



## Year End Report, Stockholm, October 22, 2010

### September 1, 2009 – August 31, 2010

**Fourth quarter report for Diamyd Medical AB (publ.), fiscal year 2009/2010**  
**(www.omxgroup.com ticker: DIAM B; www.otcqx.com ticker: DMYDY)**

#### Full year, September 1, 2009 – August 31, 2010

- Group net sales for the year was MSEK 113.0 (1.1)
- Loss before tax for the year was MSEK -0.3 (-81.8)
- Earnings per share after dilution for the year were SEK 0.0 (-3.7)
- The Group's liquid assets amounted to MSEK 501.3 (37.3) as of August 31, 2010

#### Fourth quarter, June 1, 2010 – August 31, 2010

- Group net sales for the fourth quarter was MSEK 110.2 (0.0)
- Profit before tax for the fourth quarter was MSEK 75.0 (-29.8)
- Earnings per share after dilution for the fourth quarter were SEK 2.6 (-1.3)

#### Significant events during the reporting period June 1, 2010 – August 31, 2010

- Diamyd signed an agreement with Ortho-McNeil-Janssen Pharmaceuticals, Inc., a Johnson & Johnson company, to develop and commercialize the Diamyd<sup>®</sup> diabetes therapy.
- Diamyd's agreement with Ortho-McNeil-Janssen Pharmaceuticals, Inc. received antitrust clearance.
- Diamyd received an upfront payment of USD 45 million.

#### Significant events after the reporting period

- Diamyd reported promising safety findings from Phase I study in chronic pain.
- Diamyd Trial in Chronic Pain showed Pain Relief

## CEO COMMENTS

### **A great conclusion and an exciting beginning**

The year just ended is the most important in Diamyd's history. Near the end of June we were able to announce that after almost a year of demanding negotiations with several big pharmaceutical companies, we signed an agreement with the American pharmaceutical company Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI) for the global commercial rights to the candidate drug Diamyd<sup>®</sup>. With its global resources and ambitions in the diabetes area, OMJPI is an ideal partner for a future market launch. The partnership is off to a flying start, and our people are working closely with their counterparts at OMJPI. As part of the agreement, Diamyd received an upfront payment of USD 45 million during the summer, which we periodize until the 15-month-long study period in the European trial is finished.

Our NTDDS technology, which can deliver drugs focally directly to the peripheral nervous system, is the heart of the Company's development efforts for the treatment of chronic pain. There have been no serious side effects related to the product in the Phase I study of NP2 Enkephalin in terminal cancer patients, which is important since the trial serves as a safety study for the entire NTDDS platform. The trial is not primarily designed to study efficacy, but substantial and sustained reduction in pain scores were reported by treated patients. Moreover, we have determined a suitable dosage for future studies.

In order to highlight our pain portfolio, we have decided to divide our operations into two business areas beginning with the new 2010/2011 fiscal year; Diabetes and Pain. We see a great medical need and an opportunity to quickly demonstrate the value of our pain portfolio by continuing our cancer pain program with NP2 Enkephalin. Diamyd currently has two more candidate drugs in business area Pain in addition to NP2 Enkephalin: NG2 GAD and NE2 Endomorphin, which are both promising for the treatment of different types of pain, including diabetes pain.

Diamyd has grown as our business has evolved, and with the Diamyd<sup>®</sup> partnership agreement in place and a healthy cash balance, we find ourselves standing on the threshold of a new era. We will expand our operations in the next year. We will be focusing strongly on in-licensing new candidate drugs and on continuing to develop our pain portfolio. Based on the positive Phase I observations of NP2 Enkephalin we plan to initiate a Phase II study in cancer patients with chronic pain.

I feel great confidence as I look forward to the coming year and what we are all waiting for – the first Phase III results for Diamyd<sup>®</sup>.

