current liabilities at the end of December 2011 was NOK 8,094k (NOK 13,835k) and pension liabilities totaled NOK 3,867k (NOK 3,084k). Other long term liabilities at 31 December 2011 totals NOK 1,667k (NOK 5,185k) and relates to a loan from Innovation Norway. Total balance of the loan at 31 December 2011 is NOK 3,333k, of which NOK 1,667k is classified as long term liability.

Cash flows

Net cash flow from operating activities for fourth quarter 2011 was NOK -5,435k (NOK -3,063k). The main driver for the year over year variance in operating cash flows relates to movements in the accounts payable balances. Payment of long term liabilities for the full year 2011 includes a NOK 1667k down payment of a loan from Innovation Norway. The company's cash and cash equivalents are held in bank deposits and amounted to NOK 58,859k (NOK 98,838k) on 31 December 2011.

Equity and number of shares

Effective from 30 May 2011 DiaGenic performed a reverse share split in the ratio 10:1. Consequently the number of shares in the Company was reduced from 270,236,520 shares to 27,023,652 shares, and the face value per share increased from NOK 0.05 to NOK 0.50.

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 and the success of the pharma companies' drug development programs. Reference is made to the annual report for 2010 and Prospectus dated 2 November 2010 for further information relating to risk factors. As a result of the abovementioned or other risk factors actual events and the actual result may differ significantly from that indicated in the forward looking statements. For the next 12 month period key risks are considered to evolve around entering collaborative agreements with key healthcare players, the potential terms in such collaborative agreements and the outcome of the delivery in such collaborative agreements.

FINANCIAL STATEMENT - Q4/2011

Statement of comprehensive income

	Note	2011	2010	2011	2010
(figures NOK thousands)		*Q4*	*Q4*	*1 Jan-31 Dec*	*1 Jan-31 Dec*
Operating Income					
Other income		60	1 078	3 095	1 093
Total operating revenue		**60**	**1 078**	**3 095**	**1 093**
Operating expenses					
Cost of goods sold	4	245	1 362	2 140	1 805
Total cost of goods sold		**245**	**1 362**	**2 140**	**1 805**
Operating costs					
Wages and social costs		6 872	5 944	23 643	22 129
Depreciation		222	279	961	923
Other operating costs		2 036	4 019	13 372	18 768
Total other operating costs		**9 130**	**10 242**	**37 976**	**41 820**
Total operating costs		**9 375**	**11 605**	**40 116**	**43 625**
Operating profit (loss)		**-9 315**	**-10 527**	**-37 021**	**-42 532**
Financial income		697	523	2 669	1 058
Financial expenses		103	-72	401	348
Net financial income/expense		**595**	**595**	**2 268**	**710**
Pre-tax profit (loss)		**-8 720**	**-9 932**	**-34 753**	**-41 821**
Income tax costs (benefits)		0	0	0	0
Net profit (loss)		**-8 720**	**-9 932**	**-34 753**	**-41 821**
Other comprehensive income		0	0	0	0
Comprehensive income		**-8 720**	**-9 932**	**-34 753**	**-41 821**
Net profit per share (figures in NOK)	*5*	*-0.32*	*-0.56*	*-1.29*	*-1.95*
Net profit per share after dilution	*5*	*-0.32*	*-0.56*	*-1.29*	*-1.95*

FINANCIAL STATEMENT - Q4/2011

Statement of financial position

	Note	2011	2010
(figures NOK thousands)		*31 Dec*	*31 Dec*
Assets			
Fixed assets			
Goodwill		572	572
Software		888	1 223
Fixed assets		2 133	2 614
Total non-current assets		**3 594**	**4 410**
Current assets			
Inventory	4	915	978
Trade receivables		53	2 999
Other receivables		5 183	4 476
Cash and cash equivalents		58 859	98 838
Total current assets		**65 010**	**107 291**
Total assets		**68 603**	**111 700**
Equity and liabilities			
Equity			
Share capital	2	13 512	13 512
Paid in equity	2	76 216	76 085
Retained earnings		-34 753	
Total equity		**54 975**	**89 596**
Provisions			
Pension liabilities		3 867	3 084
Total provisions		**3 867**	**3 084**
Other long term liabilities			
Other long term liabilities		1 667	5 185
Total other long term liabilities		**1 667**	**5 185**
Liabilities			
Accounts payable		1 689	6 618
Social security, VAT etc. payable		1 554	1 609
Other current liabilities		4 851	5 607
Total current liabilities		**8 094**	**13 835**
Total equity and liabilities		**68 603**	**111 700**

