



QUARTERLY REPORT

September 2011 – November 2011

Quarterly Report Diamyd Medical AB (publ), fiscal year 2011/2012
(www.omxgroup.com ticker: DIAM B; www.otcqx.com ticker: DMYDY)

Reporting period September 1, 2011 – November 30, 2011

- Group total net sales amounted to MSEK 0.1 (144.5)
- Profit before tax amounted to MSEK -7.4 (98.3)
- Earnings per share after dilution were SEK -0.26 (3.32)
- The Group's liquid assets amounted to MSEK 414 (478) as of November 30, 2011

Significant events during the reporting period

- Diamyd Medical was awarded a USD three million grant and expanded the NTDDS portfolio
- University of Florida Research Foundation and Diamyd Medical settled lawsuit

Significant events after the reporting period

- Prevention study with Diamyd Medical's diabetes vaccine was fully recruited

CEO COMMENTS

2012 will be an exciting and significant year for Diamyd Medical. We now have only a handful of subjects left to enroll in our US Phase II study in cancer pain with the drug candidate NP2 Enkephalin. Work is underway to ensure the quality of data and to prepare everything so that we will be able to obtain the results as quickly as possible after the last patient has been included in the study. Our prognosis to be able to present results from the study some time during the first half of 2012 remains unchanged. The results are important to Diamyd Medical, as it is the first time a drug candidate from the Company's NTDDS platform is tested in a larger patient population. Sustained pain relief was achieved in a smaller, non-placebo-controlled, Phase I study with NP2 Enkephalin. That study included ten subjects with cancer pain. No serious treatment-related adverse events were observed in that study.

With positive results from the Phase II study, we will be ready to actively seek partners for the further development of NP2 Enkephalin and other applications of the NTDDS platform and to start clinical trials with the next drug candidate from the platform, NG2 GAD. We have good prospects given our financial resources and our streamlined organization with valuable experience from both clinical development and from concluding significant partnership agreements with large pharmaceutical companies.

NTDDS stands for Nerve Targeting Drug Delivery System which is an innovative technology that enables delivery of therapeutics directly to the nervous system. The purpose is to achieve a local effect in the cells where the treatment is targeted without affecting the rest of the body. It is a unique concept that, if it proves successful, may provide new opportunities to address various medical problems of the nervous system which today cannot be adequately treated, such as chronic pain, neuropathy, cancer and neurodegenerative diseases.

The Annual General Meeting was held in December and we can now put the turbulent 2011 behind us and put all our focus on the future. A few weeks before the meeting, we reached an agreement with the University of Florida and could thereby settle the dispute with them. We started the new year with the good news that the Swedish prevention study with the Diamyd[®] diabetes vaccine had recruited its fiftieth and final subject. The study aims to prevent type 1 diabetes in children who are at high risk of developing the disease, and it will be very interesting to follow the coming few years.

Our measures to reduce costs have certainly had an impact during the reporting period. We are now down to one third of the costs compared to the same period last year. The Company's cash position with around SEK 400 million, corresponding to approximately SEK 14 per share, means that the financing of the existing business is secured and also provides the Company with strategic leeway. The newly elected board has continued the active strategy work which was initiated last year and is continuously evaluating different scenarios. The results from the Phase II study with NP2 Enkephalin will of course affect the Company's strategic choices going forward, but we will be well prepared regardless the outcome of the study.

Stockholm, January 25, 2012

Peter Zerhouni
President and CEO Diamyd Medical AB

SIGNIFICANT EVENTS DURING THE REPORTING PERIOD SEPTEMBER 1, 2011 – NOVEMBER 30, 2011

Diamyd Medical was awarded a USD three million grant and expanded the NTDDS portfolio. Diamyd Medical with collaborators received a USD three million grant from the US National Institutes of Health to develop the Company's patented Nerve Targeting Drug Delivery System (NTDDS) for prevention of Chemotherapy Induced Peripheral Neuropathy. The grant allows Diamyd Medical to expand the NTDDS technology to also target neuropathy, in addition to the Company's development portfolio for the treatment of pain.

University of Florida Research Foundation and Diamyd Medical settled lawsuit. University of Florida Research Foundation, Incorporated ("UFRF"), and Diamyd Medical AB jointly announced that they have settled the breach of contract litigation that UFRF filed in the United States Federal District Court in Florida against Diamyd Medical in January 2011. The dispute related to an exclusive license agreement between UFRF and Diamyd Medical, and to a sublicense of the rights under the exclusive license agreement between Diamyd Medical and Ortho-McNeil-Janssen Pharmaceuticals, Inc., which sublicense involved rights to the GAD65-based drug candidate Diamyd[®]. The settlement amount was in line with what Diamyd Medical had reserved in its accounts as per August 31, 2011 regarding litigation claims.

SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

Prevention study with Diamyd Medical's diabetes vaccine was fully recruited. A total of 50 children aged four and older with a high risk of developing type 1 diabetes have been enrolled in a researcher-initiated Phase II study, DiAPREV-IT, with Diamyd Medical's diabetes vaccine Diamyd[®]. The study is thus fully recruited. The purpose of the study is to evaluate whether preventive treatment with Diamyd[®] can delay or halt the progression of the disease so that the children do not develop clinical symptoms of type 1 diabetes. The first results are expected to be compiled three years after the last participant is enrolled, and can thereby be presented in 2015.

BUSINESS OVERVIEW

Diamyd Medical is a Swedish biotech company focusing on the development of pharmaceuticals for the treatment of pain, neuropathy and diabetes. The Company was founded in 1996. The Group consists of the Parent Company Diamyd Medical AB (publ) and three wholly-owned subsidiaries: Diamyd Therapeutics AB, Diamyd Diagnostics AB and Diamyd, Inc. The Group has its headquarter in Stockholm, Sweden, and has operations including laboratories in Pittsburgh, Pennsylvania, USA. Shares are listed on the Nasdaq OMX Small Cap list in Stockholm (ticker: DIAM B) and on OTCQX in the US (ticker: DMYDY).

Strategy, objectives and business concept

Diamyd Medical will be using the Company's cash to build shareholder value, primarily through the development of the Company's own drug candidates and development projects. The objective is to develop pharmaceuticals in areas which lack adequate treatments and thus have great unmet medical needs. The Company's business concept is to refine inlicensed candidate products in the preclinical and clinical phases through development. The products are then to be commercialized, either independently or with a partner. Partnerships with other pharmaceutical companies are an important part of Diamyd Medical's strategy and the Company is continuously evaluating various opportunities for collaboration, licensing and acquisition of projects or companies with promising products in development.

Business model

Diamyd Medical is managed according to a business model that can be adapted to the Company's operations as well as external circumstances. In order to maintain high flexibility and low fixed costs the Company applies an outsourcing model where parts of the operations have been outsourced to qualified partners with expert knowledge. A small group of employees manage, lead and implement projects in areas such as clinical and preclinical development, regulatory affairs and production. This enables the Company to develop in a cost-efficient and flexible manner while maintaining its focus on results and quality. Diamyd Medical has shown that the Company is able to develop projects from preclinical through Phase III studies at a low cost compared to industry standards and to enter favorable collaboration agreements.

Operation areas

Diamyd Medical's operations are divided into two areas; Pain and neuropathy, and Diabetes. The Company's development projects in pain are focused on the treatment of chronic pain. In addition, the Company is developing treatments for nerve damage in the peripheral nervous system, called peripheral neuropathy, for which there are currently no effective treatments. Diabetes is a chronic disease characterized by elevated blood sugar levels. People with diabetes often develop serious complications resulting in great suffering and premature death. The Company's work in diabetes focuses on the autoimmune forms of the disease, type 1 diabetes and LADA, where the body's own immune system attacks and destroys the cells that control the blood sugar levels.

PROJECT PORTFOLIO

		Drug candidate	Indication	Preclinic	Phase I	Phase II	Phase III
PLATFORM	NTDDS	NP2 Enkephalin	Cancer pain	→			
		NG2 GAD	Diabetes pain	→			
		NE2 Endomorphin	Chronic pain	→			
		NN1 Neurotrophin	Chemotherapy induced peripheral neuropathy	→			
	GAD	Diamyd®	Autoimmune diabetes	→			

Diamyd Medical's project portfolio consists of drug candidates in clinical and preclinical phases based on two independent technological platforms; NTDDS (Nerve Targeting Drug Delivery System) for the treatment of diseases and symptoms of the nervous system, and GAD for the prevention and treatment of autoimmune diabetes.

The NTDDS platform comprises three drug candidates for the treatment of various forms of chronic pain; NP2 Enkephalin, NG2 GAD, NE2 Endomorphin and one drug candidate for the prevention of chemotherapy induced peripheral neuropathy, NN1 Neurotrophin. Since January 2011, NP2 Enkephalin is being evaluated in a clinical Phase II study enrolling about 32 patients with severe cancer pain. Results from the study are expected during the first half of 2012.

The GAD platform comprises the diabetes therapy Diamyd® with the active substance GAD65 (glutamic acid decarboxylase isoform 65kDa). A Swedish researcher-initiated Phase II study is ongoing to evaluate whether Diamyd® can prevent type 1 diabetes in children who are at high risk of developing the disease. Diamyd® has previously been evaluated in a Phase III study with children already diagnosed with type 1 diabetes. The Phase III study did not meet the primary efficacy endpoint of preserving beta cell function.

The NTDDS platform

NTDDS (Nerve Targeting Drug Delivery System) is an innovative technology for the delivery of therapeutics directly to the nervous system and forms the basis of Diamyd Medical's development projects within pain and neuropathy. The technology has a wide potential and may be used for the treatment of several different diseases and symptoms in the peripheral and central nervous system such as chronic pain, neuropathy, cancer and neurodegenerative diseases. Research and development on the NTDDS platform is primarily carried out by the subsidiary Diamyd, Inc. located in Pittsburgh, USA.

