



ANNUAL REPORT

2010/11

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*This report is a translation from the Swedish original.
No guarantees are made that the translation is free from errors.*

DIAMYD MEDICAL

- Develops innovative drugs within therapeutic areas with great unmet medical needs
- Has a portfolio of drug candidates for the treatment of pain, neuropathy and diabetes in clinical and preclinical phases from two different patented platforms
- Is planning to report results of a Phase II study in cancer pain during the first half of 2012
- Participates in a Swedish Phase II study where the diabetes vaccine Diamyd® is given to children at high risk of developing type 1 diabetes, with the aim to prevent the disease
- Has experience of taking drug candidates through Phase III and to sign favorable collaboration agreements with major pharmaceutical companies
- Manages a strong cash position of more than MSEK 400 or SEK 14 per share

THE YEAR IN BRIEF

- Q1**
- Results from Phase I study in cancer pain shows promising safety data and relief of chronic pain
- Q2**
- Recruitment for US Phase III study in type 1 diabetes is completed
 - Phase II study in cancer pain is started
 - University of Florida Research Foundation initiates court case against Diamyd Medical
- Q3**
- Results of a Phase I clinical study in cancer pain is published in the medical journal Annals of Neurology
 - Peter Zerhouni is appointed President and CEO of Diamyd Medical AB
 - Results are announced from European Phase III study in type 1 diabetes, which did not meet the primary efficacy endpoint of preserving beta cell function
- Q4**
- Diamyd Medical regains all rights and thereby the control of the diabetes therapy Diamyd® after Ortho-McNeil-Janssen Pharmaceuticals, Inc. terminated collaboration agreement
 - European Phase III study in type 1 diabetes is closed and closure of a parallel US Phase III study is initiated
 - TrialNet presents results from a Phase II study with the diabetes therapy Diamyd®, which did not show a statistically significant effect of the study drug
 - Diamyd Medical reduces costs and shifts the development focus from type 1 diabetes to chronic pain and diseases of the nervous system

CEO COMMENTS

DIAMYD MEDICAL TOWARDS NEW GOALS

The past fiscal year has been both eventful and turbulent for Diamyd Medical. However, now that the dust has settled, the Company stands well-equipped to continue its important efforts to develop innovative pharmaceuticals for diseases for which there currently is no effective treatment option. Diamyd Medical's portfolio includes several highly interesting drug candidates under development and an ongoing Phase II study in cancer pain, the results of which are expected during the first half of 2012. Our financing is secured and we have a lean organization with valuable experience in conducting Phase III trials and landing significant collaboration agreements with major pharmaceutical companies. A gratifying situation in our industry!

Phase III study did not reach expectations

The event that dominated the latter part of the fiscal year was the results of our European Phase III study in type 1 diabetes with the drug candidate Diamyd®, which did not meet expectations. This was a serious setback and a great sorrow for all hopeful patients, shareholders and others who had invested their time, money and great dedication for such a long time. The Company's share fell to record-low levels and we had to rapidly reformulate our plans.

Focus on pain and neuropathy

The Company's main focus now lies on our pain and neuropathy projects, where we have several promising drug candidates under development based on our patented NTDDS technology. The most advanced project is the drug candidate NP2 Enkephalin, which is being evaluated in a Phase II study with 32 patients who suffer from severe and chronic cancer pain. The results of this study are expected sometime between January and June in 2012. The study is important not only for the continued development of NP2 Enkephalin, but also

to confirm that the NTDDS platform can deliver therapeutic substances safely and effectively to selected nerve cells. This is a unique concept and, if successful, it will generate many new opportunities for treating a range of medical problems in the nervous system that are not treatable today.

Following an evaluation of the results of the ongoing NP2 Enkephalin study, the Company plans to commence clinical studies with the next NTDDS-based drug candidate, NG2 GAD, for the treatment of other types of chronic pain. At the same time, we will also initiate efforts to actively seek partners for the further development of NP2 Enkephalin and other applications of the NTDDS platform.

The last word has not been said about the diabetes therapy Diamyd®

Parallel with the development of a competitive project portfolio in pain and neuropathy, efforts continue in the analysis of all available information from the Phase III programme with the diabetes therapy Diamyd®. Intense discussion is taking place in our global diabetes-research network regarding what we have learnt and can continue to learn from all available research data, not only from Diamyd® studies but also from other companies' attempts to develop therapies for type 1 diabetes. The next stage has not been determined yet but like many experts in the field, we remain convinced that Diamyd®, or the active substance GAD65, can thwart type 1 diabetes albeit with a different approach to that which has now been tested.

For Diamyd Medical, prevention is closest at hand as a Swedish study with Diamyd® is already ongoing with the aim of preventing type 1 diabetes in children at high risk of developing the disease. Several research groups have shown great interest in following this lead, but also in combining the Diamyd® treatment with other drugs, or to change the number of injections or dose per injection.



Strict cost control and strong cash position

After the Phase III results were presented in May, we have focused on strict cost control and have taken a number of measures to ensure that the Company's money is used for value-creating activities. The Phase III programme with the diabetes therapy Diamyd® is almost terminated and most employees in Sweden who worked with the programme have unfortunately had to leave the Company. These measures reduce the Company's costs considerably since the Phase III programme accounted for about two-thirds of the Company's total costs.

At the end of the fiscal year on August 31, Diamyd Medical had cash equivalents amounting to MSEK 436, corresponding to SEK 14 per share. The strong cash position means that our financing is secured for several years to come with our current development plan, but also provides us with strategic leeway. Many companies in our sector are finding it difficult to secure financing and we are continuously evaluating business prospects with an opportunistic view, such as acquisitions of promising development projects and companies, as well as other types of transactions.

Favorable position

To summarize, Diamyd Medical has a full agenda for the year to come. Our circumstances have changed but the Company has adapted and with our favorable starting position, we look forward to an intense and exciting year.

Stockholm, November 15, 2011

Peter Zerhouni
President and CEO of Diamyd Medical

DIAMYD MEDICAL'S OPERATIONS

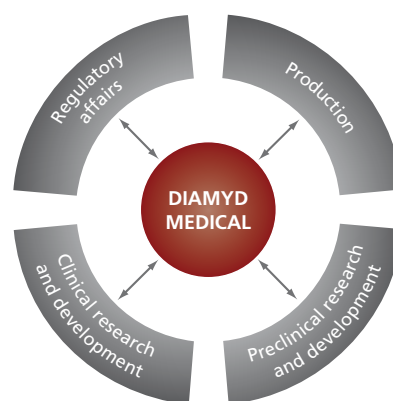
Diamyd Medical is a Swedish biotech company focusing on the development of pharmaceuticals for the treatment of pain, neuropathy and diabetes. The Company was founded in 1996. The Group consists of the Parent Company Diamyd Medical AB (publ) and three wholly-owned subsidiaries: Diamyd Therapeutics AB,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

OBJECTIVES AND BUSINESS CONCEPT

The objective for Diamyd Medical 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 in-licensed candidate products in the preclinical and clinical phases through development. The products are then to be commercialized, either independently or with a partner.

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 a low cost base 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 been able to develop a project from preclinical through Phase III studies at a low cost compared to industry standards and to enter a favorable collaboration agreement with a major pharmaceutical company.



Diamyd Medical's outsourcing model

		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	→			

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. There is a great unmet medical need for new treatments for various types 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 levels of sugar in the blood. Those who suffer from diabetes often experience serious complications that result in great suffering and premature death. Diamyd Medical develops treatments for the autoimmune forms of diabetes, type 1 diabetes and LADA, where the body's own immune system attacks and breaks down the cells of the body that control the blood sugar. There is currently no treatment on the market against the autoimmune process that causes type 1 diabetes and LADA.

PROJECT PORTFOLIO

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

The NTDDS platform comprises four drug candidates; NP2 Enkephalin, NG2 GAD, NE2 Endomorphin for the treatment of various types of chronic pain, and the drug candidate NN1 Neurotrophin for prevention of chemotherapy induced peripheral neuropathy, a common side-effect of chemotherapy for cancer.

Since January 2011 NP2 Enkephalin has been 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 year 2012. In a previous Phase I study, substantial and sustainable pain relief was observed in patients treated with NP2 Enkephalin. The Phase I study also showed that the treatment was well-tolerated and no serious side effects associated with the treatment have been reported.

The GAD platform comprises the diabetes therapy Diamyd® with the active substance GAD65 (glutamic acid decarboxylase isoform 65kDa). Diamyd® is developed for prevention and treatment of autoimmune diabetes and has been evaluated in a Phase III program with more than 650 patients newly diagnosed with type 1 diabetes participating in two parallel studies, one in Europe and one in the US. Results from the European study showed that the treatment did not meet the primary efficacy endpoint of preserving beta cell function after 15 months in patients newly diagnosed with type 1 diabetes. There is a Phase II study ongoing, aiming to evaluate if Diamyd® can prevent type 1 diabetes in children at high risk of developing the disease.



STRATEGY FOR DEVELOPMENT AND COMMERCIALIZATION

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 in clinical and preclinical phase in the areas of Pain and neuropathy, and Diabetes. Clinical studies will be conducted under the auspices of the Company or together with other pharmaceutical companies. In the long run the Company sees a possibility to manage marketing and sales of some drugs with limited target groups and thus generate a cash flow that can be used to finance other development projects.

The strategy for the Company's NTDDS-based development projects is to develop drug candidates for the treatment of various types of chronic pain and neuropathy.

The strategy for the Company's GAD platform is to continue to evaluate and analyze the results from the discontinued Phase III program to identify potential ways to use Diamyd® and the active substance GAD65 for the treatment and prevention of type 1 diabetes. One possible approach is to administer the treatment earlier in the disease process, before the disease presents, which is currently being tested in an externally funded and researcher-initiated Phase II study. The purpose of the study, ongoing since 2008, is to investigate whether treatment with Diamyd® can prevent type 1 diabetes in

children at high risk of developing the disease. Other potential ways forward are to administer more or higher doses of Diamyd® and to combine the Diamyd® treatment with other drugs. There is also a possibility that the treatment evaluated in the Phase III program could be effective in specific groups of patients with type 1 diabetes or patients with LADA, a less aggressive form of autoimmune diabetes.

PARTNERSHIPS AND ACQUISITIONS

Partnerships with other pharmaceutical companies are an important part of Diamyd Medical's strategy, both to partner proprietary projects and to identify new development projects. The Company is continuously evaluating various opportunities for collaboration, licensing and acquisition of development projects or companies with promising products in development.

In June 2010, Diamyd Medical signed an agreement with Ortho-McNeil-Janssen Pharmaceuticals, Inc., concerning the antigen based drug candidate Diamyd®. The agreement included development and worldwide commercialization of Diamyd® for the treatment and prevention of type 1 diabetes and associated diseases. Diamyd Medical received an upfront payment of USD 45 million when the agreement came into effect and under the agreement the parties equally shared the development costs until the end of May 2011 when Ortho-McNeil-Janssen Pharmaceuticals, Inc. chose to terminate the agreement. The

termination of the agreement followed the evaluation of the results from the European Phase III study reported on May 9, 2011.

The rights to the application of the GAD65 gene in the treatment of Parkinson's disease were previously out-licensed on a non-exclusive basis to the American company Neurologix, Inc. Diamyd Medical is planning a structured out-licensing process for NP2 Enkephalin in connection with the results from the ongoing Phase II study.

FINANCING

At the end of the financial year Diamyd Medical had a cash position exceeding SEK 400 million. The funds are expected to cover the Company's financial needs for the foreseeable future. Furthermore, the Company has several alternatives for financing the operations, for example out-licensing of whole or parts of the development projects on selected markets, various forms of share issues or through research grants. Diamyd Medical with partners, for example, received a three year research grant of USD 3 million from the National Institutes of Health in September 2011. The grant will fund the development of the Company's NTDDS-based drug candidate NN1 Neurotrophin for prevention of chemotherapy induced peripheral neuropathy. Diamyd Medical's research and development activities have until now been performed at a low cost compared to industry standards. Since the Company was founded, new share issues have generated SEK 740 million.

Drug development

Drug development is a very long and costly process associated with high risks. Generally it costs one billion USD to take a drug from discovery to market. A candidate drug must get through a number of stages before it can obtain market approval. These stages can be separated into discovery, preclinical phase and clinical phase. After discovery, the drug undergoes preclinical testing in disease models. The drug is then tested in the clinical phase by carrying out clinical trials in human subjects. Clinical trials consist of four stages of which the first three – Phases I, II and III – take place prior to market launch. The following is a short description of each of the phases of drug development.

Discovery phase

The drug candidate is identified and protected by patents. The discovery phase may rely on an understanding of the mechanism of a pathological process or on pharmacological knowledge about a particular substance. The discovery phase may take several years.

Preclinical phase

In the preclinical phase, the drug candidate is tested in experimental systems and disease models to establish safety and efficacy. These studies are essential for obtaining the approval of the regulatory authorities to begin human trials.

Phase I

After successfully completing the preclinical phase, the drug can then be tested on a limited number of human volunteers in order to confirm the results of the preclinical studies, i.e. to confirm the safety of the drug, and to provide indications of any possible adverse effects.

Phase II

Phase II trials are carried out on a small number of patients with the actual disease that is to be treated, prevented or alleviated. The aim is to establish the optimal dosage of the drug, prove that it is efficacious, find out how it is distributed in the body, discover how the body affects the drug and establish its safety profile.

Phase III

The drug candidate is now tested in a larger group of patients at multiple locations in order to prove statistically that it is safe and efficacious. The effects on the disease are studied, and any possible side effects recorded. If the results in Phase III achieve the stated objectives, the sponsor can apply to the regulatory authorities for marketing approval.

Phase IV

Phase IV studies are carried out after the drug has been introduced onto the market. The aim is to study the drug in everyday clinical use over an extended period of time, and to record any rare adverse effects that may later emerge. New patient groups may also be evaluated during Phase IV.

PAIN AND NEUROPATHY

Diamyd Medical develops pharmaceuticals for the treatment of pain and neuropathy. The project portfolio now includes four drug candidates in clinical and preclinical phases for the treatment of various types of chronic pain and prevention of peripheral neuropathy. The drug candidates are based on the Company's proprietary NTDDS (Nerve Targeting Drug Delivery System) platform which enables delivery of therapeutics directly to the nervous system.

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

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 today¹⁾.

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 being 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 cell being damaged. One example of peripheral neuropathy is chemotherapy induced peripheral neuropathy, i.e. nerve cell damage due to chemotherapy for cancer. Currently, between 2 and 8 percent of the population suffers from some form of peripheral neuropathy, for which there is no effective treatment presently available²⁾.

NTDDS DELIVERS THERAPEUTICS DIRECTLY TO THE NERVOUS SYSTEM

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.

Diamyd Medical is developing four drug candidates in clinical and preclinical phases that use the NTDDS technology to treat various forms of chronic pain and to prevent neuropathy. 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 bodies 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 and 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.

Treating pain with NTDDS

The body has its own painkilling systems to regulate pain signals from peripheral nerves to the brain. These systems use several natural substances including enkephalins, endomorphins and GABA (gamma-aminobutyric acid). Diamyd Medical's NTDDS-based drug candidates imitates in a sophisticated manner the body's own method to relieve pain by releasing natural painkilling substances in the synapses between the peripheral and the central nervous system where they dampen the sensation of pain.

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 has 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.

Treating neuropathy with NTDDS

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 treatment of pain.

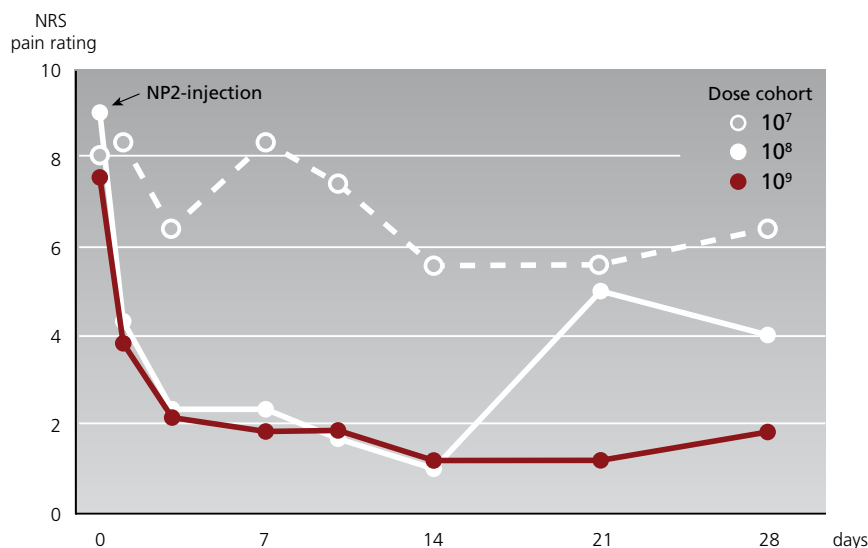
A treatment that protects nerve cells would be useful for cancer patients undergoing chemotherapy, to prevent chemotherapy induced peripheral neuropathy. The use of chemotherapy is a very important part in the treatment of cancer, but also causes serious side effects of which chemotherapy induced peripheral neuropathy is a common dose-limiting side effect. There is a great unmet medical need to be able to expand the use of chemotherapy without causing nerve cell damage. By using the NTDDS technology to deliver nerve-protecting substances to nerve cells before chemotherapy is started, chemotherapy induced neuropathy could be prevented. This could expand the possibilities of using chemotherapy in the treatment of cancer and increase the chances of survival.

Treating other diseases and symptoms in the nervous system with NTDDS

The NTDDS technology also has the potential to be used for treatment of several other types of diseases and symptoms within the nervous system, such as neurodegenerative diseases or cancer. In cancer, the NTDDS technology could be used to deliver cell-killing and immunostimulatory substances directly to the malignant tumor.

PAIN AND NEUROPATHY PORTFOLIO

Diamyd Medical has four NTDDS-based drug candidates currently under development. Three of these are being developed for the treatment of chronic pain; NP2 Enkephalin, NG2 GAD and NE2 Endomorphin. These three drug candidates usurp the body's three major signaling pathways for pain and together they lay the foundation for a comprehensive and competitive pain product portfolio. In addition, Diamyd Medical is developing the drug candidate NN1



Phase I study with NP2 Enkephalin

In a clinical Phase I study enrolling 10 persons with moderate to severe cancer pain, substantial and sustained pain relief was observed in the groups treated with the two highest doses of the drug candidate NP2 Enkephalin. The group treated with the highest dose of the drug candidate NP2 Enkephalin (the red curve in the above figure) showed an 80 percent reduction in the average weekly pain score, measured with the Numeric Rating Scale (NRS), during the first four weeks. Pain relief was also noted in the Short Form McGill Pain Questionnaire (SF-MPQ), a measuring method consisting of a quantitative compilation of 15 descriptive pain measurements. The study results also indicate that NP2 Enkephalin is well tolerated. No serious adverse events related to the treatment were observed.*

*) Fink et al. *Annals of Neurology* 2011;70:207-212

Neurotrophin for the prevention of chemotherapy induced peripheral neuropathy. NN1 Neurotrophin uses the NTDDS technology to deliver a neurotrophic factor to nerve cells in cancer patients prior to chemotherapy, with the purpose of protecting the nerve cells from damage.

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 evaluated in a Phase I study for the treatment of chronic cancer pain. Based on observations from the Phase I study, the Company has started a Phase II study with NP2 Enkephalin in the US.

Phase II study

Since January 2011, NP2 Enkephalin has been evaluated in a Phase II study enrolling approximately 32 participants with severe cancer pain. In the study, 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. Lead investigator of the study is Dr. David Fink, Professor and Chair of the Department of Neurology at the University of Michigan, USA. Results of the Phase II study are expected during the first half of 2012.

Phase I study

Diamyd Medical has conducted a Phase I study with NP2 Enkephalin in order 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 persons 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 results of the study were published in the spring of 2011 in the medical journal *Annals of Neurology*.

Lead investigator was Dr. David Fink. The Phase I study has laid the foundation for further studies with drug candidates in the NTDDS platform.



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 chronic neuropathic pain due to diabetes or spinal cord injury. Preclinical development of NG2 GAD are ongoing and are funded by a grant from the United States Department of Veterans Affairs. All preclinical activities that are required to start clinical studies are expected to be completed in 2011. 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.

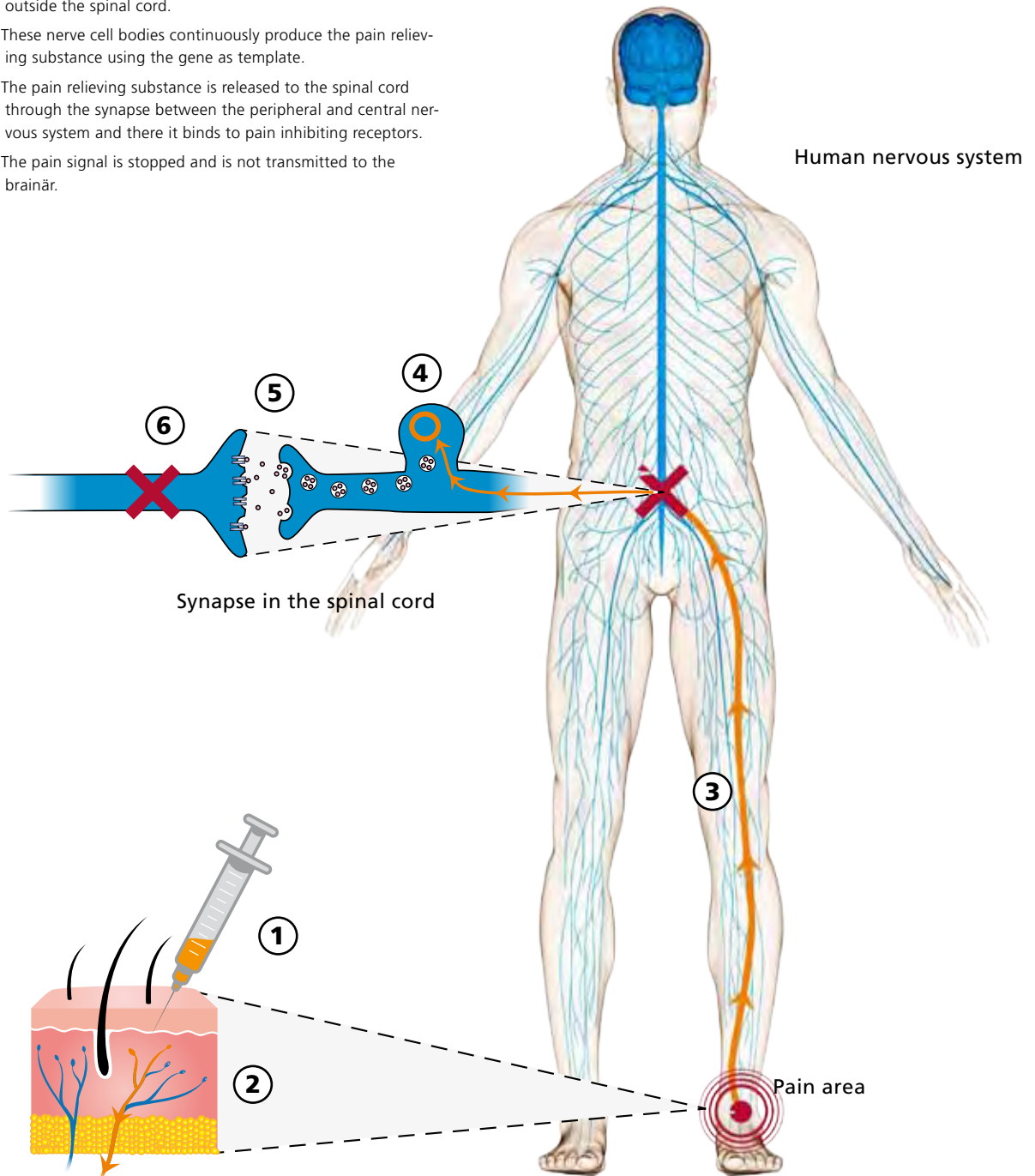
NN1 Neurotrophin

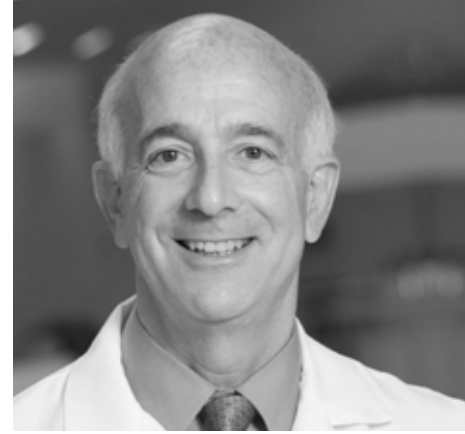
The drug candidate NN1 Neurotrophin is being developed for prevention of chemotherapy induced peripheral neuropathy, a common side-effect of treatment with chemotherapy for cancer. NN1 Neurotrophin uses the NTDDS technology to provide nerve cells with neurotrophic factors that promote survival, growth,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

HOW THE NTDDS TECHNOLOGY WORKS IN TREATMENT OF PAIN

Diamyd Medical's drugs for treatment of pain consist of a vector that carries a gene for a natural painkilling substance.