Stockholm, October 22, 2010

Elisabeth Lindner

President and CEO, Diamyd Medical AB

## SIGNIFICANT EVENTS DURING THE REPORTING PERIOD

JUNE 1, 2010 – AUGUST 31, 2010

**Diamyd signed an agreement with Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI), to develop and commercialize the Diamyd<sup>®</sup> diabetes vaccine.** Diamyd is receiving an upfront payment of USD 45 million, and according to the agreement Diamyd has the potential to receive additional development and sales milestone payments of up to USD 580 million, as well as tiered royalties on future sales. The parties will equally share costs for the development program until results from the ongoing EU Phase III study, expected in the first half of 2011. OMJPI has the right to fully assume responsibility for the development program upon reviewing the results. Following its strategy, Diamyd has secured exclusive rights for commercialization in the Nordic countries. Diamyd also retains the rights to therapeutic use of the GAD65 gene and to derivatives, fragments and variants of the GAD65 protein.

**Diamyd's agreement with Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI) received antitrust clearance.** The US Federal Trade Commission's clearance under the Hart-Scott-Rodino Anti-Trust Improvements Act is regarding the agreement between Diamyd and OMJPI for development and world-wide commercialization of the GAD65 antigen-based therapy Diamyd<sup>®</sup> for the treatment and prevention of type 1 diabetes and associated conditions.

**Diamyd received an upfront payment of USD 45 million.** The upfront payment relates to the closing of the agreement between Diamyd and OMJPI for development and commercialization of the GAD65 antigen-based therapy Diamyd<sup>®</sup> for the treatment and prevention of type 1 diabetes and associated conditions.

## SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

**Diamyd reported promising safety findings from Phase I study in chronic pain.** No drug related Serious Adverse Events have been reported by any patient included in Diamyd's Phase I clinical trial investigating NP2 as a potential therapy for chronic pain. Based upon the Phase I findings to date, the company is planning a multi-center, randomized, double-blind, placebo controlled Phase II clinical trial with NP2 in the United States.

**Diamyd Trial in Chronic Pain showed Pain Relief** Substantial and sustained reduction in pain scores were reported in the middle and high dose cohorts of Diamyd Medical's Phase I trial investigating NP2 Enkephalin as a potential therapy for chronic pain. The Phase I study is intended to test the safety of NP2 Enkephalin and the NTDDS platform. In addition to safety, measurements of pain relief and concomitant pain medications were collected. The clinical trial was designed as an open label, dose escalation study in patients with intractable pain due to cancer. Three dose levels were investigated and eight patients were evaluable at the four week time point.

## BUSINESS OVERVIEW

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

### **Business Model**

Diamyd Medical is managed using an outsourcing model, where some of its operations have been outsourced to qualified partners with expert qualifications. A small group of knowledgeable permanent employees manage, lead and implement projects in areas such as clinical and preclinical development, regulatory issues and production. Diamyd Medical does not perform any basic research internally. This model leads to lower operating expenses by sourcing qualified services as well as development projects externally, and enables the Company to develop in a flexible manner with an emphasis on results and quality.

### **Strategy and objectives**

Diamyd's business concept is to license candidate products in the preclinical and clinical phases, and to improve them through development. The products are to be subsequently commercialized, either independently or with a partner, or out-licensed. The Company's objective is to build a small pharmaceutical company with its own development operations and a sales and marketing organization in the Nordic countries: a Nordic small pharma company.

The objective of the Company's development activities within autoimmune diabetes is, in a first step, to preserve the blood sugar regulating capacity in patients recently diagnosed with type 1 diabetes with the candidate drug Diamyd®. The next step would be to prevent type 1 diabetes from manifesting by preventative treatment of individuals at high risk of developing the disease. The long term vision is to be able to cure the autoimmune form of diabetes.

Today our top priorities are the completion of the global Phase III program using the Diamyd candidate drug currently in progress; preparations to apply for market approval; and the startup of the planned Phase II study of the drug candidate NP2 Enkephalin for the treatment of chronic pain.

### **Partnerships and acquisitions**

Partnerships with other pharmaceutical companies are part of the Company's strategy, both to find a market for the Company's projects and to identify new development projects. In 2010 Diamyd Medical signed an agreement with Ortho-McNeil-Janssen Pharmaceuticals, Inc., to develop and commercialize the GAD65 antigen-based candidate therapy Diamyd for the treatment and prevention of autoimmune diabetes. The rights to the application of the GAD65 gene in the treatment of Parkinson's disease have previously been licensed out on a non-exclusive basis to the American company Neurologix, Inc. Early- and late-stage development

projects, as well as companies with promising products under development, are continually being evaluated for in-licensing or acquisition.