Mechanism of action

Diamyd Medical's NTDDS technology enables the delivery of genes, which in turn encodes for endogenous therapeutic substances, directly to nerve cells and may thus provide a local effect in the parts of the body where the treatment is targeted. NTDDS-based drugs consist of a vector which carries a gene for a therapeutic substance. The drug is injected into the skin, where the vector and the gene are taken up by nerve endings and then transported along the body's peripheral nerve pathways to nerve cell bodies that lie just outside the spinal cord. Here the nerve cell's own processes are being used to continuously produce the therapeutic substance with the gene as template. The NTDDS technology is expected to have several advantages over established therapies. Since the NTDDS is gene-based, a single dose can provide a relatively long-term therapeutic effect that may last several weeks to months. As the treatment acts locally, a very low amount of the drug may be enough to achieve the desired effect. Furthermore, systemic drug exposure is limited, a fact that may significantly reduce the risk of side effects.

For treatment of pain, an NTDDS-based drug containing a gene for a natural painkilling substance, such as the endogenous substance enkephalin, is injected into the skin over the painful area. The drug with the gene is then transported along the body's peripheral nerve pathways to nerve cell bodies located near the spinal cord, where the painkilling substance exerts its effect. Once the drug reaches the nerve cell bodies it uses the nerve cell's own processes to produce the painkilling substance for a relatively long period of time. The painkilling substance works by blocking pain signals so that they are not transmitted from the peripheral nervous system to the central nervous system. The pain signals, thus, do not reach the brain and the pain sensation is reduced or disappears.

In addition to pain, the NTDDS technology also has the potential to be used for the treatment and prevention of nerve cell damage in the peripheral and central nervous system, such as peripheral neuropathy for which there currently are no effective treatments. For the treatment and prevention of neuropathy, the NTDDS-based drug contains a gene for an endogenous neurotrophic factor, which naturally promotes survival, growth and regeneration of nerve cells. The drug with the therapeutic gene is administered in the skin to reach specific nerve cells needing treatment, in the same way NTDDS is used for the treatment of pain.

Drug candidates and clinical studies

Diamyd Medical is currently developing three products for the treatment of chronic pain, NP2 Enkephalin, NG2 GAD and NE2 Endomorphin. These drug candidates target the body's three major pain pathways, creating good prospects for the further development of a competitive product portfolio in the area of pain. For the prevention of chemotherapy induced peripheral neuropathy, a common side-effect of treatment with chemotherapy for cancer, Diamyd Medical is developing the drug candidate NN1 Neurotrophin. It uses NTDDS to deliver a neurotrophic factor to nerve cells in cancer patients prior to initiating chemotherapy, aiming to prevent damage of the nerve cells.

NP2 Enkephalin

The drug candidate NP2 Enkephalin delivers the natural painkilling substance enkephalin directly to the nervous system for the treatment of pain and is the furthest advanced drug candidate within the NTDDS platform.

NP2 Enkephalin has been tested in a Phase I study with the purpose to evaluate the safety of the drug candidate and to investigate whether it can provide pain relief for terminally ill cancer patients with chronic pain. The study was designed as a dose-escalation study with three different doses, comprising ten subjects with medium to severe cancer pain refractory to maximal doses of pain medication (opiate drugs). The results of the study were presented in the autumn of 2010. Substantial and sustained pain relief was observed in the groups treated with the two highest doses. No serious side-effects related to the treatment have been reported by any of the participants in the study. The Phase I study has formed the basis for future studies of other drug candidates using the NTDDS platform.

Based on observations from the Phase I study, the Company started a Phase II study of NP2 Enkephalin in the US in January 2011. In the study, comprising approximately 32 participants with severe cancer pain, the patients' pain levels and use of painkilling medication are being monitored. It is a multicenter, placebo controlled, double-blind and randomized study designed to enable a statistical evaluation of pain relief. The study comprises a four-week, double-blind study period, after which all patients will be offered up to two doses of active NP2 Enkephalin in an unblinded follow-up. Results from the Phase II study are expected during the first half of 2012.

NG2 GAD

The drug candidate NG2 GAD delivers the gene for the human protein GAD (glutamic acid decarboxylase) locally to nerve cells using the NTDDS technology. GAD catalyzes the body's production of GABA (gamma-amino butyric acid), which blocks pain signals. In preclinical disease models, the drug candidate has proved effective when treating neuropathic pain due to diabetes or spinal cord injury. Preclinical development of NG2 GAD is ongoing and is funded by a grant from the United States Department of Veterans Affairs. The Company plans to commence clinical studies with NG2 GAD following an evaluation of the findings from the Phase II study with the drug candidate NP2 Enkephalin.

NE2 Endomorphin

The drug candidate NE2 Endomorphin is being developed for the treatment of chronic pain and delivers the natural painkilling substance endomorphin using the NTDDS technology. Endomorphin is an opioid with morphine-like effects. Morphine has been used for centuries for pain relief and remains an important tool in modern clinical pain management. However, due to tolerance it does not always have the desired effect in chronic pain. Traditional treatment with morphine has several side-effects while treatment with the locally-acting drug candidate NE2 Endomorphin is expected to decrease the pain without the systemic side-effects of morphine. NE2 Endomorphin is currently in the preclinical phase.