1. The drug is injected into the skin at site of pain.
2. The vector and the gene are taken up by nerve endings in the skin.
3. The vector and the gene are transported along the body's peripheral nerve pathways to nerve cell bodies that lie just outside the spinal cord.
4. These nerve cell bodies continuously produce the pain relieving substance using the gene as template.
5. The pain relieving substance is released to the synapse between the peripheral and central nervous system and there it binds to pain inhibiting receptors.
6. The pain signal is stopped and is not transmitted to the brain.





REVOLUTIONARY POTENTIAL OF THE NERVE TARGETING DRUG DELIVERY SYSTEM

The idea of delivering naturally occurring therapeutic agents directly to the nervous system stems from research initiated more than 15 years ago at the University of Pittsburgh by our team of dedicated scientists. We set out to develop new approaches to treat diseases of the peripheral and central nervous system. Several of these researchers are now with Diamyd, where the continued development has resulted in a clinical gene delivery system, the Nerve Targeting Drug Delivery System (NTDDS), capable of targeting therapeutic agents to selected nerve cells in patients. Our first clinical study with NTDDS showed promising results and marks a milestone for this innovative technology.

In that Phase I trial, cancer patients suffering from chronic pain who were unresponsive to the highest tolerable doses of opiate drugs were treated with NP2 Enkephalin. We found that not only did NP2 Enkephalin seem to be safe, but at the higher doses patients experienced substantial and sustained pain relief. These results were published in the scientific journal *Annals of Neurology* this spring. Encouraged by these findings my collaboration with Diamyd continues with a randomized placebo-controlled Phase II study with NP2 Enkephalin to treat cancer-related pain. As the lead investigator in this trial, I enthusiastically look forward to the results and to continue the work of advancing this drug through the clinical development pathway.

The principal advantage of the NTDDS technology is the ability to express the active agent directly in the nerve cells where the effect is needed. In the treatment of pain, effective use of conventional drug therapies is often limited by unwanted, off-target, adverse effects at sites of the body unrelated to the pain. Local delivery to the affected site using Diamyd's NTDDS technology circumvents this problem, producing a sustained, pain-relieving effect while avoiding off-target side effects. A second attractive feature of this approach is that the NTDDS platform is used to deliver and express naturally occurring human therapeutic agents, including enkephalin, endomorphin, and GAD (glutamic acid decarboxylase).

As a practicing neurologist, it is particularly encouraging and exciting for me that the NTDDS platform offers wide therapeutic potential that is not limited to NP2 Enkephalin. For example, within the next year we hope to initiate a clinical trial with NG2 GAD for the treatment of painful diabetic neuropathy, a common complication of diabetes that severely impairs quality of life and for which there is currently no effective therapy. The development towards clinical studies with the NG2 GAD drug candidate is supported by a grant from the US Department of Veterans Affairs.

My collaboration with Diamyd is also moving forward with the development of another NTDDS candidate, NN1 Neurotrophin, designed to prevent the development of neuropathy, a common side effect from treatment with chemotherapy in cancer patients. We have recently received a substantial grant from the US National Institutes of Health to help support the development of NN1 Neurotrophin. In the coming years we plan to progress towards a clinical trial in patients with cancer who are at risk of neuropathy due to chemotherapy.

There is a long way to go, but our progress so far strengthens my belief in the revolutionary potential of the NTDDS platform.

David Fink, MD
Professor and Chair of the Department of Neurology, University of Michigan.

MARKET POTENTIAL

The medical need for new forms of treatments for various types of chronic pain is considerable. Apart from inadequate and transient efficacy, current treatments of severe and chronic pain often have side-effects and may lead to tolerance, habituation and abuse. Most companies that are developing new products for pain relief are focusing on improving formulations of existing substances where the patents have expired. There are relatively few genuinely innovative pain relief projects in development. The total market for pain management was estimated to be worth USD 46 billion in 2007 and is expected to increase by over 3 percent annually to 57 billion in 2014¹⁾.

Severe pain is one of the most feared consequences of cancer and approximately 75 percent of all cancer patients are in need of opioid treatment to relieve the pain³⁾. About 10 million people in the seven largest pharmaceutical markets (USA, Japan, France, Germany, Italy, Spain and Great Britain) are estimated to suffer from cancer pain and the number is expected to increase as the population grows older and cancer survival increases¹⁾. In US alone, the market potential for cancer pain is estimated to be more than USD 3.6 billion annually⁴⁾.

Globally, 170-270 million people are estimated to suffer from peripheral neuropathy and neuropathic pain⁵⁾ and more than 6.5 million to suffer from diabetes pain in the seven largest pharmaceutical markets. The market potential for neuropathic pain is estimated to reach USD 5.5 billion by year 2015⁵⁾.

PATENT SITUATION OF THE NTDDS PLATFORM

Diamyd Medical has been granted exclusive rights to the NTDDS platform by the University of Pittsburgh, USA. The licensed patents and patent applications protect the NTDDS technology, production methods and components such as cell lines and vectors. Patent protection in the US is projected to last until at least 2024. European and Asian patent applications are being processed.



Pain

Pain is an unpleasant sensation that normally occurs with damage or threat of damage to the body's tissues. Pain changes the affected person's behavior and acts as a protective mechanism, for example, by stopping weight bearing on a broken leg in order to prevent further damage. This type of pain, called acute or nociceptive pain, is functional and not considered pathological. Pain is normally triggered by activation of pain receptors on nerve endings. When stressed, the receptors are triggered and signals are sent through the nerve to the spinal cord, where they are routed on to the brain.

In some conditions, pain occurs without the body being exposed to any injury, or long after an injury has healed. This type of pain is not functional and is therefore considered pathological. If the pain is caused by defects in the nervous system it is called neuropathic pain or nerve pain.

Neuropathy

Neuropathy is a generic term for damage of nerve cells and may be caused by external or internal trauma, certain medications or diseases. The consequences of neuropathy differ depending on the type of nerve cell being damaged. Damage to nerve cells that activate muscles in the body could cause some loss of muscle function, while damage to nerve cells that send pain signals could cause neuropathic pain.

Neuropathy may be classified as either peripheral or central depending on its origin and on which type of nerve being affected. Peripheral neuropathy, i.e. neuropathy in the peripheral nervous system, is a common complication of diabetes, cancer and chemotherapy.

Typical symptoms of peripheral neuropathy are numbness, pain, stinging or burning sensations in hands and feet. It can cause erectile dysfunction (impotence), for example in men suffering from diabetes and prostate cancer. There is currently no effective treatment for peripheral neuropathy.

Neuropathic pain

Damage to nerve cells is often followed by a pain sensation, called nerve pain or neuropathic pain. Neuropathic pain is often chronic and may be caused by nerve cell damage due to trauma, surgery, back problems (e.g. herniated disc), diabetes, cancer, nerve infections such as herpes and shingles, as well as brain damage from stroke or Multiple Sclerosis (MS). If the damage is located in nerves that lie outside the brain and spinal cord, the resulting pain is called peripheral neuropathic pain. Diabetes pain, cancer pain and phantom limb pain are examples of peripheral neuropathic pain. Examples of central neuropathic pain include spinal cord injuries and MS.

Cancer pain

Cancer is often associated with pain. Cancer pain is often prolonged and usually it involves a combination of multiple pain types. The cancer itself may cause compression of, or direct damage to soft tissue, bone, muscle and nerves, and also cancer treatments such as chemotherapy, radiation therapy and surgery can cause various types of pain.

Diabetes pain and diabetes neuropathy

Diabetes pain is a very common complication of diabetes. The precise pathological mechanisms behind diabetes pain are unclear, but it is a fact that poorly controlled diabetes with consistently elevated and fluctuating blood sugar levels result in nerve damage. It is estimated that 50 percent of diabetes patients develop some form of diabetes-related nerve damage, which means that diabetes is one of the most common causes of neuropathy²⁾. Diabetic vascular complications cause further damage to the nervous system by reducing blood flow to the nerves. The most common form of diabetic neuropathy is peripheral nerve damage, resulting in pain or associated loss of touch sensation and numbness of the feet, legs, hands and arms.

Current treatment strategies

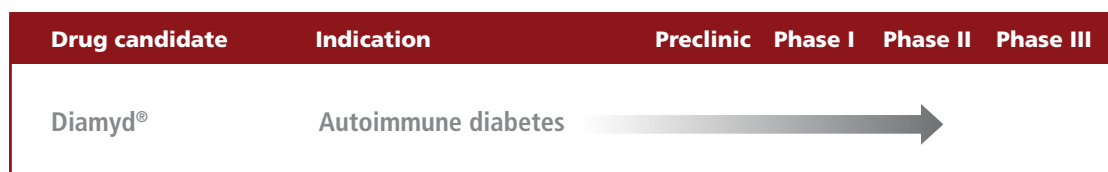
Pain, by definition, implies considerable suffering. Currently available treatments often cause sedation, and many patients are forced to choose between pain and alertness. In palliative care, many relatives find that drowsiness caused by pain-relieving medication impairs their ability to say their proper goodbyes to the patient.

There are several standard treatment options for nociceptive pain. One is to eliminate the actual cause and stop the stimulation of pain receptors. Anti-inflammatory drugs reduce the production of the chemical agents that stimulate pain receptors. Alternatively, local anesthesia can prevent nerves from transmitting pain signals. And finally, opiate drugs such as morphine, act on the body's own pain-inhibiting receptors in the brain, spinal cord and peripheral nerves.

Neuropathic pain is generally difficult to treat, primarily since it is often chronic. Due to tolerance, standard treatments for this type of pain do not have the desired effect and could cause numerous problematic side effects. Instead, transcutaneous electrical nerve stimulation, antidepressant drugs and anti-epileptic drugs are used, often with only limited effect. Surgical transection of nerves has also been tried, but with limited success and this often makes matters worse. The lack of treatments for neuropathic pain constitutes a considerable unmet medical need.

DIABETES

Diamyd Medical's development projects in diabetes originates from the protein GAD65 (the 65 kDa isoform of glutamic acid decarboxylase) which is the active substance in the Company's antigen-based diabetes therapy Diamyd® for the prevention and treatment of autoimmune diabetes. A Swedish prevention study is ongoing to evaluate whether treatment with Diamyd® can prevent type 1 diabetes in children at high risk of developing the disease.



DIABETES - A CHRONIC DISEASE

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 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 incorrectly diagnosed as type 2 diabetes. Diamyd Medical estimates that about 10 percent of all those diagnosed with type 2 diabetes actually have LADA⁶⁾. In contrast to the autoimmune forms, type 2

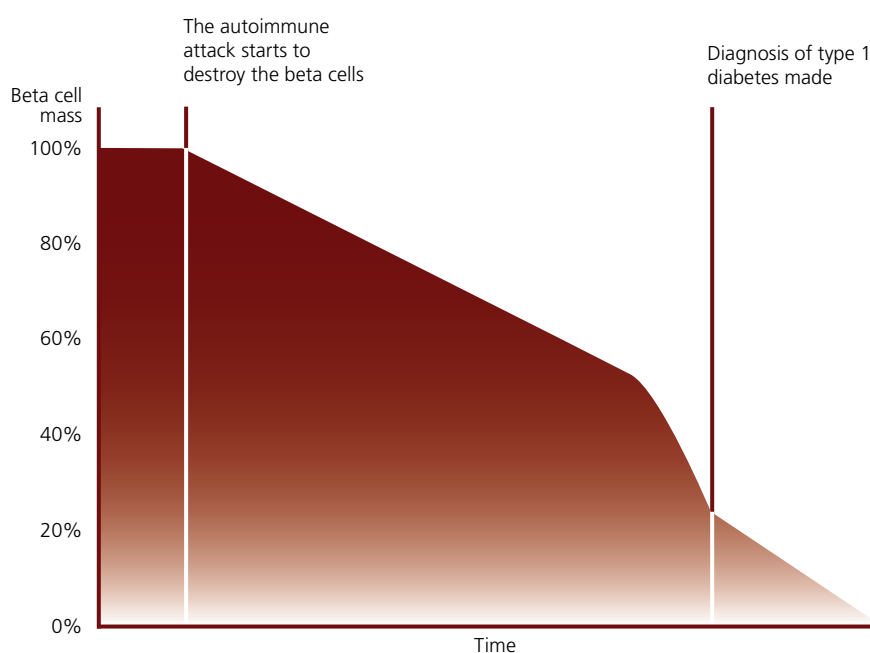
diabetes is caused by impaired insulin sensitivity and is mainly related to age and lifestyle.

There is currently no treatment in 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.

GAD65 FOR TREATMENT AND PREVENTION OF DIABETES

Diamyd Medical's platform for research in autoimmune diabetes originates from the GAD65 molecule. GAD65 (glutamic acid decarboxylase isoform 65 kDa) is a human enzyme and an important autoantigen in autoimmune diabetes. GAD65 is found in the blood sugar-regulating beta cells of the pancreas, where its function is not yet fully understood. It is however clear that GAD65 is one of the most important targets when the immune system attacks the beta cells in autoimmune diabetes.

Endogenous GAD65 can be found in the beta cells of the pancreas as well as in nerve and brain tissue. In nerve cells, GAD65 catalyzes the transformation of the neurotransmitter glutamate to the neurotransmitter GABA (gamma-amino butyric acid). Accordingly, GAD65 is thought to have potential as a drug candidate in several



The autoimmune attack destroys the insulin-producing beta cells. At the time of diagnosis only 10-20 percent of the beta cells remain.

neurological diseases, such as Parkinson's disease, as well as for chronic neuropathic pain.

The GAD platform comprises the antigen-based diabetes therapy Diamyd® for prevention and treatment of autoimmune diabetes. Diamyd® has been evaluated in a Phase III study in newly diagnosed type 1 diabetes patients. The study did not meet the primary efficacy endpoint of preserving beta cell function, as measured by meal-stimulated C-peptide. A Phase II study is underway to evaluate whether treatment with Diamyd® can prevent type 1 diabetes in children who are at high risk of developing the disease.

Mechanism of action

The autoimmune types of diabetes, type 1 diabetes and LADA, result from a deficiency of insulin caused by an autoimmune attack on the body's own blood sugar-regulating beta cells in the pancreas. Treatment with the protein GAD65 is thought to induce tolerance to the protein, thereby intervening in, or preventing, the autoimmune attack in type 1 diabetes and LADA. The hope is to be able to prevent autoimmune diabetes from developing or to preserve the the body's capacity to regulate blood sugar. This is very important as there is no such treatment available on the market today.

Treatment with GAD65 works by so-called immunomodulation and

is antigen-specific, which means that it specifically aims to induce tolerance in the autoimmune T cells that attack GAD65 in the beta cells, without impairing the immune system either wholly or in part.

PROJECT PORTFOLIO IN AUTOIMMUNE DIABETES

Diamyd Medical's development projects in autoimmune diabetes consists of the GAD65-based drug candidate Diamyd®. Diamyd® is currently under development for prevention of type 1 diabetes, treatment of newly diagnosed type 1 diabetes and treatment of LADA.

Diamyd® for prevention of type 1 diabetes

In type 1 diabetes, the autoimmune attack and the destruction of blood sugar-regulating beta cells in the pancreas starts 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.

Researcher-initiated phase II study

A Swedish researcher-initiated study with Diamyd® in children at high risk of developing type 1 diabetes has been in progress since 2008.



The purpose of the study is to evaluate whether treatment with Diamyd®, compared to placebo (inactive substance), can delay or halt the progression of the disease so that the children do not develop type 1 diabetes.

The study 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.

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.

Diamyd® for the treatment of newly diagnosed type 1 diabetes

When a patient is diagnosed with type 1 diabetes, 10 to 20 percent of the insulin-producing beta cells remain. The aim of treatment with Diamyd® is to prevent, delay, or stop the autoimmune attack on beta cells in newly diagnosed type 1 diabetes, thereby preserving the body's capacity to regulate blood sugar. Diamyd® for the treatment of newly diagnosed type 1 diabetes has been evaluated in several clinical trials.

Phase III program

In 2008, Diamyd Medical launched two parallel Phase III studies, one in Europe and the other in the US, in patients recently diagnosed with type 1 diabetes to evaluate the efficacy of the drug candidate Diamyd®. Results from the European Phase III study presented 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. In June 2011, the Company decided 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. The study demonstrated significant long-term efficacy in preserving beta cell function, i.e. the body's own capacity to control the blood sugar, compared to placebo. The Phase II study also showed that that the treatment effect was the best early in the course of disease in patients with recent onset type 1 diabetes. No serious side effects related to the treatment were reported in the study. The results were published in the fall of 2008 in the prestigious scientific journal *The New England Journal of Medicine*.

Clinical development program with Diamyd®

Phase & Country	Year initiated	Participants	Age, years	Number of patients	Trial period	Purpose
Skin prick test, Sweden	1995	Type 1 diabetes patients and healthy individuals	Adolescents	N=15	Trial period: 28 days. Completed.	Safety
Phase I, UK	1999	Healthy individuals	24–45	N=24	Trial period: 10 weeks. Completed.	Safety and tolerability
Phase IIa, Sweden	2000	LADA patients	30–70	N=47	Trial period: 6 months. Follow-up: 4, 5 years. Completed.	Dose-finding, safety and efficacy
Phase IIb, Sweden	2005	Type 1 diabetes patients	10–18	N=70	Trial period: 15 months. Follow-up: 15 months. Prolonged follow-up ongoing.	Safety and efficacy
Phase IIb, Sweden	2004	LADA patients	30–70	N=160	Trial period: 18 months. Follow-up: 12 months. Completed.	Safety
Phase III, Europe	2008	Type 1 diabetes patients	10–20	N=334	Trial period: 15 months. Completed.	Safety and efficacy
Phase III, USA	2008	Type 1 diabetes patients	10–20	N=331	Trial period: 15 months. Being closed.	Safety and efficacy

Researcher-initiated Phase II study

Diamyd® is being evaluated in a researcher-initiated Phase II study aimed to assess whether treatment with Diamyd® can preserve the body's own beta cell function. In addition, the mechanism of action of the treatment is being studied in detail, and its effect on the immune system. The study, which has recruited 145 patients from three years of age with newly diagnosed type 1 diabetes, is being conducted by the American network Type 1 Diabetes TrialNet, funded by the NIH (National Institutes of Health) and the NIDDK (National Institute of Diabetes and Digestive and Kidney Diseases). The first results, presented June 27, 2011, showed that the study did not meet the primary efficacy endpoint to preserve endogenous insulin production, as measured by meal stimulated C-peptide, in patients treated with Diamyd® compared to placebo. The results were published in the scientific journal *The Lancet* in June 2011. The study is still ongoing and participants are monitored continuously in order to study the mechanism of action and effect on the immune system. Diamyd Medical has participated in the design of the clinical study protocol and has rights to the study results.

Diamyd® for the treatment of LADA

LADA 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. Treatment with Diamyd® is intended to delay, or stop the autoimmune attack on beta cells in LADA, thereby preserving the body's capacity to regulate blood sugar.

Phase II study

Diamyd Medical has completed a randomized, double-blind, placebo controlled Phase II study with 47 LADA patients, in which various doses of Diamyd® were tested. The study was unblinded after six months and the patients were followed for another four and a half years. A five-year follow-up of the participants showed that the risk that a LADA patient will need to begin insulin treatment is significantly reduced after treatment with Diamyd® compared to placebo treatment. Only 14 percent of the patients in the group that received 20 µg of Diamyd® and completed the study needed insulin treatment five years after the initial injection, compared with 64 percent in the placebo group. No serious side effects from the treatment were reported during the five-year period. The results were published in the scientific diabetes journal *Diabetologia*, in April 2009.

PHASE III PROGRAM WITH DIAMYD®

In 2008, Diamyd Medical launched two parallel Phase III studies in type 1 diabetes with the GAD65-based drug candidate Diamyd®, one in the US and the other in Europe.

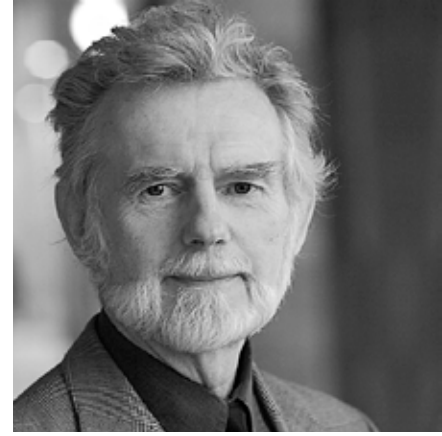
In May 2011, 15 months after all patients in the European study had received the first injection of the drug candidate, the first results of the study showed that Diamyd® did not demonstrate sufficient efficacy. The study enrolled 334 patients, 10 to 20 years old, who were diagnosed with type 1 diabetes within three months of entering the study. All of the patients had some endogenous insulin production remaining and were GAD antibody positive at study entry. The study included three treatment arms in which a third of the patients received four subcutaneous injections of Diamyd® (day 1, 30, 90 and 270), one third received two injections of Diamyd®, and one third received placebo. Diamyd® was well tolerated, as demonstrated by a similar number of adverse events reported in the groups treated with Diamyd® and in the placebo group. The levels of GAD antibodies increased significantly in the groups receiving Diamyd®, but not in the placebo group.

The primary efficacy endpoint was change in C-peptide, a measure of endogenous insulin production, between the first study visit and the visit 15 months later. In the study, the levels of C-peptide decreased similarly in all treatment groups. The primary efficacy end-

point of the study was not met, although a small positive effect was seen. Patients treated with Diamyd® had on average 16.4 percent more remaining C-peptide at 15 months compared to those who received placebo. The p-value of the primary endpoint was 0.10. The secondary efficacy endpoints included mean daily dose of insulin, hemoglobin A1c (HbA1c) and frequency of hypoglycemia. Treatment with Diamyd® did not achieve a statistically significant effect for any secondary endpoint. Given that the European Phase III study did not meet the primary efficacy endpoint, Diamyd Medical decided not to complete the follow-up period of the study, which therefore was closed on June 1, 2011. On June 23, 2011, the Company announced the decision to suspend dosing in the parallel US Phase III study and to also initiate closure of that study. The decision followed a blinded review of the efficacy data collected to date in the US study as well as the reported outcome of the European Phase III study.

The European study was led by Professor Johnny Ludvigsson at the University Hospital in Linköping, and the US study by Professor Jerry Palmer, University of Washington, Seattle.

There are still hopes that Diamyd® and the active substance GAD65 may show efficacy in the prevention of type 1 diabetes, in certain subgroups of patients newly diagnosed with type 1 diabetes, in combination with other drugs or in a different treatment regimen than the one tested in the Phase III studies.



DIAMYD® RESEARCH CONTINUES

Type 1 diabetes is a very serious disease that usually occurs in children and young people. Although treatment of the disease has considerably improved since insulin was discovered 90 years ago, we still cannot prevent or stop the process that leads to type 1 diabetes.

I personally have 40 years' experience in testing various immunological approaches to counter type 1 diabetes without managing to solve the mystery, but after the strong Phase II results with the Diamyd® diabetes vaccine, I was convinced that we were on the right track.

As principal investigator in the European Phase III study with Diamyd®, I was therefore initially surprised and very disappointed to see that the results did not meet our high expectations, even though a slight positive effect could be observed. However, on closer analysis of the study data, I regained hope!

First and foremost, the study showed that treatment with Diamyd® is safe since a similar number of side effects were reported in the groups that were treated with Diamyd® as in the group that received placebo. This was a positive finding since the safety aspect is vital in respect to drugs that are developed for children.