## BUSINESS AREAS

As of the 2010/2011 fiscal year, Diamyd Medical's business is divided into two business areas, Diabetes and Pain. The Diabetes business area consists of the antigen-based candidate drug Diamyd<sup>®</sup> for the treatment and prevention of autoimmune diabetes. The Pain business area consists of development projects that use the Company's proprietary NTDDS (Nerve Targeting Drug Delivery System) platform to administer drugs directly to the nervous system to treat pain.

		Candidate drug	Indication	Development Phase
Business Area	Diabetes	Diamyd <sup>®</sup>	Type 1 diabetes	Phase III
		Diamyd <sup>®</sup>	LADA	Phase II
		Diamyd <sup>®</sup>	Prevention	Phase II
	Pain	NP2 Enkephalin	Chronic pain	Phase I
		NG2 GAD	Neuropathic pain	Preclinical
		NE2 Endomorphin	Neuropathic pain	Preclinical

### The Diabetes business area

The Company's research in the area of diabetes originates from the GAD65 molecule and is the basis for the candidate drug Diamyd<sup>®</sup> for the treatment and prevention of autoimmune diabetes. Diamyd<sup>®</sup> is the project that has reached the most advanced stage of development, with Phase III trials in progress in Europe and the US. In 2010 the Company signed an agreement with Ortho-McNeil-Janssen Pharmaceuticals, Inc., to develop and commercialize Diamyd<sup>®</sup>.

The autoimmune forms of diabetes, type 1 diabetes and LADA (Latent Autoimmune Diabetes in Adults), are caused by the immune system's attack on the body's own beta cells in the pancreas, which control blood sugar. The beta cells are gradually destroyed during a period that is believed to vary from months to several years. Children and adolescents with type 1 diabetes usually come into contact with the healthcare system only when their condition has become acute, when only 10-20 percent of beta cell function remains. This is not sufficient for continued control of blood sugar levels. At this stage, patients must quickly receive insulin injections to survive. After diagnosis, the autoimmune attack on the remaining beta cells continues and the beta cell function ceases entirely, leaving the body with no ability to control blood sugar at all. The entire insulin requirement must be provided by externally introduced insulin. Diabetes is a chronic disease, often resulting in serious complications and secondary diseases with tremendous personal suffering and enormous costs to society for care, medication and absence from work.

Treatment with Diamyd<sup>®</sup> is intended to prevent, delay or halt the autoimmune attack on beta cells in the case of type 1 diabetes and other forms of autoimmune diabetes, preserving the body's own ability to control blood sugar levels; this has been demonstrated to significantly reduce the risk of both acute and long-term diabetes complications. This type of treatment is significant, since there is currently no treatment on the market for the autoimmune process that causes type 1 diabetes and LADA. The active substance in Diamyd<sup>®</sup> is GAD65 (the 65 kDa isoform of glutamic acid decarboxylase), a human enzyme and an important autoantigen in autoimmune diabetes. Treatment with Diamyd<sup>®</sup> is thought to induce tolerance for GAD65 which is believed to be the driver of the disease, thus intervening in the autoimmune attack and preserving the ability to control blood sugar in autoimmune diabetes patients. The Diamyd<sup>®</sup> adverse effect profile, which has been encouraging so far, is of great importance since a large proportion of type 1 diabetes patients are children and adolescents.

It is estimated that around 80,000 people develop type 1 diabetes in Europe and the US every year, and the Company estimates the potential market for the treatment of recent-onset type 1 diabetes to exceed USD 1 billion annually. If Diamyd<sup>®</sup> can also be used as a preventive measure to prevent type 1 diabetes and to treat LADA patients, the potential market is estimated to be considerably larger.

Diamyd<sup>®</sup> is currently being developed for three primary therapeutic indications: recent-onset type 1 diabetes (Phase III), LADA (Phase II) and the prevention of type 1 diabetes (Phase II).