NN1 Neurotrophin

The drug candidate NN1 Neurotrophin is being developed for prevention of chemotherapy induced peripheral neuropathy, a common side-effect of treatment with chemotherapy for cancer. NN1 Neurotrophin uses the NTDDS technology to provide nerve cells with neurotrophic factors that

promote survival, growth, connectivity and proper functioning of nerve cells. By using the NTDDS technology to deliver nerve-protecting substances to nerve cells before chemotherapy is started, chemotherapy induced neuropathy could be prevented. There is a great unmet medical need to be able to expand the use of chemotherapy without causing nerve cell damage.

In September 2011, Diamyd Medical and the University of Michigan received a research grant of more than USD 3 million from the US National Institutes of Health (NIH) for the development of the drug candidate. The grant covers the costs for advancement of the new drug candidate through preclinical efficacy studies, toxicology and biodistribution studies, manufacturing and filing of an Investigational New Drug application with the US Food and Drug Administration (FDA). NN1 Neurotrophin is currently in the preclinical phase.

Pain

Pain is a complex perceptual experience that alerts us to real or potential injury. The pain can be acute or chronic. Chronic pain refers to the type of pain that remains for a long time even though the injury has healed, or the pain following a chronic illness. While there are several established treatment options for acute pain, up to half of all people who suffer from chronic pain do not get any relief from pharmaceuticals on the market. Pain is a common complication in certain types of cancers and diabetes. That type of pain, cancer pain and diabetes pain respectively, is often chronic and difficult to treat. Chronic pain often has a very negative impact on the patient's quality of life. It would be a great step forward if effective treatments could be developed for at least some of the nearly 200 million people worldwide suffering from chronic pain today.

Neuropathy (nerve cell damage)

Neuropathy is a generic term for damage of nerve cells and may be caused by external or internal trauma, certain medications or diseases. Neuropathy may be classified as either peripheral or central depending on its origin and on which nerves that are damaged. Peripheral neuropathy is the most common type. There are more than 100 different types of peripheral neuropathy and the symptoms and consequences can vary widely, depending on the cause of the nerve cell damage and on the type of nerve cells involved. One example of peripheral neuropathy is chemotherapy induced peripheral neuropathy, i.e. nerve cell damage due to chemotherapy for cancer. Typical symptoms of peripheral neuropathy are numbness, pain, stinging or burning sensations in hands and feet. Currently, between 2 and 8 percent of the population suffers from some form of peripheral neuropathy, for which there is no effective treatment presently available.

The GAD platform

Diamyd Medical's platform for research in autoimmune diabetes originates from the GAD65 molecule. GAD65 is a human enzyme and plays an important role in the disease process in the autoimmune forms of diabetes, type 1 diabetes and LADA.

Mechanism of action

The problem in autoimmune diabetes is that the body's own immune system attacks and destroys the cells in the body that controls the blood sugar, known as pancreatic beta cells. Treatment with GAD65 is intended to prevent, delay or halt the autoimmune attack on the beta cells, thereby preserving the body's own ability to control blood sugar levels. This has been demonstrated to significantly reduce the risk of both acute and long-term diabetes complications. The hope is to be able to prevent autoimmune diabetes from developing or to preserve the body's capacity to regulate blood sugar levels. This would be very significant as there is no such treatment available on the market today.

Drug candidates and clinical studies

Diamyd Medical's development project in autoimmune diabetes consists of the GAD65-based drug candidate Diamyd[®]. A Phase II study is ongoing to evaluate whether Diamyd[®] can prevent type 1 diabetes in children who are at high risk of developing the disease.

Diamyd[®] for the treatment of recently diagnosed type 1 diabetes and LADA has been evaluated in several clinical trials. In 2008, Diamyd Medical launched two parallel Phase III studies with Diamyd[®], one in Europe and the other in the US. Each study included approximately 330 patients recently diagnosed with type 1 diabetes. Results from the European Phase III study, announced in May 2011, showed that Diamyd[®] did not meet the primary efficacy endpoint of preserving beta cell function, as measured by meal-stimulated C-peptide, although a small positive effect was seen. Furthermore, Diamyd[®] was well tolerated, as demonstrated by a similar number of adverse events in the Diamyd[®] treated groups as well as in the placebo treated group. Based on the findings the Company decided, in June 2011, not to complete the follow-up period of the European Phase III study of Diamyd[®] and to also initiate the closure of the parallel US Phase III study. The Phase III studies were launched after the Company reported positive results from a 30-month Phase II study of 70 children and adolescents with type 1 diabetes. Diamyd Medical has also completed a randomized, double-blind, placebo controlled Phase II study with 47 LADA patients, in which various doses of Diamyd[®] were tested. A five-year follow-up of the participants showed that the risk a LADA patient will need to begin insulin treatment is significantly reduced after treatment with Diamyd[®] compared to placebo treatment.