On average, the children and young people who were treated with Diamyd® retained 16.4 percent more of their own ability to make insulin (measured as C-peptide) 15 months after their first treatment versus placebo ($p = 0.10$). Analyses of pre-defined subgroups suggest that the treatment may have been effective in several of the groups, although these analyses should be interpreted with caution. One of these analyses showed that the boys in the study who were treated with Diamyd®, retained 41 percent more of their C-peptide than those who received placebo ($p < 0.01$). We also experienced some bad luck since a greater number of younger participants by chance were included in the groups that received Diamyd® than in the group that received placebo. The disease usually progresses faster in younger children than in older children, and this may have had a slightly negative impact on the chance to show an effect of the treatment.

Another observation was that among the children and young people who received their first Diamyd® injection in the spring, those treated with Diamyd® showed a statistically significant preservation of C-peptide compared with those who received placebo ($p = 0.02$). In the previous Phase II study with Diamyd®, all study participants

received their first injection of the study drug in the spring, and since the immune system is subject to seasonal variations, this may impact the effect of the treatment on the immune system. Another factor that could contribute to the different outcomes between the Phase II and Phase III studies is the use of flu vaccine. The swine flu pandemic broke out during the Phase III study. As a result, many study participants received the flu vaccine, and this may have impacted the possibility for Diamyd® to affect the immune system in the intended manner. In the Phase II study, no children received any flu vaccine.

Our research group in Linköping has analyzed immunological markers in blood samples from all of the Swedish children in the European Phase III study with Diamyd®. This has produced a large amount of data that can help us understand how patients differ immunologically and how this impacts the effect of the treatment. Hopefully, we can find common immunological patterns in some groups of patients that responded to the treatment with the Diamyd® diabetes vaccine.

Perhaps we placed the bar too high? If we draw a parallel with how care for children's cancer and allergies has developed, these treatments have gradually improved over the years by combining various treatments that individually have had a limited effect. Similarly, in type 1 diabetes, we can use what we have learnt to design new studies with a single drug, or combination of drugs, to prevent or treat the disease.

How should we proceed with Diamyd® and research into type 1 diabetes? At international level, there is great interest and intense discussion. We are a group of Nordic physicians who are investigating opportunities to initiate a major Nordic prevention study with Diamyd® to prevent type 1 diabetes, and in the Swedish network of children's diabetes clinics, we are considering an alternative approach in terms of dose and the number of doses of Diamyd® for children who have recently developed type 1 diabetes.

We are not giving up!

Johnny Ludvigsson MD, PhD
Professor of Pediatrics, Department of Clinical and Experimental Medicine, Linköping University

FUTURE MARKET POTENTIAL

Diabetes is a common disease globally, today affecting an estimated 366 million people, or 8.3 percent of the adult population. This figure is expected to rise to 552 million by 2030⁷⁾. Type 2 diabetes is on the increase worldwide, accounting for 85-95 percent of all cases⁷⁾. Several studies have shown that around 10 percent of all those diagnosed with type 2 diabetes actually have LADA, which translates into an estimated total of at least 30 million LADA sufferers worldwide⁶⁾. Type 1 diabetes is estimated to account for about 5 percent of all cases of diabetes in the Western world⁸⁾.

The prevalence of type 1 diabetes is highest in the Nordic countries. Estimates based on data from reports and articles about the number of people in different age groups who develop type 1 diabetes, as well as on the rate of increase in different regions, show that in the US and Europe alone about 80,000 people develop type 1 diabetes annually⁹⁾. In addition, new research shows that the number of children and adolescents that develop the disease in Europe is increasing by about 4 percent annually and that the age of onset of type

1 diabetes is falling¹⁰⁾. The reasons for this are unclear. Every year, 4.6 million people are estimated to die as a result of diabetes. In addition to personal suffering and life-long medication the disease burdens society with enormous annual costs for healthcare and loss of working hours. The global healthcare cost of diabetes, including treatment of complications, estimated at USD 465 billion in 2011⁷⁾. There is currently no treatment on the market against the autoimmune process that causes type 1 diabetes and LADA.

PATENT PROTECTION

Diamyd Medical has secured exclusive patent licenses for the manufacturing and therapeutic use of GAD65 and the GAD65 gene from the University of California, USA, and the University of Florida, USA. In addition to the exclusive rights to therapeutic use of GAD65, Diamyd licenses non-exclusive rights to GAD-based diagnostic applications.

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).

Type 1 diabetes, also known as juvenile diabetes, and LADA are similar in that they are both autoimmune forms of the disease. This means that the body's own immune system destroys the so-called beta cells in the pancreas that control the blood sugar level. Insulin is the hormone that regulates the level of sugar in the blood. As the disease progresses, the patient will inevitably need to self-inject with industrially manufactured insulin, since the patient's own beta cells will have been destroyed in the autoimmune attack. Type 2 diabetes on the other hand is caused by impaired insulin sensitivity and is mainly related to age and lifestyle.

The result, in all types of diabetes, is that sugar remains in the bloodstream and is not made available to the cells, which has several damaging consequences. Both very high and very low blood sugar levels are extremely dangerous and can lead to rapid and potentially fatal loss of consciousness.

There is currently no product 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 way of injections or an insulin pump. The aim is to reach as stable a blood sugar level as possible, neither too high nor too low, which is extremely difficult.

Diabetes complications

Consistently raised and fluctuating blood sugar levels cause typical diabetes complications, including kidney and eye damage, impaired circulation and cardiovascular disease as well as nerve damage including diabetes pain. There are both acute and long-term complications.

Acute complications mainly comprise severe hypoglycemia and ketoacidosis. In the case of hypoglycemia, the blood sugar level has dropped too low, which in severe cases can lead to the patient losing consciousness, and the body's functions come to a halt as the brain suffers an acute lack of nutrients. If on the other hand the patient lacks insulin, it can lead to ketoacidosis, an extremely acute, life-threatening condition that requires intensive care. This condition arises when the body begins to break down its own cells to obtain nutrients, thereby releasing ketones and acids into the bloodstream.

Long-term complications that can be caused by diabetes include cardiovascular diseases, nephropathy (kidney damage), neuropathy (nerve damage) and retinopathy (eye damage).

Researchers have found that the risk of complications can be reduced by 60–80 percent among type 1 diabetes patients who still have some remaining beta cell function of their own¹¹⁾. This clearly demonstrates the importance of at least partially preserving the endogenous ability of patients with type 1 diabetes to control blood sugar levels.

ADMINISTRATION REPORT 2010/2011

The Board of Directors and Chief Executive Officer of Diamyd Medical AB (publ), corporate registration number 556530-1420 with its registered office in Stockholm, Sweden, hereby presents its Administration Report regarding the operations of the Group and Parent Company for the fiscal year beginning September 1, 2010 and ending August 31, 2011.

GROUP STRUCTURE AND OWNERSHIPS

The Diamyd Group consists of the Parent Company Diamyd Medical AB (publ) and wholly-owned subsidiaries, Diamyd Diagnostics AB, Diamyd Therapeutics AB and Diamyd, Inc., in Pittsburgh, USA.

OPERATIONS

Diamyd Medical is a Swedish biotech company focusing on the development of pharmaceuticals for the treatment of pain, neuropathy and diabetes. The Company's business concept is to refine in-licensed candidate products in the preclinical and clinical phases through development. The products are then to be commercialized, either independently or with a partner.

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 a low cost base, 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.

Business Areas

During the fiscal year 2010/2011 Diamyd Medical's operations have been divided into two business areas, Diabetes and Pain. The business area Diabetes has consisted of the antigen-based candidate drug Diamyd® for prevention and treatment of autoimmune diabetes. The business area Pain has consisted of development projects that use the Company's patented NTDDS platform (Nerve Targeting Drug Delivery System) for the delivery of therapeutics directly to the nervous system for the treatment of chronic pain.

As of the fiscal year 2011/2012 the Company does no longer divide its operations in business areas. The operations will be divided into two areas: Pain and neuropathy, and Diabetes.

Project portfolio

Diamyd Medical's project portfolio consists of five drug candidates in clinical and preclinical development phases, based on two independent technical platforms; NTDDS (Nerve Targeting Drug Delivery System) and GAD.

NTDDS 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 diseases and symptoms in the peripheral and central nervous system such as chronic pain, neuropathy, cancer and neurodegenerative diseases.

Diamyd Medical has four NTDDS-based drug candidates currently under development. Three of these are being developed for the treatment of chronic pain; NP2 Enkephalin, NG2 GAD and NE2 Endomorphin. These three drug candidates usurp the body's three major signaling pathways for pain and together they lay the foundation for a comprehensive and competitive pain product portfolio. In addition, Diamyd Medical is developing the drug candidate NN1 Neurotrophin for the prevention of chemotherapy induced peripheral neuropathy. NN1 Neurotrophin uses the NTDDS technology to deliver a neurotrophic factor to nerve cells in cancer patients prior to chemotherapy, with the purpose of protecting the nerve cells from damage.

Diamyd Medical's platform for research in autoimmune diabetes originates from the GAD65 molecule. GAD65 (Glutamic acid decarboxylase isoform 65 kDa) is a human enzyme and an important autoantigen in autoimmune diabetes. GAD65 is found in the blood sugar-regulating beta cells of the pancreas, where its function is not yet fully understood. It is however clear that GAD65 is one of the most important targets when the immune system attacks the beta cells in autoimmune diabetes. The GAD platform comprises the antigen-based diabetes therapy Diamyd® for prevention and treatment of autoimmune diabetes. Diamyd® has been evaluated in a Phase III trial in 334 newly diagnosed type 1 diabetes patients, 10 to 20 years old. On May 9, 2011, Diamyd Medical announced that the study 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. Given that the European Phase III study did not meet the primary efficacy endpoint, Diamyd Medical decided not to complete the follow-up period of the study, which therefore was closed on June 1, 2011. On June 23, 2011, the Company announced the decision to suspend dosing in a parallel US Phase III study and to also initiate closure of that study. The decision followed a blinded review of the efficacy data collected to date in the US study as well as the reported outcome of the European Phase III study.

Ongoing clinical trials

Since January 2011, NP2 Enkephalin has been evaluated in a US Phase II study enrolling approximately 32 participants with severe

cancer pain. In the study, the patients' pain levels and use of painkilling drugs are being monitored in the study. 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. Lead investigator of the study is Dr. David Fink, Professor and Chair of the Department of Neurology at the University of Michigan, USA. Results of the Phase II study are expected during the first half of 2012.

The Phase II study is based on observations from a Phase I study where NP2 Enkephalin was evaluated for treatment of chronic cancer pain. In the Phase I study, substantial and sustained pain relief was observed in the groups treated with the two highest doses of NP2 Enkephalin. No serious side-effects related to the treatment have been reported by any of the participants in the Phase I study. The results of the study were published in the spring of 2011 in the medical journal *Annals of Neurology*.

The GAD based candidate drug Diamyd® is since 2008 being evaluated in a Swedish researcher-initiated study in children at high risk of developing type 1 diabetes. The purpose of the study is to evaluate whether treatment with Diamyd®, compared to placebo (inactive substance), can delay or halt the progression of the disease so that the children do not develop type 1 diabetes. The study 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 half receive placebo. 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.

IMPORTANT EVENTS DURING THE FISCAL YEAR

In September 2010 Diamyd Medical reported promising safety findings from a Phase I study in chronic pain with the candidate drug NP2 Enkephalin. No drug related Serious Adverse Events had been reported by any patient included in the study. Shortly thereafter, in October 2010, substantial and sustained reduction in experienced pain could also be reported in the two highest dose cohorts of the Phase I study with NP2 Enkephalin. The study, intended to test the safety of NP2 Enkephalin and the NTDDS platform, was designed as an open label, dose escalation study in patients with intractable pain due to malignant cancer. Three dose levels were investigated.

In October 2010 Diamyd Medical announced that the Company divides its operations into two business areas beginning with the fiscal year 2010/2011; Diabetes and Pain. The business area Diabetes consists of the antigen-based candidate drug Diamyd® for the treatment and prevention of autoimmune diabetes. The business area Pain

consists of development projects that use the Company's proprietary NTDDS platform to deliver therapeutics directly to the nervous system to treat pain.

In November 2010 the screening of patients for the US Phase III study, DiaPrevent, with the candidate drug Diamyd®, was completed. More than 310 recently diagnosed type 1 diabetes patients between 10 and 20 years of age had, at the completion of screening, been enrolled in the study and received their first injection of the antigen-based therapy Diamyd® or placebo.

Nasdaq OMX Stockholm Disciplinary Committee imposed, in December 2010, a penalty on Diamyd Medical AB for inadequate disclosure of information. Diamyd Medical was imposed to pay an administrative penalty of SEK 576,000, corresponding to three annual fees. The company noted the Disciplinary Committee's decision and took measures to strengthen procedures in the Company's information disclosure.

In December 2010 Nasdaq OMX Stockholm decided to move Diamyd Medical (DIAM B) from the Small Cap list to the Mid Cap list. The change was effective as of January 3, 2011.

In January 2011 Diamyd Medical started a Phase II study aiming to evaluate the ability of the candidate drug NP2 Enkephalin to reduce cancer pain. The study, which is multi-center and placebo controlled, comprises 32 patients with severe cancer pain and follows their pain scores and concomitant pain medication usage. The trial has a four week double-blind main study period and following this period, all patients will be offered up to two additional doses of active NP2 Enkephalin in an open label study extension.

In February 2011 Diamyd Medical announced that University of Florida Research Foundation (UFRRF) had initiated a court case against Diamyd Medical. UFRRF claimed that UFRRF is entitled to a percentage of the license fee paid to Diamyd Medical by Ortho-McNeil-Janssen Pharmaceuticals, Inc. regarding the rights of the GAD65-based diabetes therapy Diamyd®. Diamyd Medical has licensed certain rights related to GAD65 from UFRRF.

That same month, February 2011, the last patient in the Company's European Phase III study had completed the 15-month visit, meaning that all patients in this study had completed the main 15 month study period. This important milestone in Diamyd Medical's Phase III program was followed by an intensive period where data from more than 60 participating clinics across Europe and from the central laboratory were compiled and processed.

Results from Diamyd Medical's Phase I trial with the candidate drug NP2 Enkephalin for the treatment of intractable cancer pain, were published in the medical journal *Annals of Neurology* in April 2011.

In April 2011 Diamyd Medical's President and CEO, Elisabeth Lindner, left her position. Executive Vice President and the Compa-

ny's former Senior Director Business Development, Peter Zerhouni, was appointed Acting President and CEO.

In May 2011 Diamyd Medical reported initial results from the Company's European Phase III trial with the antigen-based diabetes therapy Diamyd®. The results from the study did not meet the primary efficacy endpoint of preserving beta cell function, as measured by meal-stimulated C-peptide, in patients recently diagnosed with type 1 diabetes. Safety data showed that 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.

Diamyd Medical announced in June 2011 that Ortho-McNeil-Janssen Pharmaceuticals, Inc. had terminated the agreement that was signed in June 2010 to develop and commercialize the diabetes therapy Diamyd®, and Diamyd Medical regained all rights to the diabetes therapy and the active substance GAD65. The termination of the agreement followed the evaluation of the results of the European Phase III study, reported on May 9, 2011.

In June 2011 Diamyd Medical decided not to complete the follow-up period of the Company's European Phase III study with Diamyd®. The decision not to complete the long-term follow-up of patients in the European study was taken after a comprehensive evaluation of the collected study data. Following consultation with the US Food and Drug Administration (FDA), Diamyd Medical also decided to suspend dosing in the Company's parallel US Phase III study and to initiate closure of the study.

That same month, in June 2011, the research consortium "Type 1 Diabetes TrialNet" presented results from a study with Diamyd Medical's candidate drug Diamyd®. The results did not show a statistically significant effect of the study drug.

At the end of June 2011 Diamyd Medical presented detailed results from the company's European Phase III study of the antigen-based diabetes therapy Diamyd®, which did not meet the primary efficacy endpoint. The results showed that patients treated with Diamyd® had on average 16.4 percent more remaining C-peptide at 15 months compared to those who received placebo. The p-value of the primary endpoint was 0.10.

In June 2011 Diamyd Medical increased shareholding in Protein Sciences Corporation, after Diamyd Medical's convertible promissory note in Protein Sciences Corporation was converted into shares. After conversion, Diamyd Medical holds about 8 percent of the Protein Sciences Corporation shares.

In July 2011 the Board of Diamyd Medical appointed the former Acting President of Diamyd Medical, Peter Zerhouni, as President of the Company. He assumed his position as President and CEO on July 4, 2011.

In August Diamyd Medical announced that the Company has cho-

sen to concentrate its resources on the Company's drug candidates for the treatment of pain and diseases of the nervous system. The termination of the Phase III program with the diabetes therapy Diamyd® was reported to mean significantly lower costs for the Company and thus creating strategic leeway.

IMPORTANT EVENTS AFTER THE END OF THE FISCAL YEAR

In September 2011 Diamyd Medical with collaborators received a three million dollar 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.

THE DIAMYD GROUP'S REVENUES AND COSTS

Net sales

The Group's net sales amounted to MSEK 280.8 (113.0). In the fiscal year 2009/2010, Diamyd Medical received an upfront payment of MSEK 327.3 in conjunction with the signing of the agreement with Ortho-McNeil-Janssen Pharmaceuticals, Inc. for the development and commercialization of the antigen-based therapy Diamyd®. The amount was accrued until February 2011 according to the Company's interpretation of IAS 18. During the fiscal year 2010/2011 MSEK 229.8 has been taken up as income.

Costs

The Group's operating costs were MSEK 176.9 (134.3). The increase in costs is attributable to the expansion of internal and external resources to pursue the Company's global Phase III program with Diamyd®.

Net profit

The Group's net profit after financial items amounted to MSEK 101.8, an increase of MSEK 102 compared to 2009/2010. The deviation is explained by higher operating revenues (MSEK 157) due to income from upfront payment and research collaboration, higher costs (MSEK -43) and reduced financial income and expense (MSEK -12) due to exchange rate differences.

Cash flow

The Group's cash flow amounted to MSEK -336.3 (464.0). The decrease in cash flow is primarily attributable to the increase in interest-bearing investments with three to six months term to maturity, classified as short-term investments (-278), and lower volume of new issues (-201) and upfront payment compared to 2009/2010 (-327).

Cash and cash equivalents

The Group's cash and cash equivalents and short term investments, amounted to MSEK 435.6 (501.3) at August 31, 2011. During the years 1996–2011, the Group has raised funds amounting to a total of MSEK 740 from the shareholders.

Shareholders' equity

At August 31, 2011, shareholders' equity amounted to MSEK 461.0 (314.8).

Investments

Investments in tangible assets for the full year were MSEK 1.9 (0.7) and were primarily attributable to research equipment.

External research and development costs

The Group's costs for research and development (R&D) were MSEK 96.0 (80.8). In accordance with the accounting policies being used, these costs were expensed on an ongoing basis rather than being capitalized in the balance sheet.

Earnings from other shares and participations

Diamyd Medical owns 19 % of Mercodia AB (Sweden). The Company has received dividends of MSEK 0.4 (0.4) from Mercodia this year. On the balance sheet date the carrying amount for this holding was MSEK 0.8.

Diamyd Medical holds about 8 % of the Protein Sciences Corporation shares. On the balance sheet date, the carrying amount for this holding was MSEK 28.4.

Staff

As of August 31, 2011, the Group had 28 (24) employees. The average number of employees during the year was 29 (19). The personnel are employed in the subsidiaries Diamyd Therapeutics AB 18 (17) and Diamyd, Inc. 10 (7). Personnel expenses for the Group were MSEK 48.8 (31.2). For additional information on the average number of employees, salaries, other remuneration and social security costs, see Note 4.

Diamyd Medical AB (publ) – parent company

The Parent Company had net sales of MSEK 280.1 (112.0). Profit before appropriations and tax amounted to MSEK 129.1 (7.1). Change in cash and cash equivalents totaled MSEK -329.4 (452.7). Of the change in cash and cash equivalents, MSEK 277.9 is attributable to increase of short term investments.

ENVIRONMENTAL AND ETHICAL POLICIES AND QUALITY ASSURANCE

Diamyd Medical's primary focus is the development of pharmaceuticals for pain, neuropathy and diabetes, serious conditions in great need of new treatment regimens. Diamyd Medical's responsibility toward society and the patient is an important part of its business as a research pharmaceutical company, and influences its work in developing new pharmaceutical products and performing clinical trials. Diamyd Medical's work has a great impact on people's lives and health, so it is of the utmost importance for Diamyd Medical to not only follow applicable laws and regulations, but also to act in a manner that is responsible and ethically proper.

Pre-clinical and clinical studies of Diamyd Medical's candidate drugs are conducted in cooperation with partners, such as contract research organizations or research groups associated with universities. The studies should always be designed in consultation between Diamyd Medical and its partners, and approved by Diamyd Medical. Diamyd Medical's clinical trials are conducted in accordance with Good Clinical Practice (GCP), and they are managed in cooperation with well-established contract research organizations. The performance of trials are regulated according to special process descriptions, i.e. Standard Operating Procedures, as well as quality agreements, in order to ensure that Diamyd Medical's trials are always conducted according to applicable practice and that laws and regulations are followed.

Diamyd Medical will work for a long-term environmental and social sustainability, both in daily operations and in collaboration with business partners, researchers and consultants. The Company's sustainability efforts will, by virtue of knowledge and experience, continually evolve. Every employee should feel a personal responsibility to help the Company meet the targets set.

Diamyd Medical does not do any manufacturing itself, and its direct environmental impact is considered to be low. However like most other companies, its business causes a certain degree of impact on the environment, primarily through emissions for travel and shipments as well as energy consumption for its offices. In addition some environmental impact may occur in connection with the manufacture of Diamyd Medical's products by external manufacturers, as well as from outsourced research activities. To ensure that Diamyd Medical always strives for long-term environmental efforts with the smallest possible environmental impact, both in its operational activities and in cooperation with manufacturers, researchers and other partners, Diamyd Medical pursues its work according to an established environmental policy including energy consumption, waste management, recycling, purchasing, manufacturing and transportation.

PRINCIPLES FOR REMUNERATION FOR MANAGEMENT

Principles applied to remuneration and other terms of employment for the CEO and other key executives are that the total remuneration package is according to market conditions and is a weighted mix of salary, pension benefits or other benefits as well as terms for notice. Diamyd Medical has no bonus program. The Board proposes that the same guidelines should be in force next year as those adopted at the AGM in 2010. These are proposed to apply for the year, and they are subject to approval at the AGM.

OPTION PROGRAM

EMPLOYEE STOCK OPTION PROGRAM 2008/2011

On December 11, 2008, the Annual General Meeting of Diamyd Medical AB (publ) approved an employee stock option plan totaling 220,000 employee stock options. The issue price for shares was set at SEK 66 per share for the stock options, which were allocated free of charge. One-third of the program was exercisable on November 15, 2009 another third on November 15, 2010 and the final third will be exercisable from November 15, 2011 until December 31, 2011. In addition to the 166,650 options that have been allocated to employees and management, Group subsidiaries have subscribed for 53,350 options intended to be used to cover the social security expenses that can arise from the option program when the options are exercised by their holders. Valuation of the program has been carried out in accordance with the Black & Scholes method and the primary parameters have been volatility 49 % and the issue price of SEK 66 per share. Interest rates comparable to a one-year treasury bill and two-year and three-year government bonds have been utilized for calculating costs. At August 31, 2011, 79,200 options were still outstanding. After the fiscal year's new share issues and split, the issue price has been adjusted to SEK 29.25. Each option entitles the holder to subscribe for 2.26 shares.

EMPLOYEE STOCK OPTION PROGRAM 2009/2012

On December 11, 2009, the Annual General Meeting of Diamyd Medical AB (publ) approved a new employee stock option plan totaling 580,000 employee stock options. The issue price for shares was set at SEK 124 per share for the stock options, which were allocated free of charge. One-third of the program was exercisable on November 15, 2010 another third will be exercisable on November 15, 2011 and the final third from November 15, 2012 until December 31, 2012. In addition to the 395,100 options that have been allocated to employees and management and the 38,900 that have been returned when employees have left their employment, Group subsidiaries have subscribed for 146,000 options intended to be used to cover the social security expenses that can arise from the option program when the options are

exercised by their holders. Valuation of the program has been carried out in accordance with the Black & Scholes model and the primary parameters have been volatility 51 % and the issue price of SEK 124 per share. Interest rates comparable to a one-year treasury bill and two-year and three-year government bonds have been utilized for calculating costs. At August 31, 2011, 395,100 options were still outstanding.