#### *Diamyd<sup>®</sup> - Type 1 diabetes*

Type 1 diabetes, also called childhood or juvenile diabetes, is an autoimmune form of diabetes that usually occurs in children and adolescents.

Two parallel Phase III studies of Diamyd are being conducted in nine European countries and the US, with the aim of confirming whether treatment with Diamyd<sup>®</sup> can stop or slow down the autoimmune destruction of the beta cell function, thus preserving the body's own ability to control blood sugar in people with recent-onset type 1 diabetes. Both studies are randomized, double-blind and placebo controlled. Approximately 320 young type 1 diabetes patients who were diagnosed less than three months ago are included in each study. Each study includes three treatment arms in which one third of the patients are given two subcutaneous injections of Diamyd<sup>®</sup> 20 µg; one third receive four subcutaneous injections of Diamyd<sup>®</sup> 20 µg; and one third receive a placebo. The treatment does not require a hospital stay. The results from each study will be analyzed 15 months after all patients have received their first injection.

The European Phase III study is fully recruited, and included its last patient in November 2009. The American DiaPrevent study is recruiting patients. The 15 month study time means that the last patient in the European study will have their 15-month appointment in February 2011, after which the study data can be collected and analyzed. We expect to be able to begin reporting clinical results in the spring of 2011. If the results are positive, the Company plans to apply to the relevant regulatory agencies for market approval in 2011.

The Company has reported positive results from a similar 30-month randomized double-blind placebo controlled Phase II study of 70 children and adolescents with type 1 diabetes. The study demonstrated significant long-term efficacy in preserving beta cell function, in this case the body's own capacity to produce insulin, in comparison with a placebo. No serious side effects related to the Diamyd<sup>®</sup> treatment were reported in the study. The study was published in the fall of 2008 in the prestigious journal *The New England Journal of Medicine*. The study has

now been extended in order to follow the participants for three more years to confirm the long-term efficacy of the treatment. Analysis of the data shows that those patients who had received Diamyd<sup>®</sup>, and who had recently developed the disease when the study began, still have better diabetes status than corresponding patients who received a placebo, even four years after treatment.

#### *Diamyd<sup>®</sup> - LADA*

LADA (Latent Autoimmune Diabetes in Adults), also known as type 1.5 diabetes, is also an autoimmune form of diabetes like type 1, but it strikes in adulthood. The disease is similar to type 1 diabetes in many respects, and gradually leads to an absolute need for insulin treatment. However the progress of the disease is slower than in type 1 diabetes. Because the disorder primarily affects adults and does not require insulin treatment immediately, LADA patients are often diagnosed with type 2 diabetes. The Company estimates that around ten percent of all patients diagnosed with type 2 diabetes actually have LADA.

Diamyd<sup>®</sup> for the treatment of LADA has reached Phase II in clinical trials. In April 2009 the respected scientific journal *Diabetologia* published the clinical results from the Company's Phase II study, which showed that treatment with Diamyd<sup>®</sup> significantly reduces the risk that LADA patients will need insulin treatment, even after five years, when compared to treatment with a placebo. Only 14 percent of the patients in the group that received 20 µg of Diamyd<sup>®</sup> needed insulin after five years, vs. 64 percent in the placebo group. No serious side effects related to the Diamyd<sup>®</sup> treatment were reported in the study.

#### *Diamyd<sup>®</sup> - Prevention*

In type 1 diabetes, the autoimmune attack and destruction of the beta cells in the pancreas that control blood sugar begin long before symptoms appear. If it were possible to stop the autoimmune attack early, before the destruction of the beta cell function has gotten far enough for symptoms to appear, it could be possible to prevent the disease from manifesting altogether. Previous studies of Diamyd<sup>®</sup> have demonstrated that the treatment is most efficacious early in the progress of the disease in newly-diagnosed type 1 diabetes patients. If these results can be confirmed in larger studies, the next logical step is further testing of the therapy on persons with a high risk of developing diabetes, i.e. prevention studies, in order to stop the disease before it manifests.