Diamyd[®] - Prevention of type 1 diabetes

In type 1 diabetes, the autoimmune attack and the destruction of blood sugar-regulating beta cells in the pancreas start long before the symptoms arise. Treatment with Diamyd[®] as a preventive measure is intended to intervene in the autoimmune process at an early stage, before the destruction of the beta cell function has led to the appearance of overt symptoms, and thus prevent the disease from developing.

Diamyd[®] is since 2009 being evaluated in a Swedish researcher-initiated Phase II study, DiAPREV-IT. The study is double-blind and placebo-controlled and includes a total of 50 children aged four and older who through analysis of diabetes markers, so-called auto-antibodies, in the blood are demonstrated to be at high risk of developing type 1 diabetes.

Half of the children receive two injections of Diamyd[®], and the remaining half receive placebo (inactive substance). The children will be monitored for a total of five years by means of sampling and glucose tolerance tests to evaluate the beta cell function, a measure of the body's own ability to regulate blood sugar levels. The first results are expected to be compiled in 2015, three years after the last participant is enrolled. The study is being conducted by a research group at Lund University and is led by Dr. Helena Elding Larsson, a pediatrician in Malmö and researcher at Lund University. The study is funded by research grants, but Diamyd Medical has participated in the design of the study and can utilize the study results.

Diabetes

Diabetes is a chronic disease characterized by elevated blood sugar levels. People with diabetes often develop serious complications resulting in great suffering and premature death. There are several types of diabetes. The three most common are type 2 diabetes, type 1 diabetes and LADA (Latent Autoimmune Diabetes in Adults). A common feature of type 1 diabetes and LADA is that they are autoimmune forms of the disease, which means that the body's own immune system attacks and destroys the beta cells in the pancreas, which control the blood sugar level. Type 2 diabetes on the other hand is caused by impaired insulin sensitivity and is mainly related to age and lifestyle.

Type 1 diabetes, also known as juvenile diabetes, usually occurs in children and adolescents and results from a deficiency of insulin caused by an autoimmune attack. Type 1 diabetes is a lifelong disease and for the majority of people diagnosed with type 1 diabetes, insulin requirements must be entirely satisfied by means of injections or an insulin pump. LADA, also known as type 1.5 diabetes, strikes during adulthood. The disease is similar to type 1 diabetes in many respects and it, too, eventually leads to an absolute need for insulin treatment. However, the progress of the disease is slower than in type 1 diabetes. Because the disorder mainly affects adults and does not immediately require insulin treatment, LADA is often diagnosed as type 2 diabetes. Diamyd Medical estimates that about 10 percent of all those diagnosed with type 2 diabetes actually have LADA.

There is currently no treatment on the market addressing the autoimmune process that causes type 1 diabetes and LADA. Current treatment strategies involve lowering the blood sugar level by adding external insulin, either by injections or an insulin pump.

FINANCIAL INFORMATION

Net sales – The Group's net sales for the first quarter were MSEK 0.1 (144.5). The agreement with Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI) was terminated during the spring 2011. The Group's operating income for the first quarter last year included remuneration for research services from OMJPI and a part of the upfront payment received when entering into the agreement.

Costs – Costs were MSEK 15.9 (47.7) in the first quarter. The decrease in costs for the first quarter, compared to the same period last year, is mainly attributable to the winding up of the Phase III program with the GAD65-based drug candidate Diamyd[®] and lower personnel costs. The decrease in personnel costs is attributable to having fewer employees compared to the same period last year and the exercise of employee options during the same period last year.

Result – Loss before tax for the first quarter was MSEK -7.4 (98.3).

Financial position and liquidity – The Group's liquid assets and short term investments were MSEK 414 (478) as of November 30, 2011. The liquid assets consist of bank account balances and interest bearing investments with less than three months term to maturity. Short term investments consist of interest bearing investments with three to six months term to maturity. During the first quarter MUSD 2 was paid in compensation to the University of Florida Research Foundation, which has a negative effect on the cash flow.

Investments – Investments in tangible assets for the first quarter were MSEK 0 (0.2).

Change in equity – As of November 30, 2011, the Company's equity amounted to MSEK 454 (431), resulting in a solidity of 94 (76) percent.

Organization – Average number of employees during the period was 23 (26). At the end of the period the number of employees was 21 (26).

Parent Company – Investments for the first quarter were MSEK 0 (0). The Parent Company's net profit for the first quarter amounted to MSEK 1.1 (99.5).

Shares – The total number of shares in Diamyd Medical as of November 30, 2011 was 29,579,133.