RISK FACTORS

Development of a medicinal drug often takes a considerable time, is capital intensive and associated with great levels of uncertainty due to its dependence on unpredictable and complex parameters regarding the course of biological and medical processes.

The following risks comprise internal and external factors that can affect Diamyd Medical's development and growth. Uncertainty regarding whether and to what extent these factors could affect Diamyd Medical's operations or financial position constitutes a risk.

Commercial risk and development risk

No guarantee can be given that Diamyd Medical's research and development projects will lead to commercially viable drugs. No guarantee exists either for the Company's clinical trials resulting in products that can be launched in the market or that they will achieve commercial success.

Financing risk

At present, Diamyd Medical has no products in the market and the business is therefore not profitable. The Company may therefore need to return to the capital markets in the future to raise funds to ensure the future of the business and of research and development projects. No guarantees are available regarding the requisite financing being in place on a timescale and cost that is acceptable to Diamyd Medical.

For more information, see Note 16, page 51 for a statement regarding the Group's financial risks and risk management.

Risk regarding intellectual property rights

There are no guarantees that the Company will develop products that can be patented, nor that granted or licensed patents can be retained, renewed, or provide sufficient protection for current or future discoveries. There is no guarantee that disputes concerning contracts and patents will not arise, or that disputes that do arise can be resolved to the Company's advantage.

Risk regarding key personnel

Diamyd Medical is dependent on its staff and certain key personnel. Diamyd Medical's organizational model consisting of a small number of staff leading projects in clinical and preclinical research, regulatory issues and production, sets high requirements for leadership skills and specialist knowledge. There is a risk that the Company's projects will

be delayed or cannot be completed if key personnel leave the Company or, for any reason, cannot complete their duties. In addition, there is a risk that the Board of Directors, the management or key personnel may negatively impact the Company through incorrect decisions.

Risk regarding collaboration and licensing

Diamyd Medical's strategy builds on development projects being licensed to collaborative partners on reaching a certain stage in their development. The Company may also assume projects or products under license. No guarantees exist that Diamyd Medical will, in the future, succeed with obtaining collaboration agreements and/or license agreements under advantageous business terms for Diamyd Medical.

Risks regarding government agency decisions

The risk cannot be discounted that the regulatory approval process at government agency level may change in regard to requirements concerning details, the scope of the documentation or some other area. Such decisions can be applied generally to the industry or applied to Diamyd Medical in particular and may entail increased costs and delays in projects or even lead to project cancellations.

Legal risk

Diamyd Medical's success depends on the Company successfully monitoring its intellectual property rights including patents and other rights regulated by agreement. From time to time, this entails the Company being forced to pursue litigation. It cannot be guaranteed that such disputes can be resolved advantageously for the Company.

Assets whose value entails risk

Investment in Protein Sciences Corporation

At August 31, 2011, the Company owned about 8 % of the shares of Protein Sciences Corporation. The value of this asset depends on Protein Science's business proceeding according to plan. For further information, see Note 13.

Investment in Mercodia AB

At August 31, 2011, the Company owned 19 % of the shares of Mercodia AB. The value of this asset depends on Mercodia AB's business proceeding according to plan.

The NTDDS research and development projects

The variables that are most sensitive when estimating the value of this asset are the likelihood that the projects will reach commercial viability and the discount factor. The impairment test that was conducted in the third quarter did not show any impairment requirement. For further information, see Note 12.

THE SHARE

The number of shares in Diamyd Medical as of August 31, 2011, amounted to 29,579,133 divided among 28,141,257 shares of Series B (1/10 vote) and 1,437,876 shares of Series A (one vote), with each Series A and B share having a nominal value of SEK 0.5. The stock is denominated in Swedish kronor (SEK).

GROUP STRUCTURE AND OWNERSHIP

At August 31, 2011, the number of shareholders was 8,554 (6,829). The ten largest shareholders held Diamyd Medical shares corresponding to 48 % (65) of the capital and 64 % (76) of the votes. Series B and A shares can be transferred freely. According to a shareholders' agreement between the main holders Bertil Lindkvist and Anders Essen-Möller, the sole Series A holder, Anders Essen-Möller may not transfer shares of Series A to a third party (inheritance transfer excepted) unless the third party buyer concurrently commits to offer to purchase series B shares on the same financial terms and conditions.

The shareholder with more than a 10 % share of voting power is Anders Essen-Möller, 34.74 %.

THE GROUP'S FUTURE DEVELOPMENT

At the end of the year, Diamyd Medical had MSEK 436 in cash and cash equivalents, including short term investments. The assessment of the Board of Directors and the CEO is that existing funds cover the Company's need for capital for the coming 12-month period by a comfortable margin.

PROPOSED ALLOCATION OF AVAILABLE FUNDS

The Parent Company's available funds according to the balance sheet:

KSEK	
Share premium reserve, non-restricted	374,741
Retained earnings	-277,726
Net profit for the year	75,599
Available funds	172,614

The Board of Directors proposes that the Parent Company's available funds of KSEK 172,614 is carried forward to a new account.

The Company's result for the fiscal year and financial balance at August 31, 2011 are presented in the attached income statement, balance sheet, cash flow statement and compilation of changes in shareholders' equity with accompanying notes.

DIVIDEND

The Board proposes that no dividend should be paid for the fiscal year 2010/2011.

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

KSEK	Note	Sep-Aug 10/11	Sep-Aug 09/10
OPERATING INCOME			
Net sales	1, 2	280,752	113,028
Other operating income		7,511	18,330
Total operating income		288,263	131,358
OPERATING EXPENSES			
Raw materials and consumables		-7	-26
External research and development costs		-95,976	-80,845
External patent and license expenses	3	-15,957	-2,916
Personnel	4	-48,794	-31,215
Other external expenses	6, 7	-15,762	-19,095
Depreciation, equipment	8	-428	-224
Total operating expenses		-176,924	-134,321
OPERATING PROFIT		111,339	-2,963
FINANCIAL INCOME AND EXPENSES			
Dividend from holdings		410	410
Financial income	9	6,305	2,278
Financial expenses	9	-16,211	-1
Total financial income and expenses		-9,496	2,687
Profit/Loss before taxes		101,843	-276
Taxes	10	727	-56
NET PROFIT/LOSS FOR THE PERIOD		102,570	-332
OTHER COMPREHENSIVE INCOME FOR THE PERIOD			
Translation gains/losses		120	-14
Other comprehensive income for the period, net of tax		120	-14
TOTAL COMPREHENSIVE INCOME FOR THE PERIOD		102,690	-346
Earnings per share before and after dilution, SEK	11	3.5	0.0
Number of shares	11	29,579,133	29,060,277
Average number of shares before dilution	11	29,449,348	27,595,347
Average number of shares after dilution	11	29,477,301	27,595,347

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

KSEK	Note	Aug 31, 2011	Aug 31, 2010
ASSETS			
NON-CURRENT ASSETS			
Intangible assets	12	16,627	16,627
Tangible assets	8	2,224	855
Financial assets	13	29,241	30,678
Total non-current assets		48,092	48,160
CURRENT ASSETS			
Inventory	14	5	17
Trade receivables		15,179	1,721
Other receivables		15,240	1,768
Prepaid expenses and accrued income	15	5,445	16,195
Short term investments	17, 19	277,859	–
Liquid assets	18, 19	157,782	501,332
Total current assets		471,510	521,033
TOTAL ASSETS		519,602	569,193
SHAREHOLDERS' EQUITY AND LIABILITIES			
SHAREHOLDERS' EQUITY			
Share capital	27, 28, 29, 30	14,790	14,530
Other capital contributions		724,737	687,438
Other reserves		266	146
Accumulated losses including results for the period		-278,819	-387,331
Total shareholders' equity		460,974	314,783
CURRENT LIABILITIES			
Trade payables		9,182	7,083
Other payables		15,323	1,434
Prepaid income and accrued expenses	22	34,123	245,893
Total current liabilities		58,628	254,410
TOTAL EQUITY AND LIABILITIES	21	519,602	569,193

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

KSEK	Share Capital	Other capital contributions	Reserves	Accumulated losses	Total
Opening balance, September 1, 2009	11,183	451,924	160	-392,550	70,717
Comprehensive income					
Net loss for the year	-	-	-	-332	-332
Translation gains/losses	-	-	-14	-	-14
Total comprehensive income	-	-	-14	-332	-346
Transactions with shareholders					
New share issue, before expenses	3,347	255,184	-	-	258,531
New share issue expenses	-	-19,670	-	-	-19,670
Employee options, see Note 28, 29, 30	-	-	-	5,551	5,551
Closing balance, August 31, 2010	14,530	687,438	146	-387,331	314,783
Opening balance, September 1, 2010	14,530	687,438	146	-387,331	314,783
Comprehensive income					
Net profit for the year	-	-	-	102,570	102,570
Translation gains/losses	-	-	120	-	120
Total comprehensive income	-	-	120	102,570	102,690
Transactions with shareholders					
New share issue	260	37,299	-	-	37,559
New share issue expenses	-	-	-	-	-
Employee options, see Note 28, 29, 30	-	-	-	5,942	5,942
Closing balance, August 31, 2011	14,790	724,737	266	-278,819	460,974

PARENT COMPANY'S INCOME STATEMENT

KSEK	Note	Sep-Aug 10/11	Sep-Aug 09/10
OPERATING INCOME			
Net sales	2	280,110	112,039
Other operating income		–	3,267
Total operating income		280,110	115,306
OPERATING EXPENSES			
Personnel	4	-785	-589
Other external expenses	6, 7	-68,913	-29,207
Other operating expenses		-220	–
Total operating expenses		-69,918	-29,796
OPERATING PROFIT		210,192	85,510
FINANCIAL INCOME AND EXPENSES			
Results from group participation	23	-74,234	-81,308
Dividend from holdings		410	410
Interest income and similar items	9	6,678	2,499
Interest expense and similar items	9	-13,900	–
Total financial income and expenses		-81,046	-78,399
Earnings before taxes		129,146	7,111
Taxes	10	-53,547	-1,957
NET PROFIT/LOSS FOR THE PERIOD		75,599	5,154

PARENT COMPANY'S BALANCE SHEET

KSEK	Note	Aug 31, 2011	Aug 31, 2010
ASSETS			
NON-CURRENT ASSETS			
Intangible assets			
Acquired research and development	12	16,627	16,627
Financial assets			
Shares in Group companies	25	1,200	1,200
Receivables in Group companies	26	8,687	20,612
Other long-term holdings	13	29,241	21,418
Other long-term receivables	13	–	9,260
Total non-current assets		55,755	69,117
CURRENT ASSETS			
Trade receivables		15,107	–
Other receivables		13,562	152
Prepaid expenses and accrued income	15	4,919	15,591
Total trade and other receivables		33,588	15,743
Short term investments	17	277,859	–
Liquid assets	18	143,228	478,882
Total current assets		454,675	494,625
TOTAL ASSETS		510,430	563,742
SHAREHOLDERS' EQUITY AND LIABILITIES			
Shareholders' equity			
Restricted equity			
Share capital	27, 28, 29, 30	14,790	14,530
Statutory reserve		96,609	96,609
Non-restricted equity			
Share premium reserve non-restricted		374,741	337,442
Profit or loss brought forward		-277,726	-138,767
Net profit/loss for the period		75,599	5,154
Total shareholders' equity		284,013	314,968
Liabilities to subsidiary	24	224,934	17,515
Current liabilities			
Trade payables		1,091	298
Other payables		392	–
Prepaid income and accrued expenses	22	–	230,961
Total current liabilities		1,483	231,259
TOTAL EQUITY AND LIABILITIES		510,430	563,742
Assets pledged		–	–
Contingent liabilities		–	–

CHANGE IN SHAREHOLDERS' EQUITY—PARENT

KSEK	Share capital	Statutory reserv	Share premium reserve non restricted	Accumulated losses	Total shareholders' equity
Opening balance, September 1, 2009	11,183	96,609	101,929	-138,832	70,889
Group contribution	–	–	–	-7,444	-7,444
Tax effects on group contribution	–	–	–	1,957	1,957
New share issue, before expenses	3,347	–	255,184	–	258,531
New share issue expenses	–	–	-19,670	–	-19,670
Employee options, see Note 28, 29, 30	–	–	–	5,551	5,551
Net profit of the period	–	–	–	5,154	5,154
Closing balance, August 31, 2010	14,530	96,609	337,443	-133,614	314,968
Opening balance, September 1, 2010	14,530	96,609	337,443	-133,614	314,968
Group contribution	–	–	–	-203,600	-203,600
Tax effects on group contribution	–	–	–	53,545	53,545
New share issue, before expenses	260	–	37,299	–	37,559
New share issue expenses	–	–	–	–	–
Employee options, see Note 28, 29, 30	–	–	–	5,942	5,942
Net profit of the period	–	–	–	75,599	75,599
Closing balance, August 31, 2011	14,790	96,609	374,741	-202,127	284,013

CONSOLIDATED STATEMENT OF CASH FLOW

KSEK	Note	GROUP		PARENT COMPANY	
		Sep-Aug 10/11	Sep-Aug 09/10	Sep-Aug 10/11	Sep-Aug 09/10
Cash flow from operations before changes in working capital					
Operating profit/loss		111,339	-2,962	210,192	85,509
Interest received		4,568	1,402	4,987	1,620
Interest paid and foreign exchange difference		-8,329	-1	-6,706	-
Dividend received		410	410	410	410
Non-cash flow items					
Depreciation		428	224	-	-
Other non-cash flow items	20	-210,015	-929	-223,636	636
Income tax paid		-	-	-	-
Net cash flow from operating activities before changes in working capital		-101,599	-1,856	-14,753	88,175
Increase (-) decrease (+) inventory		10	9	-	-
Increase (-) decrease (+) receivables		-13,689	-14,749	-15,856	-14,966
Increase (+) decrease (-) liabilities		21,251	242,370	34	234,175
Net cash flow from operating activities		-94,027	225,774	-30,575	307,384
Cash flow from investing activities					
Change in long-term subsidiary balances		-	-	-58,489	-86,059
Net investments in short-term investments		-277,859	-	-277,859	-
Purchase of tangible assets		-1,928	-700	-	-
Cash flow from investing activities		-279,787	-700	-336,348	-86,059
Cash flow from financing activities					
New share issue		37,559	238,861	37,559	238,861
Group contribution received/paid		-	-	-	-7,442
Cash flow from financing activities		37,559	238,861	37,559	231,419
Total cash flow for the period		-336,255	463,935	-329,364	452,744
Cash and cash equivalents at beginning of period		501,332	37,287	478,882	26,138
Net foreign exchange difference		-7,295	110	-6,290	-
Cash and cash equivalents at end of period		157,782	501,332	143,228	478,882

ACCOUNTING POLICIES

GROUP

Diamyd Medical prepares its consolidated financial statements in accordance with International Financial Reporting Standards, IFRS, as endorsed by the EU. In addition to IFRS, the Group also observes the Swedish Financial Reporting Board's (RFR) recommendations RFR 1 (Supplementary Accounting Rules for Groups), RFR's statements and the Swedish Annual Accounts Act. Diamyd Medical presents its income statement by cost class, implying that operating expenses are divided between external research and development costs, other external costs and personnel costs as well as depreciation, amortization and impairment. The key accounting policies applied in the preparation of these consolidated financial statements are specified below. These are the same policies as applied in the 2009/2010 Annual Report and have been consistently applied to all years reported unless stated otherwise.

PARENT COMPANY

Diamyd Medical AB, domiciled in Stockholm, continues to apply those accounting policies relevant to legal entities that prepare consolidated financial statements and are listed on a stock exchange. In brief, this means that the Company continues to apply the statements by the Swedish Financial Reporting Board, to the extent that they are appropriate for a Parent Company. Accordingly, Diamyd Medical AB observes RFR 2 Accounting for legal entities. The Parent Company's accounting policies are consistent with the Group's unless stated otherwise below. Pursuant to RFR 2, the Parent Company should structure its reports in accordance with all applicable IFRS/IAS regulations unless the standards state an exception from their application.

CONSOLIDATED FINANCIAL STATEMENTS

The Group comprises the Parent Company Diamyd Medical AB, the wholly-owned Swedish subsidiaries Diamyd Therapeutics AB and Diamyd Diagnostics AB and the US subsidiary Diamyd, Inc.

The consolidated financial statements have been prepared according to the cost method, except for revaluations of financial instruments available for sale, which are measured at fair value.

Subsidiaries are all of the companies for which the Group has the right to establish financial and operative strategies in a manner usually consistent with a shareholding of more than 50 % of the total voting rights. The existence and effects of potential voting rights that may currently be utilized or converted are considered when assessing whether the Group has a controlling influence over another entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are de-consolidated from the date that control ceases.

The purchase method of accounting is used for recognizing the

Group's business combinations. The purchase consideration for the acquisition of a subsidiary comprises the fair value of transferred assets, liabilities or shares of the Group. The purchase consideration also includes the fair value of all assets or liabilities resulting from an agreement on a contingent consideration. Acquisition-related costs are expensed as they arise. Identifiable assets acquired and liabilities assumed in a business combination are measured initially at their fair values at the acquisition date. For each acquisition, the Group determines whether all non-controlling interests in the acquired company will be recognized at fair value or at the holding's proportionate share of the acquired company's net assets.

The amount by which the purchase consideration, any non-controlling interest and the fair value at the acquisition date of earlier shareholdings surpasses the fair value of the Group's share of identifiable net assets is recognized as goodwill. If the amount is less than the fair value of the acquired subsidiary's assets, the difference is recognized directly in the statement of comprehensive income.

FOREIGN CURRENCY TRANSLATION

Functional currency and presentation currency

Diamyd Medical has a foreign subsidiary, Diamyd, Inc. Items included in the financial statements for this entity within the Group are valued in USD, since this is the subsidiary's functional currency. The Swedish krona (SEK), which is the Parent Company's functional and presentation currency, is utilized in the consolidated financial statements.

Transactions and balance sheet items

Foreign currency transactions are translated to the functional currency using the exchange rates prevailing on the transaction date. Foreign exchange gains and losses resulting from the settlement of such transactions, and from the foreign currency translation of monetary assets and liabilities at the closing day rate, are recognized in the Income statement. Gains and losses on operating receivables and liabilities are recognized net under other operating income or other operating costs.

Group companies

The results and financial positions of all of the Group entities that have a functional currency different from the presentation currency are translated into the Group's presentation currency.

Translation is conducted as follows: assets and liabilities for each balance sheet presented are translated at the closing day rate and income and expenses for each income statement are translated at average exchange rates. If the average exchange rate is not a reasonable estimate of the year's total exchange rate differences from each transaction day, income and expenses are translated for each transaction

day instead and all exchange differences that arise in connection with translation during the period are recognized in other comprehensive income and accumulated in a separate component of equity called Reserves.

FINANCIAL INSTRUMENTS, RECOGNITION, DISCLOSURE AND CLASSIFICATION

At the close of every quarter, Diamyd Medical evaluates whether there is objective evidence of any impairment requirement for a financial asset or a group of financial assets. Purchases and sales of financial assets are recognized on the trade date – the date on which the Group commits to purchase or sell the asset. Financial instruments are initially recognized at fair value plus transaction costs. Financial assets are derecognized from the balance sheet when the rights to receive cash flows from the instruments have expired or have been transferred and the Group has substantially transferred all risks and benefits associated with ownership.

FINANCIAL ASSETS MEASURED AT FAIR VALUE IN THE INCOME STATEMENT

Financial assets measured at fair value in the income statement are financial assets held for trading. Diamyd Medical recognizes short-term investments with an original duration of more than three months in this category and shareholding in companies other than associated companies. Changes in value are recognized in the income statement. Derivatives are classified as held for trading unless they have been identified as hedging instruments. Assets in this category are classed as current assets.

Financial instruments are measured at fair value at three levels according to the following valuation hierarchy:

- Level 1:** Quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2:** Other observable market inputs for the asset or liability than Level 1 inputs, either directly as price quotations or indirectly, derived from price quotations.
- Level 3:** Inputs for the assets or liability not based on observable market data.

FINANCIAL ASSETS AVAILABLE FOR SALE

Financial assets available for sale are assets that are not derivatives and are identified as sellable or not classified in any other category. They are included in non-current assets as long as management does not intend to dispose of the assets within 12 months of the balance sheet date. Investments in companies, with the exception of companies classified as associated companies, are recognized at market value through other comprehensive income and the accumulated value changes are

recognized as a component of equity. Dividends on equity instruments that can be sold are recognized in the income statement as a dividend from other securities when the Group's right to receive the payment has been established.

If the market for a financial asset is not active (and for unlisted securities), Diamyd Medical establishes fair value by using valuation techniques. These include the use of recent arm's length transactions, reference to the fair value of other instruments that are substantially the same, discounted cash flow analysis and option pricing models, making maximum use of market inputs and relying as little as possible on entity-specific inputs.

When securities that are classified as financial assets available for sale are sold or impaired, the accumulated adjustments to fair value are transferred from equity to the income statement as gains and losses from financial instruments.

In the case of shares classified as available for sale, a significant or prolonged decline in the fair value of the share below its cost is considered as an indicator that an impairment requirement exists. If any such evidence exists for financial assets available for sale, the cumulative loss – measured as the difference between the acquisition cost and the current fair value, less any impairment loss on that financial asset previously recognized in the income statement – is removed from equity and recognized in the income statement. Impairment losses on equity instruments recognized in the income statement are not reversed through the income statement.

Short-term investments in the balance sheet are classified as financial assets available for sale and fair value adjustments are recognized through other comprehensive income and the accumulated value changes are recognized as a component of equity.

Short-term investments comprise interest-bearing investments with an original duration from three up to six months.

CASH AND CASH EQUIVALENTS

Cash and cash equivalents includes cash, cash in banks and other short-term investments with maturity dates within three months of their acquisition date. They comprise liquid investments that can easily be converted into a known amount and are only exposed to an insignificant risk of value fluctuations.

LOANS AND RECEIVABLES

Accounts receivable are non-derivative financial assets, with determined or determinable payments that are not listed on an active market. Their distinguishing feature is that they arise when Diamyd Medical provides funds, goods or services directly to a customer without any intention to trade in the resulting receivable. They form part of current assets, except for items with maturities more than 12 months

from the balance sheet date, which are classified as non-current assets. Trade receivables are recognized initially at fair value and subsequently measured at amortized cost using the effective interest method, less provision for impairment. A provision for impairment of trade receivables is established when there is objective evidence that the Group will not be able to collect all amounts due according to the original terms of the receivables. The amount of the provision is the difference between the asset's carrying amount and the present value of estimated future cash flows, discounted at the original effective interest rate. The amount of the provision is recognized in the income statement.

Other receivables, and where applicable interim receivables, are recognized pursuant to the same policies.

ACCOUNTS PAYABLE

Accounts payable are initially recognized at fair value and thereafter at amortized cost.

EMPLOYEE STOCK OPTION PLANS

Scope

As of balance sheet date, Diamyd Medical has two outstanding employee stock option plans. Upon conversion/exercise, cash and cash equivalents would increase by the exercise/conversion price and the share capital by a nominal SEK 0.5 per share, with the remaining deposited amount increasing other capital contributions. For more details on the various effects of each plan and the number of outstanding options, see Notes 28, 29 and 30.

Accounting policies for employee stock option plans

Diamyd Medical recognizes its employee stock option plans in accordance with IFRS 2. The recommendation implies that Diamyd Medical values the current 2008/2011 and 2009/2012 plans at the date of issuance at fair value and then distributes the value over the vesting period as a personnel cost. This remuneration to personnel implies that Diamyd Medical issues its own equity instrument (warrants to which personnel are entitled, pursuant to the plan's agreements) and thus, for the cost associated with each period, achieves the corresponding decrease in accumulated losses (other non-restricted equity in the Parent Company). The issuance of the Company's own capital instrument is here considered to be a shareholder contribution provided by the Parent Company to the subsidiary, which is why it is recognized as an investment in a subsidiary. Like other contributions, the investment is then evaluated for any write-down requirement. If there is a need to impair shares in a subsidiary, the effect is that a financial cost is recognized in the Parent Company's income statement.