FINANCIAL STATEMENT - Q4/2011

Cash flow statements

	Note	2011	2010	2011	2010
(figures NOK thousands)		*Q4*	*Q4*	*1 Jan-31 Dec*	*1 Jan-31 Dec*
Cash flow from operating activities					
Pre-tax profit (loss)		-8 720	-9 932	-34 753	-41 821
Income taxes paid		0	0	0	0
Ordinary depreciation		222	279	961	923
Impairment of fixed assets		0	0	0	0
Fair value granted option rights	6	87	43	237	187
Loss on sale of fixed assets		0	0	0	0
Change in pension scheme liabilities		314	-96	783	514
Change in inventories, accounts receiveable and accounts payable		480	3 469	-1 920	1 602
Change in other short-term receivables and other short-term liabilities		2 182	3 174	-1 519	2 311
Net cash flow from operating activities		*-5 435*	*-3 063*	*-36 211*	*-36 284*
Cash flow from investment activities					
Proceeds from sale of fixed assets		0	0	0	0
Acquisitions of fixed assets		0	-1 482	-145	-1 626
Net cash flow from investing activities		*0*	*-1 482*	*-145*	*-1 626*
Cash flow from financing activities					
Contribution of share capital		0	93 426	-106	101 858
Proceeds from new loan		0	0	0	0
Payment of long term liabilities		-2 101	-188	-3 518	-513
Net cash flow from financing activities		*-2 101*	*93 239*	*-3 624*	*101 345*
Net change in cash and cash equivalents		*-7 487*	*88 694*	*-39 979*	*63 434*
Cash and cash equivalents		**58 859**	**98 838**	**58 859**	**98 838**

FINANCIAL STATEMENT - Q4/2011

Statement of changes in Equity and Number of Shares

(figures in TNOK exept shares)	Note	Share capital	Share prem. reserve	Other reserves	Other equity	Total equity	Number of shares
As at 1st January 2010		**3 337**	**26 036**	**0**	**0**	**29 373**	**6 673 652**
Fair value granted subscription rights		0	0	187	0	187	0
Increase of capital - 22nd February 2010	2	175	9 450	0	0	9 625	350 000
Transaction cost		0	-1 194	0	0	-1 194	0
Increase of capital - 3rd November 2010		7 000	63 000	0	0	70 000	14 000 000
Increase of capital - 3rd December2010		3 000	27 000	0	0	30 000	6 000 000
Transaction cost		0	-6 574	0	0	-6 574	0
Comprehensive income 01.01.-31.12.2010		0	187	-187	-41 821	-41 821	0
Allocation of comprehensive loss			-41 821		41 821	0	0
As at 31st December 2010		**13 512**	**76 085**	**0**	**0**	**89 596**	**27 023 652**
Fair value granted option rights	6	0	0	237	0	237	0
Transaction cost		0	-106	0	0	-106	0
Comprehensive income 01.01.-31.12.2011		0	0	0	-34 753	-34 753	0
As at 31st December 2011		**13 512**	**75 979**	**237**	**-34 753**	**54 975**	**27 023 652**

Oslo, 13 th of February 2012

Henrik Lund
Chairman

Ingrid Wiik
Deputy Chairman

Gustav Ingmar Kihlström
Board member

Ulrica Slån
Board member

Tom Pike
Board member

Erik Christensen
Managing Director

FINANCIAL STATEMENT - Q4/2011

Notes

Note 1: Presentation

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 2010 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

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.

The Company has sufficient working capital for its planned business activities over the next twelve month period.

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

Transactions with related parties by way of consultancy services took place in the quarter. The transactions in the quarter are considered not to be significant.

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

Supplier:	Related part:	Q4	Acc. pr. 31.12.11
Ingmar Kihlstrøm AB	Ingmar Kihlström	25 647	117 528
Cornucopia AS	Henrik Lund	135 000	300 000
		160 647	417 528

Note 4: Inventory – figures in thousand NOK

	Q4 2011	Q4 2010
Inventory	915	978

Inventory is valued at lower of cost and net selling price. Inventory is recorded at cost in the financial statements.

Note 5: Earnings per share - figures in NOK

The following table shows the changes in number of shares in 2011:

	Ordinary shares
Number of shares as of 1st of January (amended figure)	27 023 652
Number of shares as of 31th of December	27 023 652
Average number of shares per 31th of December	27 023 652

At this year's General Assembly it was decided to implement a reverse split in the ratio 10:1, which was executed 30 May 2011. The comparative figures for earnings per share has been amended retrospectively in the quarterly report.

Note 6: Share options

On 5th of September 2011 the Board of Directors in DiaGenic ASA allotted options to DiaGenic employees. The share options have strike price of NOK 6.00 per share, which is set based on weighted share price + 10%. The options have life of 4 years and can be exercised after 3 years.

Note 7: Events after the balance sheet date

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

DiaGenic ASA
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