A small Swedish prevention study of Diamyd<sup>®</sup> has been in progress since 2009. The study includes 50 children aged four and above who are at high risk of developing type 1 diabetes. Half of the children are being treated with two Diamyd<sup>®</sup> injections and half are receiving a placebo. The objective is to evaluate whether preventive treatment with Diamyd<sup>®</sup> can delay or halt the progress of the disease so that the children do not develop type 1 diabetes. The study is being conducted by a research group at Lund University and is led by Helena Elding Larsson, a pediatrician in Malmö and a researcher at Lund University. Diamyd has participated in the design of the study and has rights to the study results.

### **The Pain business area**

The Pain business area consists of development projects that use the Company's proprietary NTDDS (Nerve Targeting Drug Delivery System) platform to administer drugs directly to the nervous system for the treatment of chronic pain. NTDDS can deliver gene-based drugs directly

to nerve cells, providing a direct effect in the cells targeted by the treatment. Treatment entails injecting NTDDS carrying a gene for a pain-relieving substance, e.g. Enkephalin, into the skin. It is then transported along the peripheral nerves to the spinal cord where it can exert its effect by blocking pain signals to the brain. NTDDS has several advantages over other gene therapy strategies, as it is nerve specific and acts locally (the treatment does not enter the bloodstream), which means a lower risk of side effects. NTDDS does not integrate into the host cells' chromosomes, which additionally reduces the risk of side effects. Research and development on the NTDDS platform is primarily performed by the Company's subsidiary Diamyd Inc. in Pittsburgh in the USA.

The Company's project portfolio in the Pain business area consists of the candidate drugs *NP2 Enkephalin*, *NG2 GAD* and *NE2 Endomorphin*. The candidate drugs encompass treatment therapies that target the body's three major pain pathways, creating good prospects for the further development of a competitive product portfolio in the area of pain.

#### *NP2 Enkephalin*

NP2 Enkephalin is the candidate drug at the most advanced stage of development using the Company's NTDDS technology. It delivers the morphine-like substance Enkephalin directly to the nervous system for the treatment of chronic pain.

NP2 is being evaluated in a clinical Phase I study for the treatment for chronic cancer pain. The study is designed as an open label, dose escalation study in patients with intractable pain from malignant cancer. None of the study participants have reported serious side effects associated with the treatment. The trial is not primarily designed to study efficacy, but substantial and sustained reduction in pain scores were reported by treated patients. The Phase I study is a safety study for the whole NTDDS platform and will form the basis for future studies of other substances and indications. Based on the Phase I observations, the Company is planning a multi-center randomized double-blind placebo controlled Phase II study of NP2 Enkephalin in the US.

The results of previous preclinical studies show that a single dose of NP2 Enkephalin provides effective pain relief for several weeks. The treatment acts locally and can be repeated several times without causing habituation or tolerance to Enkephalin. The treatment has not caused any serious side effects in preclinical studies, in contrast to conventional treatment with morphine. There is a great medical need for new forms of treatment for cancer-related pain. Over 10 million cancer patients are considered to suffer from cancer pain and the potential market is estimated to exceed USD 2 billion annually.

#### *NG2 GAD*

The NG2 GAD candidate drug delivers GAD locally to nerve cells. In disease models it has been shown to be effective in the treatment of chronic neuropathic pain resulting from nerve damage as in e.g. diabetes and spinal cord injury. Preclinical studies of NG2 GAD are in progress, and applications for clinical studies are planned for 2011. It is estimated that 38 million people suffer from neuropathic pain, and the potential market is estimated to be USD 5 billion in 2015. It should also be possible to use the NTDDS technology in combination with GAD in the treatment of several other diseases, e.g. Parkinson's disease.



### *NE2 Endomorphin*

The candidate drug NE2 Endomorphin is a therapy developed for the treatment of neuropathic pain, where the opioid Endomorphin is conveyed to the pain area focally using NTDDS.

The opioid Endomorphin has a morphine-like effect. Morphine has been used to treat pain for centuries, and it is still an important tool of modern clinical pain relief, but due to tolerance it often does not have the intended effect in severe chronic pain. Morphine has several troubling side effects, while the locally acting Endomorphin is expected not to have morphine's systemic side effects. NE2 Endomorphin is in the preclinical stage.