Social security costs on employee stock option plans

For the outstanding plans, Diamyd Medical makes provisions for social security costs at the end of each accounting year. The provision

for social security costs is calculated according to UFR 7, IFRS 2 and Social Security Contributions for Listed Enterprises, with the application of the same valuation model used when the options were issued. The provision is revalued on each reporting date on the basis of a calculation of the charges that may be payable when the options are exercised. Diamyd Medical performs the valuation according to the Black & Scholes model, which takes into account factors including the share price, remaining time until exercise, volatility and risk-free interest rates. Payments of social security costs in connection with employee exercise of options are offset against the provision made according to the above.

To cover the social security costs inherent in its employee stock option plans, Diamyd Medical is in possession of a number of options intended for conversion into shares, which can then be sold to finance payment of the associated social security costs. Because a taxable benefit (the difference between the redemption/exercise price and market value of shares) arises when stock options are exercised, Diamyd Medical can cover the social security costs on the taxable benefit by converting a portion of its options to shares and then selling them. However, the personnel cost arising in the income statement, which is provisioned progressively pursuant to UFR 7, will not be offset by a cost reduction (income), but the effect appears exclusively in cash flow terms.

INTANGIBLE ASSETS

Intangible assets refer to license rights, acquired directly or via a business acquisition. Expenses for acquiring patent licenses are shown as an asset if the patent is considered to be the basis for a marketable product. This also applies if the licensing rights are deemed to be transferable for at least their carrying amount. The licenses are amortized using the straight line method during their useful life from the date the licenses can be utilized. Proprietary patent rights, technology rights, brands and other similar assets do not constitute any value. The research activities Diamyd Medical conducts are associated with sufficient uncertainty that the capitalization criteria of IAS 38 Intangible Assets cannot be considered satisfied. Accordingly, all research and development costs are expensed as they arise.

For acquired research and development projects that are not amortized on an ongoing basis, an impairment test is performed annually whereby future cash flows generated by the asset are discounted. The cash flows used in the impairment test are adjusted for an assessed possibility that the project will reach a commercial phase and thereby generate a cash flow.

TANGIBLE ASSETS

Depreciation

Diamyd Medical calculates depreciation using the straight line method to allocate the cost of property, plant and equipment over its

estimated useful life. In accordance with IAS 16 Property, Plant and Equipment and IAS 38 Intangible Assets, depreciation according to plan is calculated on original costs with depreciation rates based on estimates of the assets' financial life-span. None of the tangible assets are deemed to have any residual value at the end of their useful lives, so this value is zero when calculating recognized depreciation.

IMPAIRMENT

Review of tangible and intangible fixed assets for impairment is performed whenever internal or external indications of a potential impairment requirement arise pursuant to IAS 36.

For assets with an unlimited useful life, including goodwill, and assets that have not yet been depreciated, this examination is performed annually, irrespective of whether there is an indication of decreased value. Examination is performed through an estimation of the realizable amount. The recoverable amount is the higher of an asset's value in use and fair value less costs to sell. If the recoverable value is lower than the asset's carrying amount, an impairment loss is recognized.

SHAREHOLDERS' EQUITY

Changes in equity, with comparative years, in the Group and Diamyd Medical AB in the context of recognized profits, loss carry forward, appropriation of profits, exchange rate differences and share capital, are recognized on pages 33 and 36. Consolidated shareholders' equity is recognized in accordance with the Swedish Financial Reporting Board's statement UFR 8 Accounting for Group Equity.

REVENUE RECOGNITION

Revenue comprises the fair value of what has been or may be received for research collaboration agreements, goods and services sold, other services in the Group's continuing operations and interest income. The revenue is recognized excluding value added tax, returns and discounts and after elimination of intra-Group sales. Diamyd Medical recognizes revenue when the amount of revenue can be reliably measured, it is probable that future economic benefits will flow to the entity and specific criteria have been met for each of the Group's activities as described below.

Revenue from research collaboration agreements

Upfront payments

Upfront payments are received on entering a collaboration agreement and are not refundable.

According to Diamyd Medical's interpretation of IAS 18, an upfront payment for which the Company has obligations remaining regarding the execution of services is to be recognized as a prepayment. In such a case, the Company has not fully discharged its obligations connected with earning the revenue until the estimated or

stipulated collaboration period expires. The amount is then treated as accrued income from the date of the agreement until the expiration of the estimated or stipulated collaboration period.

If no reservation or other obstacle exists to receive the consideration and it is not related to future performance by Diamyd Medical, the initial consideration is recognized as revenue on entering the agreement.

Milestone payments

Milestone payments agreed with counterparties are recognized when the criteria defined in the out-licensing agreement have been met and agreed with the counterparty. Such criteria can comprise study results, registration of pharmaceuticals or sales goals achieved.

Research services

Research services, performed by Diamyd Medical in accordance with collaboration agreements and which generate payments from collaboration partners, are recognized as revenue in pace with Diamyd Medical's performance of the services.

Revenue from the sale of goods

Revenue is recognized when the significant risks and rewards of ownership of the goods have been transferred to the buyer and the amount of revenue can be measured reliably.

Revenue from other services

Revenue from other services primarily comprises research grants received by the subsidiary Diamyd, Inc. These are recognized as other operating revenues in the income statement for the same period as the costs that the research grants are intended to compensate.

Interest income

Interest income is recorded in the period to which it is attributable. The calculation is based on the underlying yield of the asset according to the effective interest method.

Dividends

Dividend income is recognized when the right to receive dividends is established.

BUSINESS SEGMENTS

IFRS 8 requires that segment information be presented from the management's perspective, which entails reporting information in the same manner it as is reported internally. The reportable operating segments are defined by the internal reporting as it is reported and followed up by the chief operating decision maker. As the chief operating decision maker in this context, the Group has identified the CEO. The Group has identified the segments that are followed up via

the Company's internal reporting, which has resulted in the Company presenting the segments divided into countries. The performance measurement that is followed up is the operating result, meaning the operating result before financial items, see Note 1.

PENSION LIABILITY AND PENSION COSTS

Diamyd Medical applies IAS 19. All Company employees are provided with individual pension schemes which are defined contribution plans and for which the Company has an agreement with an insurance company to administer these future schemes. For defined contribution plans, the Group pays contributions to publicly or privately administered pension insurance plans on a mandatory, contractual or voluntary basis. The Group has no further payment obligations once the contributions have been paid. The contributions are recognized as employee benefit expenses when they fall due. Prepaid contributions are recognized as an asset to the extent that a cash refund or a reduction in the future payments will fall in favor of the Company.

INCOME TAX

Deferred tax is recognized in total in accordance with the balance sheet method, on all temporary differences that arise between the tax base on assets and liabilities and their recognized values in the consolidated financial statements. The deferred tax is not recognized if it arises from a transaction that constitutes the first recognition of an asset or a liability that does not arise from the acquisition of a business and, which at the time of the transaction, affects neither the recognized earnings nor the earnings for tax purposes. Deferred tax assets are calculated according to the applicable tax rates and laws that have been adopted or announced by the balance sheet date and are expected to be in force when the deferred tax will be realized or when the deferred tax liability will be settled.

Deferred tax is calculated on temporary differences which arise on participation in Group companies and in associated companies except when the timing of the deferred tax assets can be controlled by the Group and it is likely that the temporary difference will not be reversed in the foreseeable future.

Pursuant to IAS 12, deferred tax assets should only be recognized to the extent that it is likely that deductions will be utilized.

Note 10 reports items including the estimated deductible deficits accumulated in the Group. The taxable deficits of the Group have no expiry date. The treatment of potential deferred tax on temporary differences is reported and explained in Note 10. The various constituent items of consolidated total tax are also explained.

RELATED-PARTY TRANSACTIONS

Diamyd Medical recognizes remuneration and benefits to key execu-

tives pursuant to IAS 19 Employee Benefits and IFRS 2 Share-based Payments. Other information on related parties is reported pursuant to IAS 24. The various amounts are specified in Note 5.

SIGNIFICANT ASSESSMENTS AND ESTIMATES

When the Board and CEO prepare reports in accordance with generally accepted accounting principles, certain assessments and assumptions must be made that affect the values recorded in the final accounts. These assessments and assumptions constitute the basis of the carrying amounts of assets, liabilities, revenues and expenses in those cases where these cannot be determined simply through information from other sources. The areas which contain a high degree of assessment, which are complex or in which assumptions and estimations are of considerable importance comprise primarily the Group's non-current assets, which are not held for trading. The development of the various research projects is the most important consideration in the assessment of the assets below. As long as the projects are proceeding ahead, the project constitutes value and no impairment requirement exists.

Intangible assets

Licenses and intellectual property rights are valued at cost with straight-line amortization over the estimated economic life time. The impairment requirement is assessed on the basis of the expected future return.

For further details on the assets' impairment testing, see Note 12.

Financial assets

Holdings in companies other than associated companies are impaired if a decrease in value is determined as permanent. These assets are valued according to available information on an ongoing basis, see Note 13.

Revenue recognition

Diamyd Medical's interpretation of IAS 18 is that payment received on signing a license agreement, so-called upfront payments, for which obligations remain for the licensor to perform services, is to be recognized as a prepayment, see Note 2.

CASH FLOW STATEMENT

The cash flow statement has been prepared in accordance with IAS 7 and is reported by applying the indirect method. Recognized cash flow only encompasses those transactions that have caused payments to be made or received. Cash and cash equivalents include cash and bank balances, plus short-term investments including commercial papers with maximum duration of three months from the acquisition

date, and are recognized in accordance with IAS 7. They comprise liquid investments that can easily be converted into a known amount and are only exposed to an insignificant risk of value fluctuations.

LEASING

Leasing where a substantial part of the risks and advantages of ownership are retained by the lessor is classified as operational leasing.

Payments that are made during the lease period are expensed in the income statement straight-line over the duration of the lease. The Group has no financial lease agreements.

INVENTORIES

Inventories are stated at the lower of cost and net realizable value.

Clinical study drugs are not recognized in inventories.

PROVISIONS

Provisions are recognized when the Group enters into legal or informal undertakings arising from earlier events, where resources will likely be expended to settle the obligation and the amount has been reliably calculated. In cases where it has not been possible to make a reliable assessment or where there is uncertainty about the obligation, the obligation/situation is shown as a contingent liability.

EVENTS AFTER THE BALANCE SHEET DATE

Any events after the balance sheet date that confirm the circumstances on the balance sheet date have been considered in the Annual Report.

NEW AND REVISED STANDARDS THAT HAVE NOT YET COME INTO EFFECT AND HAVE NOT BEEN APPLIED IN ADVANCE BY DIAMYD MEDICAL

IFRS 9 *Financial instruments* – (applicable to fiscal years beginning on or after January 1, 2013). IFRS 9 addresses the recognition and measurement of financial instruments. The standard contains two primary categories: amortized costs and fair value. Classification takes place based on the Company's business model and characteristics of the contractual cash flows. If the Company's business model includes holding the financial asset in order to receive contractual cash flows and these contractual cash flows are solely payments of principal and interest, the asset is measured at amortized cost. All other financial assets are measured at fair value. The standard will be supplemented with additional sections. Its impact on the consolidated financial statements will be evaluated once the standard is complete.

Otherwise, none of the other standards that have been updated have any effect on the Group's accounting, which is why no information on other standards has been provided.

NOTES

NOTE 1 SEGMENT REPORTING – GROUP

The management follows up operations through reports from two geographical areas, Sweden and the US. 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 reporting for the fiscal year

KSEK	10/11			09/10		
	Sweden	USA	Group	Sweden	USA	Group
Total net sales for segments	330,905	17,039	347,944	127,305	7,914	135,219
Inter-segment sales	-50,255	-16,937	-67,192	-14,583	-7,608	-22,191
Total net sales	280,650	102	280,752	112,722	306	113,028
Operating result	113,149	-1,810	111,339	-3,250	287	-2,963

Segment assets and liabilities

KSEK	10/11			09/10		
	Sweden	USA	Group	Sweden	USA	Group
Assets	512,246	7,356	519,602	565,870	3,323	569,193
Liabilities	58,491	137	58,628	253,494	916	254,410
Investments	281	1,647	1,928	380	320	700

Inter-segment sales are completed under market terms. The asset totals reported to the management are valued according to the same principles as in the annual report. These assets are distributed ac-

ording to the operations of the segment and the physical location of the asset. Income from external customers is derived primarily from research collaboration agreements and research services, see Note 2.

NOTE 2 SALES – GROUP

KSEK	GROUP		PARENT COMPANY	
	10/11	09/10	10/11	09/10
Income from research collaboration agreements	229,806	97,494	229,806	97,494
Research services	50,304	14,545	50,304	14,545
Other services	642	989	–	–
Total	280,752	113,028	280,110	112,039

In June 2010, Diamyd Medical signed an agreement with Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI), for the development and commercialization of Diamyd®. Diamyd Medical received an upfront payment of MSEK 327.3 in connection to the signing of the agreement whereof MSEK 229.8 has been recognized as income in the

fiscal year 2010/2011. The amount has been accrued according to the Company's interpretation of IAS 18. The agreement has entailed the parties sharing the development costs equally during the agreement. During the fiscal year 2010/ 2011, this amounted to MSEK 50.3 in research services.

NOTE 3 EXTERNAL PATENT AND LICENSE EXPENSES

Diamyd Medical has licensed certain rights related to GAD65 from the University of Florida Research Foundation, Inc. (UFRF).

UFRF filed in February 2011 a lawsuit against Diamyd Medical in the United States Federal District Court in Florida. According to an agreement between Diamyd Medical and UFRF, ten percent of licensing fees, excluding royalties, less the cost of future development of the UFRF technology, were to accrue to UFRF. In June 2010, Diamyd received from Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI) MUS\$ 45 in licensing fees, from which, according to the agreement,

costs for continued development should be deducted prior to the ten percent being applied. Development costs from June 2010 and future development costs pertaining to the UFRF technology are being assessed, as are such matters as the importance of the fact that the UFRF's rights comprise only a portion of the rights licensed out to OMJPI.

The Company's management has arrived at the assessment that the claim for compensation from UFRF leads to a provision of MSEK 12.8 in the financial accounts as per August 31, 2011, which is disclosed in Accrued expenses.

NOTE 4 PERSONNEL COSTS AND REMUNERATION OF THE BOARD, KEY EXECUTIVES AND EMPLOYEES – GROUP

Average number of employees	10/11	Women	Men	09/10	Women	Men
Sweden	19	70%	30%	14	71%	29%
USA	10	56%	44%	5	57%	43%
Total	29	65%	35%	19	67%	33%

Gender balance among the Board and key executives	Aug 31, 2011		Aug 31, 2010	
	Women	Men	Women	Men
Board of Directors	14%	86%	17%	83%
Key executives	50%	50%	67%	33%

REMUNERATION AND PENSIONS DURING THE FISCAL YEAR

The Board of Directors

The Board Chairman and the members elected at the Annual General Meeting (AGM) are remunerated according to the resolution of the AGM. The Executive Chairman of the Board received a fixed salary. In addition has the Chairman of the Board during the fiscal year, up to and including April, received occupational pension premiums amounting to 35% of the annual salary. No other benefits are paid to the Board. During the year, KSEK 716 (500) in remuneration was paid to the Board. In addition KSEK 123 has been paid to Board member Joseph Janes as compensation for consulting services. As Executive Chairman of the Board, Anders Essen-Möller was paid a fixed salary of KSEK 1,483 (1,483). Pension costs for the Chairman of the Board were KSEK 300 (519) for fiscal year 2010/2011.

Key executives – CEO

Peter Zerhouni entered as acting President on April 26, 2011 and assumed the position of President on July 4 the same year. As a CEO he received salary and remuneration amounting to KSEK 552 and other benefits amounting to KSEK 4. The Company pays occupational pension insurance premiums amounting to 35 % of annual salary to the CEO, the amount however not to exceed ten price base amounts per year. Pension benefits are based on a retirement age of 65. The contract between the Company and the CEO is subject to six months' notice by either party. The CEO's employment agreement does not include any provisions for severance pay. The CEO holds 30,500 employee options.

During the year, former CEO Elisabeth Lindner received, in her position as CEO, salary and remuneration amounting to KSEK 1,158

(1,805), other benefits amounting to KSEK 8 (12) and pension benefits amounting to KSEK 461 (585).

Other key executives

Other key executives refer to the five people who make up the executive management team in addition to the CEO. The other key executives have received KSEK 4,647 (3,823) in salary and remuneration and other benefits of KSEK 20 (26). The Company pays occupational pension insurance premiums amounting to 20 % of annual salary to the other key executives, which during the year amounted to KSEK 787 (531). Pension benefits are based on a retirement age of 65. The group holds 158,750 employee options. The contracts between the Company and key executives are subject to three months' notice by either party. Employment agreements make no provisions for severance pay. For information regarding guidelines for remuneration of key executives, see page 29.

For further information regarding the Board of Directors and key executives, see pages 66–69 or the Company website www.diamyd.com.

Other personnel

Other personnel have received salaries and other remuneration amounting to KSEK 12,485 (7,055) and benefits of KSEK 46 (29). The Company pays occupational pension insurance premiums amounting to 20 % of annual salary to the permanent employees and 5 % to temporary employees, which amounted to KSEK 2,027 (630) during the year. This group of individuals holds 315,550 employee options.

Salaries, other remuneration and social security costs

Group and Parent Company	10/11			09/10		
	Salaries and remuneration	Social security costs	Pension costs	Salaries and remuneration	Social security costs	Pension costs
Parent Company	839	106	–	500	89	–
Subsidiaries	20,403	8,861	3,640*	14,234	8,330	2,265*
Group total	21,242	8,967	3,640*	14,734	8,419	2,265*

* Of the Group's total pension costs KSEK 826 (1,104) relates to the Board of Directors and CEO, KSEK 787 (531) other key executives and the remaining KSEK 2,027 (630) other personnel.

Salaries and other remuneration allocated by country and for the Board of Directors and CEO, the key executives and other personnel

Group and Parent Company	10/11		09/10	
	Board of Directors and CEO	Other key executives and other personnel	Board of Directors and CEO	Other key executives and other personnel
Parent Company				
Sweden	839	–	500	–
Group total	839	–	500	–
Subsidiaries				
Sweden	3,205	11,632	3,300	7,162
USA	–	5,566	–	3,772
Total	3,205	17,198	3,300	10,934
Group total	4,044	17,198	3,800	10,934

Salaries and remuneration the Board of Directors, CEO and other key executives

2010/2011					
KSEK	Salary/ Remuneration	Pension costs	Other benefits	Equity related Remuneration*	Total
Anders Essen-Möller, Chairman of the Board	1,483	300	–	31	1,814
Lars Jonsson, Board Member	125	–	–	–	125
Sam Lindgren, Board Member	125	–	–	–	125
Henrik Bonde, Board Member	125	–	–	–	125
Maria-Teresa Essen-Möller, Board Member	125	–	–	–	125
Göran Petterson, Board Member	125	–	–	–	125
Joseph Janes, Board Member	214 **	–	–	–	214
Peter Zerhouni, CEO from 26 April 2011 and onwards	552	65	4	56	677
Elisabeth Lindner, CEO until 26 April 2011	1,158	461	8	799	2,426
Total, Board of Directors and CEO	4,032	826	12	886	5,756
Other key executives	4,647	787	20	1,785	7,239
Total	8,679	1,613	32	2,671	12,995

* Share-based payments relate to the expenses affecting net profit according to the Company's interpretation of IFRS 2.

**The amount includes consulting fees amounting to KSEK 123.

2009/2010					
KSEK	Salary/ Remuneration	Pension costs	Other benefits	Equity related remuneration*	Total
Anders Essen-Möller, Chairman of the Board	1,483	519	–	69	2,071
Lars Jonsson, Board Member	100	–	–	–	100
Sam Lindgren, Board Member	100	–	–	–	100
Henrik Bonde, Board Member	100	–	–	–	100
Maria-Teresa Essen-Möller, Board Member	100	–	–	–	100
Göran Petterson, Board Member	100	–	–	–	100
Elisabeth Lindner, CEO	1,805	585	12	874	3,276
Total, Board of Directors and CEO	3,788	1,104	12	943	5,847
Other key executives	3,823	531	26	1,883	6,263
Total	7,611	1,635	38	2,826	12,110

* Share-based payments relate to the expenses affecting net profit according to the Company's interpretation of IFRS 2.

NOTE 5 RELATED PARTY TRANSACTIONS

During the year, companies represented by immediate family members of the Chairman of the Board were retained as consultants. Total fees paid during the year amounted to KSEK 1,422 (650) excluding VAT. Fees were for IT services, website maintenance and publishing of press releases. Pricing has been set by the arm's length principle. Remuneration of immediate family members of the Chairman amounted to a total of KSEK 1,011 (1,376) during the year. No other Board members, key executives or related party to these 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 current fiscal year. Neither has the Company granted any loans, provided any guarantees or surety for the benefit of any member of the Board of Directors, key executives or auditors in the Company. For further information regarding remuneration of key personnel, see Note 4.

KSEK	10/11	09/10
Purchase of intercompany services *	67,192	22,192
Salaries	1,011	1,376
Share-based payments **	639	647
Consultant fees	1,422	650

* Regards transactions between subsidiaries.

** For more information, see Note 4.

NOTE 6 COSTS FOR AUDITING AND AUDIT CONSULTING

KSEK	GROUP		PARENT COMPANY	
	10/11	09/10	10/11	09/10
Öhrlings PricewaterhouseCoopers AB				
Auditing	305	428	290	344
Auditing activities over and above audit assignment	107	204	197	204
Tax advice	27	–	27	–
Other services	60	–	60	–
Total	499	632	574	548
Lally & Co				
Auditing	47	111	–	–
Auditing activities over and above audit assignment	–	–	–	–
Tax advice	–	–	–	–
Other services	68	22	–	–
Total	114	133	–	–

NOTE 7 LEASE CONTRACTS

Diamyd Medical's premises leasing agreement runs until December 31, 2012. Notice of termination must be given at least nine months before the contractual end date; otherwise the contract is automatically renewed for an additional three years. The leasing agreement for Diamyd,

Inc.'s premises has a notice period of one month. The Group (incl. Diamyd, Inc.) has paid rent amounting to KSEK 1,329 (1,143) during the fiscal year 2010/2011. For the upcoming fiscal year 2010/2011, the rent will amount to KSEK 1,370 according to the contracts.

NOTE 8 TANGIBLE ASSETS AND DEPRECIATION

Equipment is depreciated over five years and computers over three years.

KSEK	10/11	09/10
Cost, opening balance	1,710	996
Investments during the year	1,928	714
Cost, closing balance	3,638	1,710
Opening depreciation	-855	-631
Depreciation for the year	-428	-224
Translation gains/losses	-131	–
Closing depreciation	-1,414	-855
Net book amount, August 31	2,224	855

The Parent Company has no tangible assets.

NOTE 9 FINANCIAL INCOME AND COSTS

KSEK	GROUP		PARENT COMPANY	
	10/11	09/10	10/11	09/10
Interest income, bank	6,305	36	6,238	–
Interest income, Group companies	–	–	440	257
Foreign currency fluctuation gains	–	2,242	–	2,242
Financial income	6,305	2,278	6,678	2,499
Interest expenses	0	-1	–	–
Foreign currency fluctuation losses *	-16,211	–	-13,900	–
Financial expenses	-16,211	-1	-13,900	–

* Diamyd Medical's policy is to keep some liquidity in foreign currency for payments, in particular USD and EUR. The stronger Swedish Krona has reduced the value of these investments, but this is balanced by the corresponding lower expenses for payments in these currencies.

NOTE 10 TAX

The Company does not have any temporary differences other than tax loss carry-forwards. Deferred income tax assets are recognized for tax loss carry-forward to the extent that the realization of the related tax benefit through the future taxable profits is probable. Diamyd, Inc. recognizes a deferred tax income of KSEK 727 (tax cost 56) due to the utilization of capitalized tax loss carry-forwards in the Company.

The Group did not recognize deferred tax assets amounting to KSEK 49,979 (100,349) in respect of accumulated losses for tax purposes amounting to KSEK 190,033 (381,554) that can be carried forward against future taxable income. For Swedish limited companies, there is no expiration date regarding the possibility of utilizing loss carry-forwards. The weighted average tax rate for the Group was -0.7 % (-20.4).