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

KSEK	Note	3 months Sep-Nov 2011/2012	3 months Sep-Nov 2010/2011	12 months Sep-Aug 2010/2011
OPERATING INCOME				
Net sales	1, 2	54	144,472	280,752
Other operating income		2,579	-	7,511
Total operating income		2,633	144,472	288,263
OPERATING EXPENSES				
Raw materials and consumables		-	-1	-7
External research and development costs		-7,699	-21,669	-95,976
External patent and license expenses		264	-599	-15,957
Personnel	3	-4,744	-14,962	-48,794
Other external expenses	3	-3,578	-3,110	-15,762
Other operating expenses		-	-7,248	-
Depreciation, equipment		-134	-75	-428
Total operating expenses		-15,891	-47,664	-176,924
OPERATING PROFIT/LOSS		-13,258	96,808	111,339
Net Financial Income/Expense	4	5,877	1,520	-9,496
Profit/Loss before taxes		-7,381	98,328	101,843
Taxes		-311	-	727
NET PROFIT/LOSS FOR THE PERIOD		-7,692	98,328	102,570
Other comprehensive income for the period				
Translation gains/losses		-201	46	120
Other comprehensive income for the period, net of tax		-201	46	120
TOTAL COMPREHENSIVE INCOME FOR THE PERIOD		-7,893	98,374	102,690
Earnings per share before dilution, SEK		-0.26	3.37	3.48
Earnings per share after dilution, SEK		-0.26	3.32	3.48
Number of shares per closing day		29,579,133	29,289,376	29,579,133
Average number of shares before dilution		29,579,133	29,181,821	29,449,348
Average number of shares after dilution		29,579,133	29,607,076	29,477,301

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

KSEK	Note	Nov 30 2011	Nov30 2010	Aug 31 2011
ASSETS				
Non-current assets				
Intangible assets		16,627	16,627	16,627
Tangible assets		2,244	977	2,224
Financial assets		29,241	30,057	29,241
Total non-current assets		48,112	47,661	48,092
Current assets				
Inventory		6	19	5
Trade receivables		84	20,542	15,179
Other receivables		15,574	2,082	15,240
Prepaid expenses and accrued income		5,308	16,889	5,445
Short term investments		257,876	332,311	277,859
Liquid assets		155,872	145,341	157,782
Total current assets		434,720	517,184	471,510
TOTAL ASSETS		482,832	564,854	519,602
SHAREHOLDERS' EQUITY AND LIABILITIES				
Shareholders' equity				
Share capital		14,790	14,645	14,790
Other capital contributions		724,737	703,047	724,737
Other reserves		65	192	266
Accumulated losses including results for the period		-285,595	-286,848	-278,819
Total shareholders' equity		453,997	431,036	460,974
Current liabilities				
Trade payables		8,842	8,955	9,182
Other payables		1,826	1,863	15,323
Prepaid income and accrued expenses		18,167	122,991	34,123
Total current liabilities		28,835	133,809	58,628
TOTAL EQUITY AND LIABILITIES	5	482,832	564,845	519,602

CONSOLIDATED STATEMENT OF CASH FLOW

KSEK	3 months Sep-Nov 2011/2012	3 months Sep-Nov 2010/2011	12 months Sep-Aug 2010/2011
Cash flow from operations before changes in working capital			
Operating profit/loss	-13,258	96,809	111,339
Interest received	4,552	597	4,568
Interest paid	-14	-3	-8,329
Dividend received	-	-	410
<i>Non-cash flow items</i>			
Depreciation	134	75	428
Other non-cash flow items	-13,324	-117,128	-210,015
Net cash flow from operating activities before changes in working capital	-21,910	-19,650	-101,599
Increase (-) decrease (+) inventory	-	-2	10
Increase (-) decrease (+) receivables	14,201	-18,396	-13,689
Increase (+) decrease (-) liabilities	-16,583	-1,021	21,251
Net cash flow from operating activities	-24,292	-39,069	-94,027
Cash flow from investing activities			
Increase (-) decrease (+) short term investments	19,983	-332,310	-277,859
Purchase of tangible assets	-	223	-1,928
Net cash flow from investing activities	19,983	-332,533	-279,787
Cash flow from financing activities			
New share issue after issue expenses	-	15,722	37,559
Cash flow from financing activities	-	15,722	37,559
Total cash flow for the period	-4,309	-355,880	-336,255
Cash and cash equivalents at beginning of period	157,782	501,332	501,332
Net foreign exchange difference	2,399	-111	-7,295
Cash and cash equivalents at end of period	155,872	145,341	157,782

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

KSEK	Share Capital	Other capital contributions	Reserves	Accumulated losses	Total
Sep 1, 2010 – Aug 31, 2011					
Opening balance, September 1, 2010	14,530	687,438	146	-387,331	314,783
Comprehensive income					
Net loss for the period	-	-	-	102,570	102,570
Translation gains/losses	-	-	120	-	120
Total comprehensive income	-	-	120	102,570	102,690
Transactions with owners					
New share issue	260	37,299	-	-	37,559
New share issue expenses	-	-	-	-	-
Employee options	-	-	-	5,942	5,942
Total transactions with owners	260	37,299	-	5,942	43,501
Closing balance, August 31, 2011	14,790	724,737	266	-278,819	460,974
Sep 1, 2010 – Nov 30, 2010					
Opening balance, September 1, 2010	14,530	687,438	146	-387,331	314,783
Comprehensive income					
Net loss for the period	-	-	-	98,328	98,328
Translation gains/losses	-	-	46	-	46
Total comprehensive income	-	-	46	98,328	98,374
Transactions with owners					
New share issue	115	15,609	-	-	15,724
New share issue expenses	-	-	-	-	-
Employee options	-	-	-	2,155	2,155
Total transactions with owners	115	15,609	-	2,155	17,879
Closing balance, November 30, 2010	14,645	703,047	192	-286,848	431,039
Sep 1, 2011 – Nov 30, 2011					
Opening balance, September 1, 2011	14,790	724,737	266	-278,819	460,974
Comprehensive income					
Net loss for the period	-	-	-	-7,692	-7,692
Translation gains/losses	-	-	-201	-	-201
Total comprehensive income	-	-	-201	-7,692	-7,893
Transactions with owners					
New share issue	-	-	-	-	-
New share issue expenses	-	-	-	-	-
Employee options	-	-	-	916	916
Total transactions with owners	-	-	-	916	916
Closing balance, November 30, 2011	14,790	724,737	65	-285,595	453,997