## RISK FACTORS

Pharmaceutical development is associated with a high level of uncertainty, since it entails new, unpredictable, complex parameters concerning biological and medical processes. Thus an investment in Diamyd Medical entails high financial uncertainty and risk. Every investor should independently identify and judge various potential risk factors and their potential effect on the Company's future development. The following are examples (in no particular order) of risk factors that may be important when assessing an investment in Diamyd Medical:

### **Commercial and development risk**

There is no guarantee that Diamyd Medical's research and development projects will result in pharmaceuticals that can be sold on the market. Nor is there any guarantee that the company's clinical trials will result in marketable products, or that they will be a commercial success.

### **Risks regarding intellectual property portfolio**

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.

### **Key personnel**

The Company is dependent on its staff and certain key personnel. There is a risk that the Company's projects will be delayed or cannot be completed if they leave the Company or cannot conduct their duties for any reason.

### **Financing risk**

Diamyd Medical does not yet have any products on the market, and the Company is therefore not profitable at the present. Therefore the Company may need to turn to the capital market for financing in the future, in order to secure business development, as well as research and development projects undertaken.

## FINANCIAL PERFORMANCE

**Net sales**– The Group's net sales for the fourth quarter were MSEK 110.2 (0.0). During the fourth quarter Diamyd received an upfront payment of MSEK 327.3 in connection to signing of the agreement between Diamyd Medical and Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI), for the development and commercialization of the GAD65 antigen-based therapy Diamyd<sup>®</sup>. The amount is accrued until February 2011 according to Diamyd interpretation of IAS 18. See note 2 for more. Included in the Groups operating income for the fourth quarter is remuneration for research services of MSEK 14.5. The net sales for the year were MSEK 113.0 (1.1).

**Costs** – Costs were MSEK 41.2 (30.0) in the fourth quarter. The Group's costs for the year were MSEK 134.3 (89.8). The increase in costs, compared to the same periods last year, is mainly attributable to increased research and development costs with the inclusion of more patients in the Company's Phase III trials.

**Result** – Profit before tax for the fourth quarter was MSEK 75.0 (-29.8). The Group's Loss before tax for the year was MSEK -0.3 (-81.8).

**Financial position and liquidity** – The Group's liquid assets were MSEK 501.3 (37.3) as of August 31, 2010. In November 2009, liquidity was strengthened through a preferential rights issue which brought in MSEK 219 before issue expenses. In March 2010, liquidity was strengthened through a direct placement of MSEK 35. In July 2010 the Company received an up-front payment of MSEK 327.3 in connection with the agreement between Diamyd Medical and OMJPI.

**Investments** – Investments in tangible assets for the fourth quarter were MSEK 0.0 (0.0). Investments in tangible assets for the period were MSEK 0.7 (0.1).

**Change in equity** – As of August 31, 2010, the Company's equity amounted to MSEK 314.8 (70.7), resulting in a solidity of 55 (79) percent.

**Personnel** – The Group had 24 (14) employees as of August 31, 2010, of whom 8 (6) were men and 16 (8) were women.

**Parent Company** – The Parent Company's net sales for the fourth quarter was MSEK 112.0 (0.0). The net sales for the year were MSEK 112.0 (0.0) and are remuneration from research collaboration agreement and research services. Investments for the period were MSEK 0 (0). The Parent Company's net profit for the fourth quarter amounted to MSEK 80.7 (-29.8). Net profit for the year amounted to MSEK 5.2 (-82.3). As a result of the net sales that are reported, all accumulated taxable loss carry-forwards of the parent company will be used, a total of 75.7 MSEK. In addition, a group contribution has been sent to the subsidiary Diamyd Therapeutics of 7.4 MSEK. The tax effect on the group contribution is 2.0 MSEK.

The Parent Company's income statement for the period has been charged with MSEK 81.3 (71.8) in shareholders' contributions that the Parent Company provided to its subsidiaries during the period to finance research and development.

**Shares** – The total number of shares in the Company as of August 31, 2010 was 29,060,277. In January, 2010, a division of shares (a split) was executed, meaning that each share has been divided into two shares of the same class. Key figures and result per share have been adjusted for the split in this report.