KSEK	10/11	09/10
Tax	–	–
Deferred tax	727	-56
Total	727	-56

Reconciliation between actual and nominal tax

KSEK	GROUP		PARENT COMPANY	
	10/11	09/10	10/11	09/10
Reported profit/loss before tax	101,842	-276	129,146	7,111
Tax according to applicable Swedish tax rate of 26.3 %	-26,784	72	-33,965	-1,870
Effect of foreign tax rate	132	-8	–	–
Tax effect of non-taxable revenue	1,115	109	159	108
Tax effect of non-deductible items	-1,950	-2,477	-19,691	-20,097
Tax effect on deductible items that has not been accounted for	8,160	–	–	–
Tax effect on profit/loss carry-forward	–	–	–	–
Tax loss carry-forwards for which no deferred tax claim has been recognized	-49	–	-49	–
Utilization of tax loss carry-forwards which previously were not recognized	20,103	2,248	–	19,902
Tax on reported profit/loss	727	-56	-53,547	-1,957

NOTE 11 EARNINGS PER SHARE

The calculation of earnings per share before dilution is based on the division of the earnings assignable to the shareholders of Diamyd Medical AB by the number of shares outstanding during the period.

	10/11	09/10
Net profit for the year, KSEK	102,570	-332
Average number of shares outstanding before dilution	29,449	29,595
Average number of shares outstanding after dilution	29,477	29,595
Earnings per share before dilution	3.5	0
Earnings per share after dilution	3.5	0

For calculation of earnings per share after dilution, adjustments are made in the weighted-average number of shares outstanding for dilution

effects of potential ordinary shares. The Company has only outstanding employee stock options.

NOTE 12 INTANGIBLE ASSETS AND DEPRECIATIONS

Intangible assets are partly composed of the Company's licensed patent rights regarding GAD65 from the University of Florida and the University of California. These are utilized in research and are amortized over five years. The acquisition value amounts to KSEK 10,200. They were amortized over five years, and were completely amortized as of August 31, 2008. During the third quarter, the NTDDS-based development project acquired by the Company was subjected to an impairment test, as required by IFRS for intangible assets that are not amortized on an ongoing basis. The Company has not begun amortizing this intangible asset, because it has not yet been utilized. On the balance sheet date, the net book value of the intangible asset was KSEK 16,627 (16,627). The impairment test did not show any impair-

ment requirement. The impairment test was performed the same way as for the third quarter accounts on May 31, 2010, where future estimated cash flows generated by this asset were discounted, using a discount rate of 14 % (14 %). The cash flows used in the impairment test were adjusted for the estimated likelihood that the project would come to commercial fruition and thus generate cash flow. The probability assessments varies depending on the phase each project is in, and is based on statistical information obtained from external sources. A sensitivity analysis was performed which raised the discount rate to 19 %. This higher discount rate did not show any impairment requirement, either. No impairment test was performed in the fourth quarter.

The risk-free interest that was used in deriving the discount rate corresponds to a ten-year treasury bond.

KSEK	GROUP		PARENT COMPANY	
	10/11	09/10	10/11	09/10
Cost opening balance, patent	10,200	10,200	-	-
Cost opening balance, research project	16,627	16,627	16,627	16,627
Additions, research projects	-	-	-	-
Disposals, research projects	-	-	-	-
Cost, closing balance	26,827	26,827	16,627	16,627
Accumulated depreciation opening balance, patent	-10,200	-10,200	-	-
Disposals	-	-	-	-
Depreciation for the year, patents	-	-	-	-
Closing balance depreciation	-10,200	-10,200	-	-
Net book value, August 31	16,627	16,627	16,627	16,267

NOTE 13 FINANCIAL ASSETS – GROUP/PARENT COMPANY

Financial fixed assets consist of a holding of shares in Mercodia AB, Corporate Registration Number 556157-5100, and a holding of shares in Protein Sciences Corporation, Corporate Registration Number 2008700. Holdings in Mercodia AB are 19 % of capital, or 1,000 shares with a net book value of KSEK 800. Diamyd Medical AB's holding in Protein Sciences Corporation is about 8 % of capital, or 5,768,548 shares. The net book value is KSEK 28,441. The holdings in Mercodia AB and Protein Sciences Corporation are not publicly

listed. Other parameters than market quotations have therefore been used in the valuation of these holdings. An assessment of the companies' financial performance and position and development of their portfolio of projects motivates the valuation of the holdings. If the valuation results in an assessed value change, the effect is recognized in the consolidate statement of comprehensive income. The assessment as of August 31, 2011 has given the result that no value change in the holdings has been recognized.

KSEK	10/11	09/10
Opening balance, cost	30,678	21,418
Adjusted interest, convertible promissory note 2009/2010	-643	–
Interest, convertible promissory note 2010/2011	112	–
Exchange rate fluctuation	-906	–
Reclassification	–	9,260
Cost, closing balance	29,241	30,678
Net book value, August 31	29,241	30,678

NOTE 14 INVENTORY

The inventory consists of GAD protein for sale. There has been no obsolescence deduction.

NOTE 15 PREPAID EXPENSES AND ACCRUED INCOME

KSEK	GROUP		PARENT COMPANY	
	10/11	09/10	10/11	09/10
Prepaid patent fees	533	58	56	58
Prepaid insurance fees	381	383	99	101
Accrued research services	1,719	14,545	1,719	14,545
Accrued interest income	2,324	241	2,709	488
Other prepaid expenses	488	968	336	399
Total	5,445	16,195	4,919	15,591

NOTE 16 FINANCIAL RISKS

The Group is exposed to various financial risks in the course of its business. The financial operations of the Group primarily include exposure to financing risk, currency risk, credit risk, capital risk and interest rate risk.

Financial policy

Diamyd Medical's financial policy specifies goals, governing principles and assignment of responsibility within the financial operations. The financial policy regulates the principles applied for calculation, control and reporting of financial risks. Diamyd Medical's financial policy is evaluated and approved annually by the Board of Directors. Financial risk management is conducted by the Group's central accounting and finance function in accordance with the guidelines of the financial policy.

Financing risk

The financing risk is defined as the risk of the Company having insufficient funds to operate its business. Diamyd Medical's policy is to ensure that cash and cash equivalents are available to finance operations for a period of at least 12 months ahead. Since Diamyd Medical is a research and development company, sources of finance primarily comprise revenues from licensing agreements and the issue of new shares. To some extent the projects managed by Diamyd, Inc. are funded by grants. Evaluation of various forms of financing is conducted on an ongoing basis. The Group has no interest-bearing liabilities. Current liabilities comprise accounts payable that fall due within 30 days.

Maturity analysis, accounts payable KSEK	GROUP		PARENT COMPANY	
	10/11	09/10	10/11	09/10
Amounts becoming due within 1 year	9,182	7,083	1,091	298
Amounts becoming due after more than one year	-	-	-	-
Total	9,182	7,083	1,091	298

Forecasts and follow-up of the cash flow is carried out on a monthly basis to assess the need for liquidity. At August 31, 2011, liquid assets and short term investments amounted to MSEK 436.

Foreign exchange risk

Foreign exchange risk is defined as the risk that Diamyd Medical's earnings and cash flow are affected by fluctuations in the exchange rate. Diamyd Medical operates in an international market with a relatively high proportion of incoming and outgoing payments in foreign currencies. Diamyd Medical has its greatest exposure to the US dollar (USD) and to the Euro (EUR).

A portion of Diamyd Medical's foreign exchange risk arises from transactions between the Parent Company and the American subsidiary, Diamyd, Inc., including the purchase of research services. In addition, an exchange rate effect arises on translation of Diamyd, Inc.'s income statement and balance sheet to SEK, which affects the Group's equity. The amount totaled KSEK 120 for the fiscal year 2010/2011. Diamyd Medical's expenses during the fiscal year amounted to MSEK 177, of which approximately 45 % was expenses in foreign currencies, primarily USD and EUR. Exchange rate movements have positive and negative effects on the Company's earnings. Fluctuations are reduced through the Company holding a certain degree of cash and cash equivalents in USD and EUR for current payments and utilizing currency futures contracts for more substantial transactions. The Company's operating profit had a MSEK 0.5 net effect from currency hedging. Expenses in USD are balanced, to a certain extent, by income in the same currency from research collaboration projects.

NOTE 17 SHORT TERM INVESTMENTS

Short term investments consist of interest bearing investments with three to six months term to maturity.

KSEK	GROUP		PARENT COMPANY	
	10/11	09/10	10/11	09/10
Short term investments	277,859	-	277,859	-
Total	277,859	-	277,859	-

NOTE 18 LIQUID ASSETS

The liquid assets consist of bank account balances and interest bearing investments with less than three months term to maturity. The liquid assets can easily be converted to a predictable amount and they are exposed to an insignificant risk of value changes.

KSEK	GROUP		PARENT COMPANY	
	10/11	09/10	10/11	09/10
Liquid assets	157,782	501,332	143,228	478,882
Total	157,782	501,332	143,228	478,882

The Group's policy is to hedge 75 % of foreign currency flows that are known with a high degree of probability. During the fiscal year, an average USD/SEK exchange rate 10 % higher would have resulted in increased expenses of approximately MSEK 6. A comparably higher EUR/SEK exchange rate would have resulted in increased expenses of MSEK 2.

Credit risk

Credit risk is defined as the risk that a counterpart cannot fulfill its financial obligations to Diamyd Medical. A credit risk arises in cash management when excess liquidity is invested. The credit risk is managed through only investing in counterparties of a high credit rating within investment limits set in the financial policy. The maximum duration of an investment until maturity is six months.

Capital risk

Diamyd Medical's objective regarding the capital structure is tailored to ensure the ability of operations to continue to be able to generate a return to shareholders and benefit for other stakeholders in the long-term. Diamyd Medical defines capital as Shareholders' equity. The capital structure can be maintained or adjusted through the issue or repurchase of new shares.

Interest rate risk

The interest rate risk is defined as the risk that the Group's earnings are affected by changes in interest rate levels.

Diamyd Medical has no interest-bearing liabilities. Interest rate risk arises in Diamyd Medical's financial operations in conjunction with investment of liquid assets and short term investments and that the return on these investments can vary in relation to the general interest rate levels depending on the tenor of the investment. Investments are made so they mature at regular intervals to enable, in so far as is possible, the matching of investment maturities with the consumption rate of funds by operations.

NOTE 19 FINANCIAL INSTRUMENTS BY CATEGORY

The link between IAS 39 categories and Diamyd Medical's balance sheet items in the Balance Sheet.

KSEK	Financial assets recognized at fair value in the Income Statement	Liquid assets	Accounts receivable and other receivable	Borrowings and accounts payable	Financial assets held for sale	Total
Financial assets held for sale					29,241	29,241
Accounts receivable and other receivables			16,857			16,857
Accrued income and deferred costs			5,445			5,445
Short term investments	277,859					277,859
Liquid assets		157,782				157,782
Accounts payable and other payables				11,243		11,243
Total as of Augusti 31, 2011	277,859	157,782	22,302	11,243	29,241	498,427

KSEK	Financial assets recognized at fair value in the Income Statement	Liquid assets	Accounts receivable and other receivables	Borrowings and accounts payable	Financial assets held for sale	Total
Financial assets held for sale					9,260	9,260
Accounts receivable and other receivables			3,489			3,489
Accrued income and deferred costs						–
Short term investments						–
Liquid assets		501,332				501,332
Accounts payable and other payables				8,517		8,517
Total as of Augusti 31, 2010	–	501,332	3,489	8,517	9,260	522,598

Financial assets recognized at fair value**2010/2011**

KSEK	Carrying amount	Measurement at fair value at the end of the period based on		
		Tier 1	Tier 2	Tier 3
Financial assets recognized at fair value in the Income Statement:				
Short term investments	277,859	277,859		
Financial assets held for sale	29,241			29,241
Total as of Augusti 31, 2011	307,100	277,859	–	29,241

2009/2010

KSEK	Carrying amount	Measurement at fair value at the end of the period based on		
		Tier 1	Tier 2	Tier 3
Financial assets recognized at fair value in the Income Statement:				
Financial assets held for sale	9,260	–	–	9,260
Total as of Augusti 31, 2010	9,260	–	–	9,260

NOTE 20 CASH FLOW ANALYSIS

The amount includes upfront payment of MSEK 229.8.

NOTE 21 LIABILITIES

All company liabilities are non-interest bearing.

NOTE 22 PREPAID INCOME AND ACCRUED EXPENSES

KSEK	GROUP		PARENT COMPANY	
	10/11	09/10	10/11	09/10
Accrued vacation pay	1,910	356	–	–
Accrued salaries	2,318	–	–	–
Accrued social security expenses	924	1,174	–	47
Accrued social security expenses on employee options	566	3,034	–	–
Accrued research expenses	15,571	9,920	–	–
Accrued patent fees*	12,834	–	–	–
Other accrued expenses	–	1,603	–	1,108
Prepaid income **	–	229,806	–	229,806
Total	34,123	245,893	–	230,961

* See Note 3 page 45

** The amount consists of the upfront payment

NOTE 23 RESULTS FROM GROUP PARTICIPATION

Shares in Group companies were impaired by KSEK 74,234 (81,308) during the year. Impairment of shares during the year in Group companies refers to the impairment of shares equivalent to shareholders' contributions during the year. These contributions amounted to KSEK 74,234 (81,308) to Diamyd Therapeutics.

NOTE 24 LIABILITIES TO SUBSIDIARIES

KSEK	10/11	09/10
Liabilities, Diamyd Therapeutics AB	224,543	14,450
Liabilities, Diamyd, Inc.	391	3,065
Total	224,934	17,515

NOTE 25 SHARES IN SUBSIDIARIES

Subsidiary	Corporate Registration Number	Registered office	Equity (KSEK)	Earnings (KSEK)	Share-holding	Number of shares	Book value (SEK)
Diamyd Therapeutics AB	556242-3797	Stockholm, Sweden	1,000	-45,775	100%	1,000,000	1,100,000
Diamyd Diagnostics AB	556552-2280	Stockholm, Sweden	350	45	100%	1,000	100,000
Diamyd, Inc.	3695413	Pittsburgh, PA, USA	-335	-1,532	100%	1,000	7

KSEK	10/11	09/10
Opening book value	1,200	1,200
Shareholder contribution provided	74,234	81,308
Impairment of book value	-74,234	-81,308
Closing book value	1,200	1,200

NOTE 26 PARENT COMPANY'S RECEIVABLES FROM SUBSIDIARIES

KSEK	10/11	09/10
Long-term receivables from Diamyd Therapeutics AB	–	14,192
Long-term receivables from Diamyd Diagnostics AB	155	156
Long-term receivables from Diamyd, Inc.	8,531	6,264
Total	8,687	20,612

NOTE 27 SHARE CAPITAL

A specification of the changes in shareholder's equity can be found in the summary "Changes in shareholder's equity - Group" (page 33). At August 31, 2011, the assets of Diamyd Medical were divided among 28,141,257 series B shares (1/10 vote) and 1,437,876 series A shares

(1 vote). At the end of the fiscal year, the share capital in Diamyd Medical was SEK 14,789,567 (14,530,139). The nominal value is SEK 0.5 (0.5). All shares issued are fully paid.

NOTE 28 EMPLOYEE STOCK OPTION PLAN 2007/2010

On December 11, 2007, the Annual General Meeting of Diamyd Medical approved an employee stock option plan with underlying warrants. This was a modification to the employee stock option plan that was approved at the extraordinary shareholders' meeting on May 22, 2007. A specified portion of the warrants was reserved to cover social security contributions and other related costs. The program included 200,000 employee stock options, which also cover social security expenses. The valuation was made in accordance with IFRS 2 Share-Based Payments. Employee stock options were vested annually over one, two and three years and were exercisable from November 15, 2008, November 15, 2009, November 15, 2010 and until December 31, 2010. The value was set at SEK 22.90, SEK 26.09 and SEK 28.97. The options were received free of charge.

After new issues and splits during the fiscal year 2009/2010, the issue price was changed to SEK 35.90. Each option entitled the holder to 2.26 shares.

Effect on financial statements

The cost charged to the income statement in 2010/2011 regarding the program amounts to KSEK 222 (904), with a corresponding entry to equity. The amount which has been charged regarding social security costs is an income of KSEK 1,280 (cost 959). The program matured in December 2010. The accounting policies for employee stock option programs are described on page 40.

NOTE 29 EMPLOYEE STOCK OPTION PLAN 2008/2011

On December 11, 2008, the Annual General Meeting of Diamyd Medical approved an employee stock option plan totaling 220,000 employee stock options. The issue price for shares was set at SEK 66 per share for the stock options, which were allocated free of charge. One-third of the program was exercisable on November 15, 2009 another third on November 15, 2010 and the final third is exercisable from November 15, 2011 until December 31, 2011. In addition to the 166,650 options that have been allocated to employees and management, Group subsidiaries have subscribed for 53,350 options intended to be used to cover the social security expenses that can arise from the option program when the options are exercised by their holders. Valuation of the program has been carried out in accordance with the Black & Scholes model and the primary parameters have been volatility 49 % and the issue price of SEK 66 per share. Interest rates comparable to a one-year treasury bill and two-year and three-year government bonds have been utilized for calculating costs. After new share issues and split during the fiscal year 2009/2010, the issue price was adjusted to SEK 29.25. Each option entitles the holder to subscribe for 2.26 shares.

with the exercise price. Additional costs occurring as an effect of the program, consisting primarily of payroll taxes levied upon exercise, will be covered by the exercise of the additional warrants held to cover such costs. There will be no adverse effect on the Company's financial position from the program, provided that the percentage at which payroll taxes are levied does not change significantly during the remainder of the exercise period. The accounting policies for employee stock option programs are described on page 40.

Increase in number of shares

Exercise of all options outstanding in the program would lead to an increase of the number of shares by approximately 2 %, including the warrants required to cover social security expenses.

Effect on financial statements

The cost charged to the income statement in 2010/2011 amounts to KSEK 906 (2,025), with a corresponding entry to equity and a positive effect of social security costs of KSEK 2,046 (cost 1,847). The future exercise of employee stock options will have a positive effect on the Company's financial position, since plan participants will pay monies to the Company to exercise options in accordance

Number of stock options

Approved, December 11, 2008	220,000
Allocated	166,650
Forfeited	-9,900
Exercised	-77,550
Outstanding, August 31, 2011	79,200

NOTE 30 EMPLOYEE STOCK OPTION PLAN 2009/2012

On December 11, 2008, the Annual General Meeting of Diamed Medical approved an employee stock option plan totaling 580,000 employee stock options. The issue price for shares was set at SEK 124 per share for the stock options, which were allocated free of charge. One-third of the program is exercisable on November 15, 2010 another third on November 15, 2011 and the final third from November 15, 2012 until December 31, 2012. In addition to the 353,200 options that have been allocated to employees and management and the 80,800 that have been returned when employees have left their employment, Group subsidiaries have subscribed for 146,000 options intended to be used to cover the social security expenses that can arise from the option program when the options are exercised by their holders. Valuation of the program has been carried out in accordance with the Black & Scholes model and the primary parameters have been volatility 51 % and the issue price of SEK 124 per share. Interest rates comparable to a one-year treasury bill and two-year and three-year government bonds have been utilized for calculating costs.

Effect on financial statements

The cost charged to the income statement in 2010/2011 amounts to KSEK 4,812 (2,621), with a corresponding entry to equity and a positive effect of social costs of KSEK 309 (cost 758). The future exercise of employee stock options will have a positive effect on the Company's financial position, since plan participants will pay monies to the Company to exercise options in accordance with the exercise price. Additional costs occurring as an effect of the program, consisting primarily of payroll taxes levied upon exercise, will be covered

by the exercise of the additional warrants held to cover such costs. There will be no adverse effect on the Company's financial position from the program, provided that the percentage at which payroll taxes are levied does not change significantly during the remainder of the exercise period.

The accounting policies for employee stock option programs are described on page 40.

Increase in number of shares

Exercise of all options outstanding in the program would lead to an increase of the number of shares by approximately 2 %, including the warrants required to cover social security expenses.

Number of stock options	
Approved, December 11, 2009	580,000
Allocated	433,800
Forfeited	38,700
Exercised	–
Outstanding, August 31, 2011	395,100

NOTE 31 DEFICITS IN SUBSIDIARIES

The Parent Company grants capital cover annually for the Swedish subsidiaries since they are running deficits. For 2010/2011, the Parent Company's outstanding capital cover amounted to KSEK 74,234 (81,308) which was settled via a shareholder contribution.

The Board of Directors and the President assure that the consolidated Financial Statement as well as the Annual Report have been prepared according to the international accounting standards as intended in the European Parliament and Council's regulation (EC No 1606/2002) of July 19, 2002 concerning the application of international accounting standards and generally accepted accounting principles and gives a fair overview of the Group's and the Parent's position and results. The

Administration Report for the Group and the Parent Company gives a fair overview of the Group's and the Parent Company's operations, position and results, and describes significant risks and uncertainties faced by the Parent Company and Group member companies. The balance sheet and income statement will be presented for adoption at the Annual General Meeting of Shareholders on December 7, 2011.

Stockholm, November 15, 2011

Peter Zerhouni
President and CEO

Anders Essen-Möller
Chairman of the Board

Henrik Bonde
Board Member

Maria-Teresa Essen-Möller
Board Member

Joseph Janes
Board Member

Lars Jonsson
Board Member

Sam Lindgren
Board Member

Göran Pettersson
Board Member

Our auditor's report has been submitted on November 15, 2011.
Öhrlings PricewaterhouseCoopers

Eva Blom
Authorized Accountant

AUDIT REPORT

TO THE ANNUAL MEETING OF THE SHAREHOLDERS OF DIAMYD MEDICAL AB (PUBL)

Corporate identity number 556530-1420

We have audited the annual accounts, the consolidated accounts, the accounting records and the administration of the board of directors and the managing director of Diamyd Medical AB for the year beginning 1st of September 2010 to 31st of August 2011. The company's annual accounts and the consolidated accounts are included in the printed version on pages 25–58. The board of directors and the managing director are responsible for these accounts and the administration of the company as well as for the application of the Annual Accounts Act when preparing the annual accounts and the application of international financial reporting standards IFRSs as adopted by the EU and the Annual Accounts Act when preparing the consolidated accounts. Our responsibility is to express an opinion on the annual accounts, the consolidated accounts and the administration based on our audit.

We conducted our audit in accordance with generally accepted auditing standards in Sweden. Those standards require that we plan and perform the audit to obtain reasonable assurance that the annual accounts and the consolidated accounts are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the accounts. An audit also includes assessing the accounting principles used and their application by the board of directors and the managing director and significant estimates made by the board of directors and the managing director when preparing the annual accounts and consolidated accounts as well as evaluating the overall presentation of information in the annual accounts and the consolidated accounts. As a basis for our opinion concerning discharge from liability, we examined significant decisions, actions taken and circumstances of the company in order to be able to determine the liability, if any, to the company of any board member or

the managing director. We also examined whether any board member or the managing director has, in any other way, acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association. We believe that our audit provides a reasonable basis for our opinion set out below.

The annual accounts have been prepared in accordance with the Annual Accounts Act and give a true and fair view of the company's financial position and results of operations in accordance with generally accepted accounting principles in Sweden. The consolidated accounts have been prepared in accordance with international financial reporting standards IFRSs as adopted by the EU and the Annual Accounts Act and give a true and fair view of the group's financial position and results of operations. The statutory administration report is consistent with the other parts of the annual accounts and the consolidated accounts.

We recommend to the annual meeting of shareholders that the income statements and balance sheets of the parent company and the group be adopted, that the profit of the parent company be dealt with in accordance with the proposal in the administration report and that the members of the board of directors and the managing director be discharged from liability for the financial year.

Stockholm, November 15, 2011
Öhrlings PricewaterhouseCoopers AB

Eva Blom
Authorized Accountant

CORPORATE GOVERNANCE REPORT

Diamyd Medical AB is a Swedish public company listed on NASDAQ OMX Stockholm. Corporate governance is based on the Swedish Companies Act, the NASDAQ OMX Rules for Issuers and the Swedish Code of Corporate Governance (the Code), and other applicable Swedish laws and regulations. This corporate governance report forms an integrated part of the Annual Report for 2010/2011 and has been reviewed by the Company's auditors. The Company has deviated from the Code in terms of the number of members in the Audit Committee, see the Audit Committee below.