PARENT COMPANY INCOME STATEMENT

KSEK	Note	3 months Sep-Nov 2011/2012	3 months Sep-Nov 2010/2011	12 months Sep-Aug 2010/2011
OPERATING INCOME				
Net sales	2	-	144,472	280,110
Other operating income		538	-	-
Total operating income		538	144,472	280,110
Operating expenses				
Personnel		-	-	-785
Other external expenses		-4,221	-21,051	-68,913
Other operating expenses		-	-6,756	-220
Total operating expenses		-4,221	-27,807	-69,918
OPERATING PROFIT/LOSS		-3,683	116,665	210,192
Financial income and expenses				
Result from group participation		-916	-18,780	-74,234
Dividend from holdings		-	-	410
Interest income and similar items		5,662	1,605	6,678
Interest expense and similar items		-	-	-13,900
Total financial income and expenses		4,746	-17,175	-81,046
Profit/Loss before tax		1,063	99,490	129,146
Taxes		-	-	-53,547
NET PROFIT/LOSS FOR THE PERIOD		1,063	99,490	75,599

PARENT COMPANY'S BALANCE SHEET

KSEK	Note	Nov 30 2011	Nov 30 2010	Aug 31 2011
ASSETS				
Non-current assets				
<i>Intangible assets</i>				
Acquired research and development		16,627	16,627	16,627
<i>Financial assets</i>				
Shares in Group companies		1,200	1,200	1,200
Receivables at Group companies		46,643	34,718	8,687
Other long-term bond holdings		29,241	21,418	29,241
Financial instruments available for sale		-	8,639	-
Total non-current assets		93,711	82,602	55,755
Current assets				
Trade receivables		-	18,717	15,107
Other receivables		12,923	203	13,562
Prepaid expenses and accrued income		4,742	15,789	4,919
Total trade and other receivables		17,665	34,709	33,588
Short term investments		257,876	332,311	277,859
Liquid assets		143,068	121,657	143,228
Total current assets		418,609	488,677	454,675
TOTAL ASSETS		512,320	571,280	510,430
SHAREHOLDERS' EQUITY AND LIABILITIES				
Shareholders' equity				
Restricted equity				
Issued capital		14,790	14,645	14,790
Statutory reserve		96,609	96,609	96,609
Non-restricted equity				
Share premium reserve non-restricted		374,741	347,564	374,741
Profit or loss brought forward		-201,212	-126,194	-277,726
Net profit/loss for the period		1,063	99,490	75,599
Total shareholders' equity		285,991	432,115	284,013
Liabilities to subsidiary	6	225,490	35,368	224,934
Current liabilities				
Trade payables		725	234	1,091
Other payables		114	104	392
Prepaid income and accrued expenses		-	103,459	-
Total current liabilities		839	103,797	1,483
TOTAL EQUITY AND LIABILITIES		512,320	571,280	510,430
Assets pledged		-	-	-
Contingent liabilities		-	-	-

Notes

Accounting principles

This interim report was prepared as per IAS 34, Interim Financial Reporting. For a more detailed description of the accounting principles used by the Group, reference is made to the most recent annual report.

Note 1 – Segment results

The operating segments derive their income primarily from research collaboration agreements and research services. The performance measurement that is followed up is the operating result.

Segment results 3 months	2011-09-01 – 2011-11-30			2010-09-01 – 2010-11-30		
	Sweden	USA	Group	Sweden	USA	Group
KSEK						
Total net sales for segments	-	3,388	3,388	162 203	3,284	165,487
Inter-segment sales	-	-3,335	-3,335	-17 731	-3,284	-21,015
Total net sales	-	54	54	144 472	-	144,472
Operating result	-12,693	-565	-13,258	95 969	839	96,808

Note 2 – Distribution of net sales

Distribution of net sales 3 months	Group		Parent Company	
	Sep-Nov 2011/2012	Sep-Nov 2010/2011	Sep-Nov 2011/2012	Sep-Nov 2010/2011
Revenues from research collaboration agreement	-	126,742	-	126,742
Research services	-	17,730	-	17,730
Other services	54	-	-	-
Total	54	144,472	-	144,472

Note 3 – Related-party transactions

During the period companies represented by immediate family members of the Chairman of the Board were contracted as consultants. Total compensation during the first quarter amounted to KSEK 223 (311) excluding VAT and was attributable to IT-services. Pricing has been set by the arm's length principle. Total compensation to immediate family members of the Chairman amounted to a total of KSEK 196 (275) during the first quarter. No other members of the Board of Directors, key executives, or their immediate family members have been directly or indirectly involved in any business transaction with the Company that is or was unusual in its character or terms and conditions and took place during the period. Neither has the Company given any loans, provided any guarantees or surety to or for the benefit of any member of the Board of Directors, key executives or auditors in the Company.