SHARES AND SHAREHOLDERS

Diamyd Medical AB's share capital consists of Series A shares (one vote) and Series B shares (1/10 vote). The Series A share is not listed. On August 31, 2011, the number of shareholders was 8,554, which is an increase of 25 % compared with the preceding year.

Major shareholders

The table below shows the share ownership in Diamyd Medical representing the ten largest shareholders in the Company at August 31, 2011.

Name	Number of Series A shares	Number of Series B shares	Share of capital, %	Share of voting power, %
Bertil Lindkvist	–	4,070,279	13.76	9.57
Avanza Pension	–	3,294,840	11.14	7.75
Anders Essen-Möller	1,437,876	392,225	6.19	34.74
Östersjöstiftelsen	–	1,504,828	5.09	3.54
Nordnet Pensionsförsäkring AB	–	1,177,412	3.98	2.77
Ålandsbanken AB, W8IMY	–	634,122	2.14	1.49
SIX SIS AG, W8IMY	–	443,715	1.50	1.04
Robur Försäkring AB	–	434,757	1.47	1.02
Healthinvest Value Fund	–	391,524	1.32	0.92
Försäkrings AB Skandia	–	317,673	1.07	0.75
	1,437,876	12,661,375	47.67	63.59

OVERVIEW OF DIAMYD MEDICAL'S CORPORATE GOVERNANCE

Responsibility for corporate governance at Diamyd Medical is divided among the Annual General Meeting and any Extraordinary General Meetings, the Board of Directors, the Board's Committees and the CEO.

Nasdaq OMX's Rules for Issuers are available at www.nasdaqomx.com and the Swedish Code of Corporate Governance is available at www.corporategovernanceboard.se.



Diamyd Medical's corporate governance model

External regulations

- Swedish Companies Act
- Accounting standards
- Nasdaq OMX Stockholm Rules for Issuers
- Swedish Code of Corporate Governance
- Other applicable laws and regulations

Internal regulations

- Articles of Incorporation
- Formal work plan for the Board of Directors and instructions for the CEO
- Instructions to the Audit Committee and the Compensation Committee
- Other applicable policies and instructions

ANNUAL GENERAL MEETING

Diamyd Medical's highest decision-making body is the Annual General Meeting, where shareholders' influence in the Company is exercised. The Annual General Meeting, according to the Articles of Incorporation, is held not later than six months after the end of the fiscal year. At the Annual General Meeting, the shareholders resolve such issues as the election of the Board of Directors and Chairman of the Board, how the Nomination Committee will be appointed, election of auditor, adoption of the financial statements, allocation of profit/loss, remuneration of the Board and auditors and guidelines for remuneration to the CEO and other senior executives.

To be entitled to participate in a general meeting of shareholders, shareholders must be recorded in the Company's register of shareholders administered by Euroclear Sweden AB at least five business days before the Annual General Meeting (AGM) and have provided notification of attendance within the time period stipulated in the notification. There are no limitations regarding the number of votes each shareholder may cast at the AGM.

ANNUAL GENERAL MEETING, DECEMBER 9, 2010

Some of the resolutions passed at the AGM included the following:

- A resolution that profit for the year amounting to KSEK 5,154 combined with previously accumulated funds totaling KSEK 203,829 is carried forward, and abstain from distributing a dividend to shareholders.
- A resolution to re-elect Anders Essen-Möller, Lars Jonsson, Sam Lindgren, Henrik Bonde, Göran Pettersson and Maria-Teresa Essen-Möller, to elect Joseph Janes as new Board member and re-elect Anders Essen-Möller as Chairman of the Board.
- A resolution to authorize the Board of Directors, on one or more occasions during the period until the next Annual General Meeting, to resolve on a new share issue up to a limit of 10 percent of the total number of shares, and to be able to deviate from the shareholders' preferential rights in so doing.
- A resolution to authorize the Board of Directors, during the period until the next Annual General Meeting, to resolve on a buy-back of Series B shares in Diamyd Medical. The highest number of buy-

back shares must be such that the Company's holding of treasury shares does not at any time exceed 5 percent of all shares in the Company.

- A resolution that the terms and conditions for outstanding employee stock option plans are changed in such a manner that the options, since they were vested, can continuously be utilized for the acquisitions of stocks until they expire and not only during a certain period.

The minutes of the AGM are available on Diamyd Medical's website, www.diamyd.com.

NOMINATION COMMITTEE

The principles applied for appointing the Nomination Committee for the AGMs in 2010 and 2011 have been as follows: The Nomination Committee is to be comprised of representatives of the three principle (by voting power) shareholders of the Company and the Chairman of the Board, who convenes the meetings. The Nomination Committee must be made public at least six months before the AGM.

Nomination Committee for the AGM for fiscal year 2009/2010, December 9, 2010

Before the 2009/2010 AGM, the Nomination Committee consisted of Johannes Falk (Chairman and representative of shareholder and Chairman of the Board, Anders Essen-Möller), lawyer Erik Nerpin, (representative of shareholder, Bertil Lindkvist) and Åke Smids (representative of shareholder, Östersjöstiftelsen). The Nomination Committee formulated proposals regarding the Board and the Chairman of the Board, Directors' remuneration, Chairman of the AGM as well as proposals for the nomination process before the AGM for the fiscal year 2010/2011.

Nomination Committee for the AGM for fiscal year 2010/2011, December 7, 2011

The existing Nomination Committee of Diamyd Medical comprises Erik Nerpin (representative of shareholder, Bertil Lindkvist), who is also Chairman, Åke Smids (representative of shareholder, Östersjöstiftelsen) and shareholder Anders Essen-Möller, who is also the Chairman of the Board. The Board is of the opinion that the current Nomination Committee complies with the Code's requirements regarding independence and composition. The proposals of the Nomination Committee will be presented in conjunction with the notification of the AGM at the latest.

THE BOARD OF DIRECTORS

The Board has the overall task of managing the Company's affairs on behalf of the shareholders in the best possible manner. The Board's duties include determining the Company's operational objective and

strategy. The Board's responsibilities include supervising the CEO's work by monitoring the operations on a regular basis. The Board is also responsible for ensuring that the Company has effective systems in place for monitoring and controlling the Company's compliance with laws and other regulations that apply for the Company's operations.

According to the Articles of Incorporation, the Board must consist of between three and eight members, and zero to three alternates. The current Board of Directors and its Chairman were elected at the AGM on December 9, 2010 and consist of Anders Essen-Möller (Chairman), Henrik Bonde, Maria-Teresa Essen-Möller, Joseph Janes, Lars Jonsson, Sam Lindgren and Göran Pettersson.

The Board's work is regulated primarily by the Companies Act, the Articles of Incorporation, the Code and the work plan that the Board has established for its work. According to its work plan, the Board must hold at least seven ordinary Board meetings between each AGM. At four of the meetings, quarterly reports and year-end reports are considered. According to the work plan, a meeting notice and supporting documents for decisions and reports must be distributed to the Board of Directors one week before each Board meeting. The Company's auditor attends Board meetings as needed, normally twice per year. Pursuant to the Companies Act, the Board's work plan is reviewed on an annual basis.

The Chairman of the Board, Anders Essen-Möller, must ensure that the Board's work is performed efficiently and that the Board carries out its duties. In addition, the Chairman must verify that the Board's decisions are effectively implemented, and that the Board's work is evaluated annually.

In addition to his duties as the Chairman of the Board, the founder of the Company Anders Essen-Möller is also a Diamyd Medical employee. His primary job duties consist of dealing with long-term strategic issues that are outside the scope of the CEO's strategic work with respect to the prevailing business plan, out-licensing of the Company's development projects and patent issues. The Chairman is not part of the Group's executive management. The CEO participates in the meetings of the Board of Directors.

In the Board's judgment, it fulfills the Code's requirements for independence from the Company, Company management and major shareholders (owners, directly or indirectly, of more than 10 percent of the shares or votes in the Company).

THE BOARD OF DIRECTORS' WORK DURING FISCAL YEAR 2010/2011

During the year, the Board of Directors held 16 meetings for which minutes were taken, including one statutory meeting, seven ordinary Board meetings and eight extra Board meetings. The Board

of Directors' work has been intense during the year with extensive strategy efforts both before and after May 9, 2011 when the results of the Company's European Phase III study in type 1 diabetes were presented. During the latter part of the fiscal year, the Board's work focused on the Company's strategic direction with greater emphasis on the NTDDS platform. The Board also placed particular emphasis on monitoring cost reduction and cost control. The Company's auditor was present and reported her observations at the Board meeting in October 2010, when the preceding year's annual financial statements were reviewed. At the statutory meeting in December 2010, the Board resolved to establish a dedicated Audit Committee, see below. Other material issues dealt with during the year have included appointing a new CEO, goals and strategic direction for the operations, business plans, financial plans and forecasts, capital and financing issues, interim reports and the annual financial statements and evaluation of the work of the Board, the CEO and the executive management. Members of the executive management have participated in certain meetings to make presentations. The Board also held a strategy meeting in which the entire management group participated. During the year, the Company's CFO served as the Secretary to the Board of Directors. For information regarding the remuneration of the Board of Directors, see Note 4 in the Annual Report, pages 45–47.

AUDIT COMMITTEE

During the year, the Audit Committee consisted of Board member Maria-Teresa Essen-Möller (Chairman), and independent Board member Henrik Bonde. According to the Code, the Audit Committee must consist of at least three Board members. In the light of the scale of operations and subsequent issues that must be handled, the Board deems it fully adequate that Maria-Teresa Essen-Möller and Henrik Bonde perform the Committee's duties. Diamyd Medical has therefore chosen to deviate from this rule during the fiscal year 2010/2011. The Committee advises the Board and has no right to make its

own decisions. During the year, the Audit Committee supervised and assured the quality of the Company's financial reporting, risk management and the effectiveness of internal controls. The Committee held three meetings where minutes were taken during the year. In conjunction with the adoption of the annual financial statements in October 2011 and the third-quarter interim report in June 2011, the Company's auditor reported the audit findings from the review of the annual financial statements and the interim financial statements and gave an opinion of the internal controls.

COMPENSATION COMMITTEE

During fiscal year 2010/2011, the Compensation Committee was made up of independent Board member, Göran Pettersson and Board Chairman, Anders Essen-Möller (Chairman). The Committee advises the Board and has no right to make its own decisions. In accordance with guidelines approved at the previous AGM on December 9, 2010, the Committee is charged with drafting and deciding on issues concerning the compensation of senior executives, with the exception of the CEO. The Committee is also charged with proposing guidelines for compensation of senior executives at the next AGM. However, issues concerning incentive programs and the CEO's remuneration are drafted and decided on by the Board of Directors. The Compensation Committee held four meetings where minutes were taken during the fiscal year.

For information on the principles for remuneration of senior executives and other terms of employment adopted at the AGM on December 9, 2010, and on remuneration during the fiscal year 2010/2011, see page 29 and Note 4, pages 45–47 of the Annual Report.

CEO AND EXECUTIVE MANAGEMENT

Peter Zerhouni, the former Executive Vice President and Senior Director of Business Development, took office as acting President and CEO in Diamyd Medical on April 26, 2011 and became the Company's ordinary President and CEO on July 4, 2011. The CEO leads the

Name	Member since	Independent	Attendance at Board meetings	Attendance at Compensation Committee	Attendance at Audit Committee
Anders Essen-Möller	1996, Chairman	No *)	16/16	4/4	
Henrik Bonde	2007	Yes	16/16	1/1 (***)	3/3
Maria-Teresa Essen-Möller	2009	No *)	14/16		3/3
Joseph Janes	2010	Yes	9/11 (**)		
Lars Jonsson	2007	Yes	14/16		
Sam Lindgren	2007	Yes	14/16		
Göran Pettersson	2008	Yes	13/16	3/3 (***)	

* Anders Essen-Möller is not considered independent since he is a major shareholder in the Company and employed by the Company. Maria-Teresa Essen-Möller is not considered independent since she is the daughter of the Company's Chairman Anders Essen-Möller. Other Board members are considered independent of the Company and major shareholders.

** Joseph Janes was elected at the AGM on December 9, 2010. For information regarding Diamyd Medical's Board members, see page 66–67 of the Annual Report.

*** Henrik Bonde was a member of the Compensation Committee until December 9, 2010. Göran Pettersson has been a member of the Committee since December 9, 2010.

Company's operations and day-to-day administration in accordance with the instructions of the Board of Directors and is responsible for keeping the Chairman of the Board and other Board members informed regarding development of the Company and for ensuring that requisite information is made available to the Board of Directors upon which they can make well-supported decisions. The Company's former President and CEO, Elisabeth Lindner, stepped down from her position on April 26, 2011 due to disagreement with the Board concerning certain important matters.

The Company's executive management comprised six to seven people, including the CEO, during the year. The executive management meets once per week and deals with issues regarding the development operations, financial position and business development. During the year, the executive management's work was marked by strategy work both before and after May 9, 2011 when the results of the Company's European Phase III study in type 1 diabetes were presented. Before the study's results were published, the executive management's focus was on leading the intensive Phase III program with the Diamyd® diabetes therapy in collaboration with Ortho-McNeil-Janssen Pharmaceuticals, Inc. and preparing the Company for market launch. After the publication of the results, which did not meet expectations, the executive management changed its focus to restructuring the operations due to a decision to terminate the Phase III program. Diamyd Medical's steering model builds on having a small organization with a limited number of employees who lead projects in pre-clinical and clinical development, regulatory affairs and production where most of the operational activities are out-sourced to qualified partners. A key aspect of the executive management's work is controlling and monitoring this operation. Each head of department is responsible for ensuring that the decisions made at executive management meetings are implemented and monitored.

For more information regarding executive management, see pages 68–69 of the Annual Report.

AUDIT

Diamyd Medical's auditors are Öhrlings PricewaterhouseCoopers AB with Eva Blom as the auditor in charge. Eva Blom has been an authorized public accountant since 1986. She is a member of FAR, and has been Diamyd Medical's auditor in charge since February 19, 2010. In addition to her assignment with Diamyd Medical, Eva Blom also is also an auditor for Unilever Sweden AB, NCC Roads Holding AB, Baxter Medical AB, Glaxo Smith Kline AB and Orion Pharma AB. Since 2007, Öhrlings PricewaterhouseCoopers AB has been selected for a term of four years. A proposal concerning reelection of the current auditor will be presented at the AGM 2011. For information on audit fees, see Note 6 on page 48 of the Annual Report.

INTERNAL CONTROLS AND RISK MANAGEMENT IN CONJUNCTION WITH FINANCIAL REPORTING

According to the Swedish Companies Act and the Swedish Code of Corporate Governance, Diamyd Medical's Board is responsible for internal controls of the Company's financial reporting. Internal controls and risk management regarding financial reports are processes that intend to provide reasonable certainty concerning the reliability of external financial reporting and to ensure that financial reports are prepared and published in accordance with generally accepted accounting principles, applicable laws and regulations and other requirements for listed companies. Diamyd Medical's internal controls in this respect consist of five main components: a control environment, risk assessment, control activities, information and communication, and monitoring.

Control environment

Diamyd Medical's control environment is the foundation of internal controls regarding the financial reporting. The control environment is composed of the Company's organizational structure, decision paths, work procedures and the powers and responsibilities of management and other personnel, as well as their attitudes and values. The control environment is documented and communicated in governing documents, such as the Board of Directors' work plan, instructions to the Audit Committee and Compensation Committee, the instructions to the CEO and policies and other instructions including the finance handbook, finance policy, information policy, personnel manual and authorization instructions. These documents must be evaluated and updated at least once per year, and in connection with changes to legislation, accounting standards or listing rules, for example.

Financial reports are to be prepared on a monthly and quarterly basis for the Group, the Parent Company and the subsidiaries. The Board bears the overall responsibility for meeting the Company's auditor on a regular basis to keep up to date on the scope and direction of the audit, as well as to discuss the risks facing the Company and the coordination of internal controls and the external audit.

Risk assessment

Diamyd Medical's risk assessment consists of identifying, measuring (as far as possible in practice) and identifying the source of the risks that affect internal controls regarding financial reporting. This task also includes reviewing documents and policies according to the above. Risk assessment is an integrated part of the reporting made to management and the Board of Directors. Risk assessment is focused on critical accounting issues, and encompasses issues including the identification of entries in the income statement and balance sheet

with an elevated risk of significant errors or deficiencies, either typically or in an individual instance.

In Diamyd Medical's case, accrued project expenses can reach significant amounts, the size of which is largely based on management's assessments. This has been deemed as possibly giving rise to risks, since such assessments are always associated with uncertainty. Other critical accounting issues may be changes to estimates or judgments, events after the balance sheet date, revenue recognition and valuation of the Company's assets. For a more detailed description of various financial risks and their management, refer to the risk section of the Administration Report of the Annual Report, pages 29–30.

Control activities

Control activities encompass both general and more detailed controls, which are intended to prevent, detect and correct errors and deviations in financial reporting. Financial reports are built on policies and instructions and are prepared on a monthly basis. The Company's accounting and finance department conducts a thorough analysis and control of important accounting entries. The analysis and control of items is carried out by several people and comprises comparisons of actual outcome with the budget and forecasts. Monitoring takes place on a monthly basis through meetings with project managers and the CEO. This monitoring enables the analysis of significant changes, which reduces the risk of errors in financial reporting. In the course of preparing the accounts and report, particular emphasis is placed on specifying and commenting on important income statement and balance sheet entries. The control activities also entail that the principle of duality is applied in the accounting and finance department, and that instructions to the CEO indicate which decisions require the Board's consent.

Information and communication

Employees' understanding of Diamyd Medical's risks in the financial reporting is a key component in the work with internal controls. Material guidelines and instructions of significance for financial reporting are updated continuously and communicated to the employees concerned. Internal communication is characterized by the fact that the organization is small, which facilitates direct and frequent communication. The Company's information policy regulates how financial information is communicated internally between management and other employees, and externally to the market. The Company's information must be correct, relevant and presented in a uniform and clear manner. All communication must take place in accordance with NASDAQ OMX Rules for Issuers. Information is provided to shareholders through the Annual Report, interim reports, press releases and on the Company's website.

Monitoring

At every Board meeting, the Board of Directors considers the Company's and the Group's financial position through reports including the financial statements that the CEO continually provides to the Board of Directors. The reports include outcomes versus budget and earnings and cash flow forecasts, all with their accompanying variance analysis and management comments. The Board of Directors is kept continually updated of the financial risks of the Group and how they are managed. The financial reports enable the Board of Directors to continually monitor the performance of the business. Controls and analyses are carried out by the Board, Audit Committee, management and the accounting and finance department. These also intercept the need for measures or proposals for improvement. Monitoring also takes place through audits conducted by the Company's external auditors.

Internal audit function

Diamyd Medical has no dedicated internal audit function. It is the Board's opinion that since the organization is small and surveyable, this enables sufficiently effective control as the audit function is well covered by various employees within the organization. The Board has thereby assessed that there is no need to establish a dedicated function for internal auditing.

The Board of Diamyd Medical AB

AUDITOR'S REPORT ON THE CORPORATE GOVERNANCE REPORT

To the annual meeting of the shareholders in Diamyd Medical AB (publ), corporate identity number 556530-1420.

It is the board of directors who is responsible for the corporate governance report and that it has been prepared in accordance with the Annual Accounts Act. As a basis for our opinion that the corporate governance report has been prepared and is consistent with the annual accounts and the consolidated accounts, we have read the corporate governance report and assessed its statutory content based on our knowledge of the company.

In our opinion, the corporate governance report has been prepared and its statutory content is consistent with the annual accounts and the consolidated accounts.

Stockholm, November 15, 2011

Eva Blom

Authorized Public Accountant

THE BOARD



ANDERS ESSEN-MÖLLER

Chairman

Born in 1941. M.Sc. Founder and former CEO of Diamyd Medical. Board member since 1996, Chairman since 2007. Anders Essen-Möller also founded Synectics Medical AB, which was sold to Medtronic Inc. in 1996.

Other assignments: Member of the Kancera AB board.

Holdings in Diamyd Medical as of August 31, 2011: 1,437,876. A shares; 392,225 B shares.



HENRIK BONDE

Independent Board Member

Born in 1972. M.Sc. in Business Administration. Board member since 2008. Henrik Bonde is the Chief Investment Officer of the Östersjöstiftelsen. Treasurer and board member at Gälöstiftelsen.

Other assignments: Member of the Boards of Morphic Technologies AB and Iris Group AB. Chairman at Iris Förvaltning AB.

Holdings in Diamyd Medical as of August 31, 2011: 1,024 B shares.



MARIA-TERESA ESSEN-MÖLLER

Board Member

Born in 1970. M.Sc. in Business Administration. Board member since 2009. Account Manager at Creuna AB. Maria-Teresa Essen-Möller was Head of Investor Relations and Corporate Communications for Diamyd Medical 1997–1999.

Other Assignments: Member of the boards of Creative Antibiotics AB and Stiftelsen Adolf Fredriks och Gustav Vasa Barnkrubba.

Holdings in Diamyd Medical as of August 31, 2011: 36,000 B Shares.



JOSEPH JANES
Independent Board Member

Born in 1965. Juris Doctor from The American University, Washington College of Law, Washington DC. Board member since 2010. Previously member of the Board 2005-2007, during which he served as Chairman between 2006 and 2007. Joseph Janes lives and works in the USA.

Other Assignments: None.

Holdings in Diamyd Medical as of August 31, 2011: 15,000 B Shares.



LARS JONSSON
Independent Board Member

Born in 1948. B.Sc. Stanford Graduate Business School Senior Executive Program. Board member since 2007. Chairman and CEO of the Seattle-based Stellar Holdings Group. This also includes the ByggVesta Group in Sweden. Swedish Honorary Consul in State of Washington and Oregon. Ambassador for Barndiabetesfonden (The Childhood Diabetes Foundation).

Other assignments: None.

Holdings in Diamyd Medical as of August 31, 2011: 2,300 B shares.



SAM LINDGREN
Independent Board Member

Born in 1955. M.D., Ph.D., MBA. Board member since 2007. More than 15 years' experience from leading positions in the pharmaceutical industry, in the areas of diabetes at Novo Nordisk, CNS (Lundbeck) and asthma at Astra. Medical and Science Director at Astra Zeneca

Other assignments: None.

Holdings in Diamyd Medical as of August 31, 2011: 1,280 B shares.



GÖRAN PETERSSON
Independent Board Member

Born in 1945. M.Pharm.Sc., MBA. Board member since 2009.

40 years' experience from leading positions in Sweden and abroad in KabiVitrum, Pharmacia, Pharmacia&UpJohn and Meda.

Other assignments: Chairman in Medivir AB, OxyPharma AB, Axelar AB and Vivoxid Oy. Member of the boards of Recipharm AB, and Pfizer Pensionsstiftelse 1.

Holdings in Diamyd Medical as of August 31, 2011: 0.

KEY EXECUTIVES



PETER ZERHOUNI
President and CEO

Born in 1972. M.Sc. in Biology and a B.Sc. in Economics & Business Administration from Lund University and UC Berkeley. From 1999 to 2006 Peter Zerhouni held various positions at ING Bank in Brussels and Amsterdam. Peter Zerhouni joined Diamyd Medical in 2006.

Other assignments: None.

Holdings in Diamyd Medical as of August 31, 2011: 1,297 B shares, 5,500 employee options 2008/2011 and 25,000 employee options 2009/2012.



KERSTIN ANNAS
Senior Director of Quality

Born in 1970. M.Sc. in Chemistry from Stockholm University. Previous experience includes Qualified Person of manufacturing and wholesale at SBL Vaccin/Crucell Sweden and quality assurance at FreseniusKabi. Kerstin Annas joined Diamyd Medical in 2010.

Other assignments: None.

Holdings in Diamyd Medical as of August 31, 2011: 11,000 employee options 2009/2012.



ERIKA HILLBORG
Senior Director of Clinical Development

Born in 1967. M.Sc. in Biomedicine from the Karolinska Institute in Stockholm, with a Science Journalism degree from Uppsala University. Erika Hillborg joined Diamyd Medical in 2006.

Other assignments: None.

Holdings in Diamyd Medical as of August 31, 2011: 18,000 B shares, 5,500 employee options 2008/2011 and 25,000 employee options 2009/2012.



ANNA STYRUD
Chief Financial Officer

Born in 1961. B.Sc. in Business Administration from Uppsala University. Previous experience includes Group Treasurer of Vasakronan and various positions within finance, treasury and control at Flåkt AB and National Board of Public Building. Anna Styrud joined Diamyd Medical in 2010.

Other assignments: None.

Holdings in Diamyd Medical as of August 31, 2011: 1,500 B shares and 25,000 employee options 2009/2012.



JAMES WECHUCK

**Senior Director Manufacturing Development,
Diamyd Inc., USA**

James Wechuck, Born in 1973. Ph.D. in Chemical Engineering, University of Pittsburgh. James Wechuck was previously Director of Manufacturing, Human Gene Therapy Applications Laboratory and Research Assistant Professor in Bioengineering at the University of Pittsburgh. James Wechuck joined Diamyd Medical in 2006.

Other assignments: None.

Holdings in Diamyd Medical as of August 31, 2011: 57,036 B shares, 2,750 employee options 2008/2011 and 17,500 employee options 2009/2012.



DARREN WOLFE

CEO, Diamyd Inc., USA

Born in 1968. Ph.D. in Molecular Biology and Biochemistry, Pennsylvania State University. Darren Wolfe was previously a Research Assistant Professor in the Department of Molecular Genetics and Biochemistry at the University of Pittsburgh. Darren Wolfe joined Diamyd Medical in 2006.

Other assignments: None.

Holdings in Diamyd Medical as of August 31, 2011: 57,520 B shares, 16,500 employee options 2008/2011 and 25,000 employee options 2009/2012.

AUDITORS

Diamyd Medical's auditors are Öhrlings PricewaterhouseCoopers AB, domiciled at 113 97 Stockholm. Eva Blom is the principal auditor. Eva Blom has been an authorized public accountant since 1986. Eva Blom is a member of FAR, and has been Diamyd Medical's principal auditor since February, 2010. The auditing firm was chosen in 2007 for a four year period.

ORGANIZATION, EMPLOYEES AND SUSTAINABLE DEVELOPMENT

Diamyd Medical is driven by the strong desire to find effective and safe treatments for pain, neuropathy, and diabetes. Achieving success in research and development, clinical trials and business transactions demands a highly qualified and efficient organization. Diamyd Medical's organization is small and has always been characterized by efficiency. The decision paths are short and the internal communication open and direct.

Diamyd Medical has undergone reorganization because the results from the Company's European Phase III study with the diabetes therapy Diamyd® did not meet expectations, thus the company had to focus on cost control. The number of employees has been reduced significantly in the activities focused on the Company's clinical research in diabetes.

ORGANIZATION AND EMPLOYEES

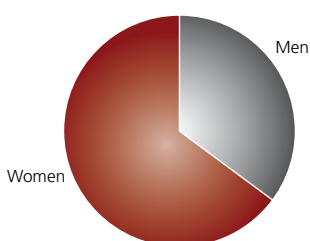
The Diamyd Medical Group consists of the Parent Company Diamyd Medical AB (publ) and the wholly-owned subsidiaries, Diamyd Diagnostics AB, Diamyd Therapeutics AB and Diamyd, Inc., in Pittsburgh, USA. The head office is in Stockholm, Sweden.

Diamyd Medical is managed using an outsourcing model where parts of the operations have been outsourced to qualified partners with expert knowledge, and a limited number of employees manage, lead and implement projects in areas such as clinical and preclinical development, regulatory affairs, production and business development. This enables Diamyd Medical to pursue external research from

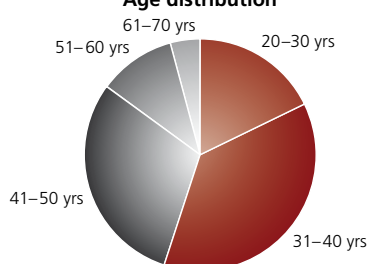
the point of early discovery, conduct pre-clinical and clinical trials, and manage regulatory processes for the company's drug candidates, and run out-licensing processes. The model also contributes to a high degree of flexibility, where resources can be quickly reallocated among different projects as needed.

As of August 31, 2011 the Group had 28 employees, whereof 10 men and 18 women. The level of qualifications among employees is high, with a large percentage having academic degrees, including several Ph.D.s. Diamyd Medical has access to expertise in its areas of research via a scientific and medical advisory board composed of leading scientists from the US, the Netherlands, England and Sweden.

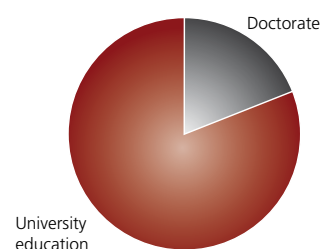
Gender balance



Age distribution



Level of education



HEALTH AND WORK ENVIRONMENT

Diamyd Medical shall provide a safe and healthy work environment. Diamyd Medical observes established policies concerning issues such as ethics and the environment, work environment, quality and equality. Diamyd Medical shall offer equal opportunity to all employees and applicants, regardless of gender, nationality, religion, age, disability or sexual orientation.

Diamyd Medical's outlook is that a good work environment aids workplace morale, reduces sick leave and supports the efforts of its employees. Workloads must be customized to the individual and make a healthy balance between work and leisure possible. To avoid work related strain injuries all employees are offered ergonomic working tools. Health awareness is encouraged through fitness subsidies and free fruit at the workplace.

RESPONSIBILITY, ENVIRONMENT AND QUALITY CONTROL

Diamyd Medical's primary focus is the development of pharmaceuticals for pain, neuropathy and diabetes, serious conditions in great need of new treatment regimens. Diamyd Medical's responsibility toward society and the patient is part of its business as a research pharmaceutical company, and influences its work in developing new pharmaceutical products and performing clinical trials. Diamyd Medical's work has a great impact on people's lives and health, so it is of the utmost importance for Diamyd Medical to not only follow applicable laws and regulations, but also to act in a manner that is responsible and ethically proper.

Pre-clinical and clinical studies of Diamyd Medical's candidate drugs are conducted in cooperation with partners, such as contract research organizations or research groups associated with universities.

The studies should always be designed in consultation between Diamyd Medical and its partners, and approved by Diamyd Medical. Diamyd Medical's clinical trials are conducted in accordance with Good Clinical Practice (GCP), and they are managed in cooperation with well-established contract research organizations. The performance of trials are regulated according to special process descriptions, i.e. Standard Operating Procedures, as well as quality agreements, in order to ensure that Diamyd Medical's trials are always conducted according to applicable practice and that laws and regulations are followed.

Diamyd Medical will work for a long-term environmental and social sustainability, both in daily operations and in collaboration with business partners, researchers and consultants. The Company's sustainability efforts will, by virtue of knowledge and experience, continually evolve. Every employee should feel a personal responsibility to help the Company meet the targets set.

Diamyd Medical does not do any manufacturing itself, and its direct environmental impact is considered to be low. However like most other companies, its business causes a certain degree of impact on the environment, primarily through emissions for travel and shipments as well as energy consumption for its offices. In addition some environmental impact may occur in connection with the manufacture of Diamyd Medical's products by external manufacturers, as well as from outsourced research activities. To ensure that Diamyd Medical always strives for long-term environmental efforts with the smallest possible environmental impact, both in its operational activities and in cooperation with manufacturers, researchers and other partners, Diamyd Medical pursues its work according to an established environmental policy including energy consumption, waste management, recycling, purchasing, manufacturing and transportation.

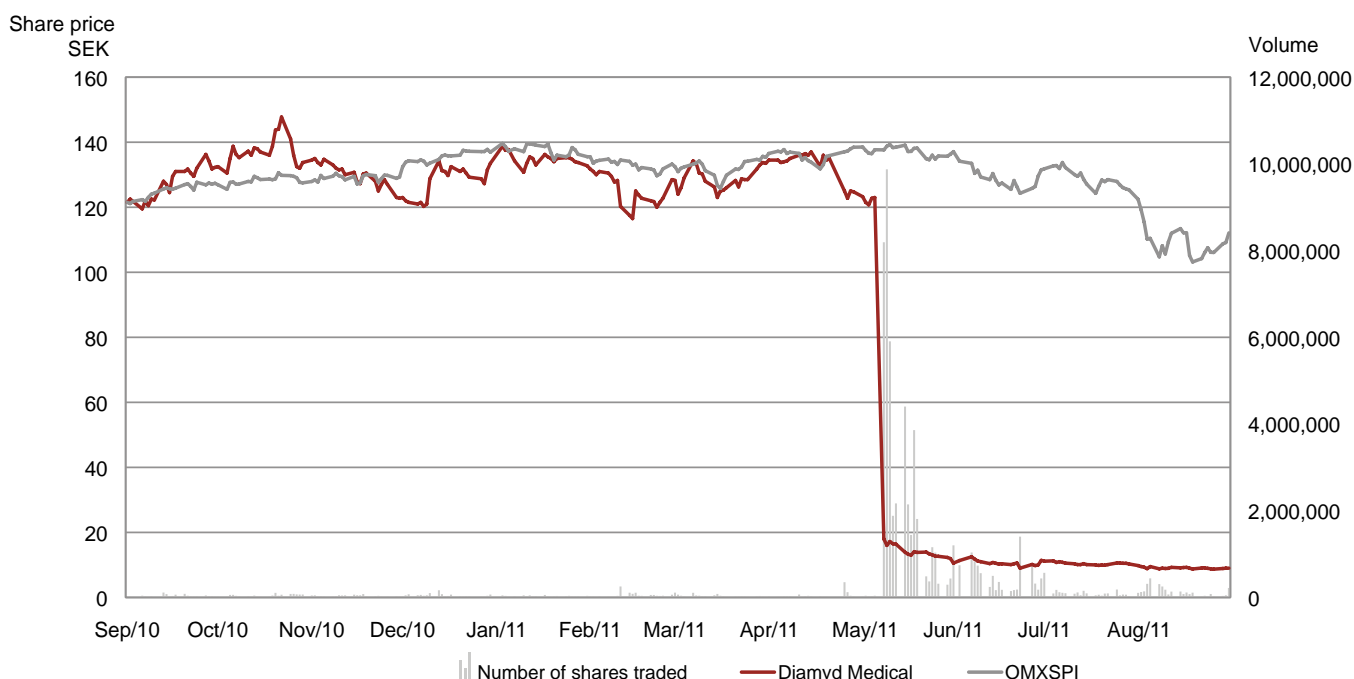
DIAMYD MEDICAL ON THE STOCK EXCHANGE

The stock and share capital

On August 31, 2011, the share capital of Diamyd Medical amounted to 29,579,133 divided among 28,141,257 Series B shares (1/10 vote) and 1,437,876 Series A shares (one vote). The share is denominated in Swedish kronor (SEK), with each Series A and B share having a nominal value of SEK 0.50. Series B shares are listed on the NASDAQ OMX Stockholm Mid Cap list (ticker symbol DIAM B) and are traded through American Depository Receipts (ADRs) on the American OTCQX list via Bank of New York Mellon (PAL) (ticker symbol DMYDY). Diamyd Medical's share price at the end of the fiscal year, August 31, 2011, was SEK 9.0 (119.5), which gives a market

valuation of MSEK 253 (3,301). During the fiscal year 2010/2011, the share price changed by -92.6 % (174.7 %) versus the OMX Stockholm PI (OMXSPI) which changed by -7.7 % (13.5 %) over the same period. The highest share price paid during the period was SEK 147.8 (164.5) and the lowest share price paid was SEK 8.3 (42.5). The average share price during the fiscal year 2010/2011 was SEK 91.8 (103.5). During the year, the total trading volume amounted to 68,786,681 (19,782,108) shares with an accumulated value of MSEK 1,852 (2,758). The following chart shows the share price trend and volumes traded for Diamyd Medical's Series B-share during the period September 1, 2010 through August 31, 2011 versus the OMXSPI.

Share price trend and volumes traded for Diamyd Medical's Series B share during the period September 1, 2010 through August 31, 2011



Share capital development

Year	Transaction	Terms	Share capital (increase, SEK)	Series A shares (increase, number)	Series B shares (increase, number)	Share capital (accumulated, SEK)
1996	Company founded*	–	126,288	150,000	102,575	126,288
1996	Stock dividend**	–	638,787	–	512,500	765,075
96/97	Rights issue	–	771,335	785	770,550	1,536,410
97/98	Rights issue	–	1,536,410	150,785	1,385,625	3,072,820
99/00	Rights issue	–	768,205	75,390	692,815	3,841,025
01/02	Rights issue	1:1, 40 kr	762,214	94,240	667,974	4,603,239
02/03	Exercise of warrants	1:1, 22.10 kr	12,232	–	12,232	4,615,471
02/03	Exercise of warrants	1:1, 21.79 kr	13,106	–	13,106	4,628,577
02/03	Exercise of warrants	1:1, 56.00 kr	7,801	–	7,801	4,636,378
02/03	Rights issue	2:1, 40 kr	2,318,189	–	2,318,189	6,954,567
03/04	Private placement	40.00 kr	1,390,913	–	1,390,913	8,345,480
04/05	Exercise of warrants	1:1 18.36 kr	72,563	–	72,563	8,418,043
05/06	Non-cash issue, Nurel Therapeutics	55.00 kr	317,173	–	317,173	8,735,216
06/07	Warrants	–	912,262	90,471	821,791	9,647,478
06/07	Exercise of warrants	1:1 50.00 kr	30,000	–	30,000	9,677,478
06/07	Exercise of warrants	1:1 50.00 kr	25,000	–	25,000	9,702,478
06/07	Private placement	145.75 kr	70,000	–	70,000	9,772,478
07/08	Exercise of warrants	1:1 50.00 kr	15,000	–	15,000	9,787,478
07/08	Exercise of warrants	1:1 50.00 kr	45,000	–	45,000	9,832,478
07/08	Exercise of warrants	1:1 50.00 kr	10,000	–	10,000	9,842,478
07/08	Exercise of warrants	1:1 50.00 kr	2,500	–	2,500	9,844,978
07/08	Exercise of warrants	1:1 50.00 kr	15,000	–	15,000	9,859,978
07/08	Exercise of warrants	1:1 50.00 kr	5,000	–	5,000	9,864,978
07/08	Exercise of warrants	1:1 50.00 kr	2,500	–	2,500	9,867,478
07/08	Exercise of warrants	1:1 50.00 kr	13,092	–	13,092	9,880,570
07/08	Exercise of warrants	1:1 50.00 kr	10,000	–	10,000	9,890,570
07/08	Exercise of warrants	1:1 50.00 kr	10,000	–	10,000	9,900,570
07/08	Exercise of warrants	1:1 50.00 kr	10,000	–	10,000	9,910,570
07/08	Private placement	73.00 kr	991,000	–	991,000	10,901,570
08/09	Exercise of warrants	1:1 100.00 kr	280,902	–	280,902	11,182,472
09/10	Exercise of warrants	70.00 kr	3,131,091	157,267	2,973,824	14,313,563
09/10	Exercise of warrants	1:1.13 71.80 kr, 54.90 kr, 58.50 kr	16,931	–	16,931	14,330,494
09/10	Split***	1:2	–	718,938	13,611,556	28,660,988
09/10	Exercise of warrants	1:2.26 54.90 kr, 58.50 kr	23,725	–	47,450	28,708,438
09/10	Private placement	1:120	145,834	–	291,668	29,000,106
09/10	Exercise of warrants	1:2.26 35.90 kr	7,533	–	15,066	29,015,172
09/10	Exercise of warrants	1:2,26 35.90 kr, 27,45 kr	15,021	–	30,042	29,045,214
09/10	Exercise of warrants	1:2.26 35.90 kr	7,531.50	–	15,063	29,060,277
10/11	Exercise of warrants	1:2.26 35.90 kr, 29.25 kr	53,767	–	107,533	29,167,810
10/11	Exercise of warrants	1:2.26 35.90 kr, 29.25 kr	41,401	–	82,802	29,250,612
10/11	Exercise of warrants	1:2.26 35.90 kr, 29.25 kr	19,382	–	38,764	29,289,376
10/11	Exercise of warrants	1:2.26 35.90 kr, 29.25 kr	91,430	–	182,859	29,472,235
10/11	Exercise of warrants	1:2.26 29.25 kr	28,589	–	57,178	29,529,413
10/11	Exercise of warrants	1:2.26 29.25 kr	24,860	–	49,720	29,579,133
TOTAL			14,789,567	1,437,876	28,141,257	29,579,133

* Nominal value of the share, SEK 0.50 ** Nominal value of the share, SEK 1 *** Nominal value of the share after split, SEK 0.50

GROUP STRUCTURE AND OWNERSHIP

On August 31, 2011 the number of shareholders was 8,554 (6,829). The ten largest shareholders held Diamyd Medical shares corresponding to 48 % (65 %) of the capital and 64 % (76 %) of the votes. Series B and A shares are freely transferable. According to a shareholders' agreement between the main holders Bertil Lindkvist and Anders

Essen-Möller, the sole Series A shareholder, Anders Essen-Möller, may not transfer shares of Series A to a third party (inheritance transfer excepted) unless the third party buyer concurrently commits to offer to purchase all Series B shares on the same terms and conditions.

SUMMARY TEN LARGEST SHAREHOLDERS AS OF AUGUST 31, 2011

Name	Number of Series A shares	Number of Series B shares	Share of capital, %	Share of voting power, %
Bertil Lindkvist	–	4,070,279	13.76	9.57
Avanza Pension	–	3,294,840	11.14	7.75
Anders Essen-Möller	1,437,876	392,225	6.19	34.74
Östersjöstiftelsen	–	1,504,828	5.09	3.54
Nordnet Pensionsförsäkring AB	–	1,177,412	3.98	2.77
Ålandsbanken AB, W8IMY	–	634,122	2.14	1.49
SIX SIS AG, W8IMY	–	443,715	1.50	1.04
Robur Försäkring AB	–	434,757	1.47	1.02
Healthinvest Value Fund	–	391,524	1.32	0.92
Försäkrings AB Skandia	–	317,673	1.07	0.75
	1,437,876	12,661,375	47.67	63.59

SHAREHOLDING STRUCTURE DIVIDED BY SIZE OF HOLDINGS AS OF AUGUST 31, 2011

Number of shares	Number of shareholders	Number of Series A shares	Number of Series B shares	Holdings, %	Votes, %	Market value, KSEK
1–500	4,966	–	872,108	2.95	2.05	7,849
501–1,000	1,470	–	1,198,007	4.05	2.82	10,782
1,001–5,000	1,625	–	3,865,560	13.07	9.09	34,790
5,001–10,000	244	–	1,835,725	6.21	4.32	16,522
10,001–15,000	72	–	917,532	3.10	2.16	8,258
15,001–20,000	44	–	782,359	2.64	1.84	7,041
20,001–	133	1,437,876	18,669,975	67.98	77.73	168,030
Total	8,554	1,437,876	28,141,257	100.00	100.00	253,271

DIVIDENDS AND DIVIDEND POLICY

Diamyd Medical has not paid a dividend to date. In consideration of Diamyd Medical's financial position, the Board does not intend to propose dividend payments in the year ahead. The Company's financial assets will primarily be used to finance research projects. There is no established date for a dividend. If a shareholder can't be

reached, the shareholder's claim remains with Diamyd Medical (or a custodian where appropriate) and is only limited by regulations on limitations applicable at any given time. There are no restrictions concerning the right to dividends for persons residing abroad.

KEY RATIOS AND DEFINITIONS

Group	12 months Sep-Aug 2010/2011	12 months Sep-Aug 2009/2010
Earnings per share before dilution, SEK	3.5	-0.01
Earnings per share after dilution, SEK	3.5	-0.01
Shareholders' equity per share before dilution, SEK	15.7	10.8
Shareholders' equity per share after dilution, SEK	15.6	10.8
Cash flow per share, SEK	-11.4	16.8
Dividend	–	–
Share price, SEK	9.0	119.5
Closing share price/shareholders' equity per share, SEK	0.6	10.5
P/E ratio, times	2.6	Neg
Return on equity, %	26.4	-0.2
Equity ratio, %	89	55
Average number of employees	29	19
Research and development costs, MSEK	96.0	80.8
Investment in fixed assets	–	–
Number of shares	29,579,133	29,060,277
Average number of shares before dilution	29,449,348	27,595,347
Average number of shares after dilution	29,477,301	27,595,347

KEY RATIO DEFINITIONS

Average number of shares before dilution

The weighted number of shares during the year, taking into account new share issues during the period.

Average number of shares after dilution

The weighted number of shares during the year, taking into account the dilution effect on outstanding warrants.

Cash flow per share

The cash flow divided by the average number of shares.

Closing share price/shareholders' equity per share

The closing share price divided by the shareholders' equity per share.

Earnings per share after dilution

The net result divided by the diluted number of shares. If the Company does not make a profit, the average number of shares is nevertheless used in the calculations, because improving the earnings per share is not allowed according to the IFRS.

Earnings per share before dilution

The net result divided by the average number of shares.

Equity ratio

The shareholder's equity divided by the balance sheet total, expressed as a percentage.

P/E ratio

The closing share price divided by the earnings per share.

Return on equity

The net result divided by the average number of shares.

Share price

The final closing price on the closing date August 31, 2011 versus 2010.

Shareholders' equity per share after dilution

The shareholder's equity divided by the number of shares, diluted. If there are no dilution effects, meaning that if the shareholders' equity per share after dilution shows higher earnings than before dilution, the key ratio corresponds to shareholders' equity per share before dilution.

Shareholders' equity per share before dilution

The shareholder's equity divided by the number of shares at year-end.

ANNUAL GENERAL MEETING OF SHAREHOLDERS

The Annual General Meeting of Shareholders (AGM) of Diamyd Medical AB will be held on December 7, 2011 at 3:00 p.m., with registration beginning at 2:00 p.m.

Location: Stora Hörsalen, Garnisonen, Karlavägen 100 i Stockholm.

Shareholders who wish to attend must be recorded in the Company's register of shareholders, held by Euroclear Sweden AB by December 1, 2011, and must notify the Company of their intention to attend not later than December 2, 2011 at 4:00 p.m. Shareholders who wish to participate in the AGM and whose shares are registered in custodial accounts must re-register the shares temporarily in the shareholder's own name with Euroclear Sweden AB. This re-registration should be requested well before December 1, 2010 with the bank or stockbroker that holds the shares in custody. The shareholder's rights at the AGM may be exercised by a representative. If a legal entity is represented by a representative, the power of attorney should be signed by the person authorized to sign for the entity and a copy of the current certificate of incorporation must be enclosed to validate the signatory power.

Registration to attend can be made:

On the website www.diamyd.com

By post to Diamyd Medical AB, Karlavägen 108,
SE-115 26 Stockholm, Sweden.

By e-mail: investor.relations@diamyd.com

When registering shareholders should state:

Their name or the name of their representative.

Personal identity number (corporate registration number).

Address and phone number.

Number of shares.

SOURCES CITED

- 1) The Pain Management Market Outlook to 2014, Business Insights 2009
- 2) Hughes, R.A. *BMJ* 2002;324:466-469
- 3) Van den Beuken-van Everdingen et al. *Ann Oncol* 2007;18:1437-1449
- 4) Cancer pain, WWMR, Inc. 2009
- 5) Peripheral Neuropathy and Neuropathic Pain 2008, BioPharm Reports (VennBio Ltd.) 2009
- 6) Based on own clinical studies and for example the following scientific papers; Turner et al. *Lancet* 1997;350:1288-1293, Tuomi et al. *Diabetes* 1999;48:150-157, Pietropaolo et al. *Diabetes* 2000;49:32-38
- 7) International Diabetes Federation, Web 14 November 2011; <http://www.idf.org>
- 8) American Diabetes Association, Web 14 November 2011; <http://www.diabetes.org>
- 9) Based on data from for example Diabetes Atlas, 1st Edition; International Diabetes Federation 2000, US Centre for Disease Control (CDC), Web 3 November 2009; <http://www.cdc.gov/diabetes/projects/cda2.htm>, Patterson et al. *Lancet* 2009;373:2027-2033
- 10) Patterson et al. *Lancet* 2009;373:2027-2033
- 11) Palmer et al. *Diabetes* 2004;53:250-264



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