KSEK	Sep-Nov 2011/2012	Sep-Nov 2010/2011
Purchase of intercompany services*	3,335	21,014
Salaries to related parties	196	275
Share-based payments to related parties	94	230
Consultant fees to related parties	223	311

*Transactions between subsidiaries

Note 4 – Net Financial Income/Expense

Net Financial Income/Expense for the first quarter amounts to MSEK 5.9 and consists of interest income of MSEK 2.4 on liquid assets and short term investments and exchange rate differences of MSEK 3.5.

Note 5 – Equity and liabilities

All Group debts are non-interest-bearing.

Note 6 – Liabilities to subsidiary

The amount includes group contribution to Diamyd Therapeutics AB of MSEK 203.6, accounted for last year.

Key figures	3 months Sep-Nov 2011/2012	3 months Sep-Nov 2010/2011	12 months Sep-Aug 2010/2011
Earnings per share before dilution, SEK	-0.3	3.4	3.5
Earnings per share after dilution, SEK	-0.3	3.3	3.5
Research and development costs, MSEK	-7.7	-21.7	-96.0
Shareholders' equity per share, SEK	15.3	14.8	15.7
Cash flow per share, SEK	-0,1	16.4	-11.4
Return on equity, %	-1.7	26.4	26.4
Solidity, %	94	76	89
Share price per closing, SEK	8.1	122.8	9.0
Share price/shareholders' equity per share, SEK	0.5	8.4	0.6
Number of shares per closing	29,579,133	29,289,376	29,579,133
Average number of shares before dilution	29,579,133	29,181,821	29,449,348
Average number of shares after dilution	29,579,133	29,607,076	29,477,301

Significant risks and uncertainties

Diamyd Medical's business is subject to certain risks and uncertainties. These include both internal and external factors that could materially affect the Company's development and growth and thus an investment in the Diamyd Medical share. Development of a medical drug often takes a considerable time, is capital intensive and associated with significant levels of uncertainty due to its dependence on unpredictable and complex parameters regarding the course of biological and medical processes. Diamyd Medical's development projects are in preclinical and clinical phases where a number of different parameters affect the probability of success. No guarantee can be given that the Company's development projects will lead to marketable drugs or that they will achieve commercial success.

The Company's operations are associated with risks related to, inter alia, drug development, commercialization, financing, intellectual property, collaborations with partners, authority decisions, certain assets and key personnel. For a more detailed description of the Company's risks and uncertainties, please see the Company's Annual Report for the fiscal year 2010/2011. No significant changes with respect to risks and uncertainties have occurred since the Annual Report was issued.

This interim report has not been reviewed by the Company's auditors.

The Board of Directors and the CEO certify that the interim report gives a fair overview of the business, position and profit or loss of the Parent Company and the Group, and describes the principal risks and uncertainties that face the Parent Company and the companies in the Group.

Stockholm, January 25, 2012

Anders Essen-Möller, Chairman of the Board

Lars Jonsson, Board Member

Maria-Teresa Essen-Möller, Board Member

Christer Lindberg, Board Member

Joseph Janes, Board Member

Peter Zerhouni, President and CEO

About Diamyd Medical

Diamyd Medical is a Swedish biotech company focusing on the development of pharmaceuticals for the treatment of pain, neuropathy and diabetes. The portfolio of development projects for the treatment of chronic pain and neuropathy uses the Company's patented NTDDS (Nerve Targeting Drug Delivery System) platform to administer therapeutic agents directly to the nervous system. The development project within the area of diabetes consists of the protein GAD65 for the treatment and prevention of autoimmune diabetes.

Diamyd Medical has offices in Sweden and in the US. Shares are listed on Nasdaq OMX (segment Small Cap) in Stockholm (ticker: DIAM B) and on OTCQX in the US (ticker: DMYDY) administered by the Pink OTC Markets and the Bank of New York Mellon (PAL). Further information is available on the Company's website: www.diamyd.com.

This information is disclosed in accordance with the Swedish Securities Markets Act, the Swedish Financial Instruments Trading Act, or the requirements stated in the listing agreements.

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Note: This document has been prepared in both Swedish and English. The Swedish version shall govern in case of differences between the two documents. The document contains certain statements about the Company's operating environment and future performance. These statements should only be regarded as reflective of prevailing interpretations. No guarantees can be made that these statements are free from errors.