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

KSEK	Note	3 months Jun-Aug 2009/2010	3 months Jun-Aug 2008/2009	12 months Sep-Aug 2009/2010	12 months Sep-Aug 2008/2009
<b>OPERATING INCOME</b>					
Net sales	1, 2	110,242	29	113,028	1,105
Other operating income		3,530	-	18,330	4,295
<b>Total operating income</b>		<b>113,772</b>	<b>29</b>	<b>131,358</b>	<b>5,400</b>
<b>OPERATING EXPENSES</b>					
Raw materials and consumables		-22	-1	-26	-17
External research and development costs		-24,261	-17,292	-80,845	-47,218
External patent and license expenses		-630	-822	-2,916	-3,836
Personnel	3	-9,732	-5,670	-31,215	-21,059
Other external expenses	3	-6,520	-5,434	-19,095	-17,515
Other operating expenses		-	-803	-	-
Depreciation, equipment		-66	17	-224	-128
<b>Total operating expenses</b>		<b>-41,231</b>	<b>-30,005</b>	<b>-134,321</b>	<b>-89,773</b>
<b>OPERATING PROFIT/LOSS</b>		<b>72,541</b>	<b>-29,976</b>	<b>-2,963</b>	<b>-84,373</b>
<b>FINANCIAL INCOME AND EXPENSES</b>					
Dividend from other bonds		410	-	410	385
Financial income		2,072	729	2,278	2,435
Financial expenses		-	-525	-1	-250
<b>Total financial income and expenses</b>		<b>2,482</b>	<b>204</b>	<b>2,687</b>	<b>2,570</b>
<b>Profit/Loss before taxes</b>		<b>75,023</b>	<b>-29,772</b>	<b>-276</b>	<b>-81,803</b>
Taxes		-37	-20	-56	-142
<b>NET PROFIT/LOSS FOR THE PERIOD</b>		<b>74,986</b>	<b>-29,792</b>	<b>-332</b>	<b>-81,945</b>
<b>Other comprehensive income for the period</b>					
Translation gains/losses		11	-111	-14	-111
<b>Other comprehensive income for the period, net of tax</b>		<b>11</b>	<b>-111</b>	<b>-14</b>	<b>-111</b>
<b>TOTAL COMPREHENSIVE INCOME FOR THE PERIOD</b>		<b>74,997</b>	<b>-29,903</b>	<b>-346</b>	<b>-82,056</b>
Earnings per share before dilution, SEK		2.58	-1.33	-0.01	-3.73
Earnings per share after dilution, SEK		2.55	-1.33	-0.01	-3.73
Number of shares		29,060,277	22,364,944	29,060,277	22,364,944
Average number of shares before dilution		29,043,587	22,364,944	27,595,347	22,001,696
Average number of shares after dilution		29,453,480	22,364,944	27,595,347	22,001,696

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

KSEK	Not e	Aug 31 2010	Aug 31 2009
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible assets		16,627	16,627
Tangible assets		855	365
Financial assets		30,678	21,418
<b>Total non-current assets</b>		<b>48,160</b>	<b>38,410</b>
<b>Current assets</b>			
Inventory		17	25
Trade receivables		1,721	4
Other receivables		1,768	1,603
Prepaid tax		-	822
Prepaid expenses and accrued income		16,195	3,018
Financial assets that can be sold	4	-	7,841
Liquid assets	5	501,332	37,287
<b>Total current assets</b>		<b>521,033</b>	<b>50,600</b>
<b>TOTAL ASSETS</b>		<b>569,193</b>	<b>89,010</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity</b>			
Share capital		14,530	11,183
Other capital contributions		687,438	451,924
Other reserves		146	160
Accumulated losses including results for the period		-387,331	-392,550
<b>Total shareholders' equity</b>		<b>314,783</b>	<b>70,717</b>
<b>Current liabilities</b>			
Trade payables		7,083	11,651
Other payables		1,434	969
Prepaid income and accrued expenses	6	245,893	5,673
<b>Total current liabilities</b>		<b>254,410</b>	<b>18,293</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>7</b>	<b>569,193</b>	<b>89,010</b>

## CONSOLIDATED STATEMENT OF CASH FLOW

KSEK	3 months Jun-Aug 2009/2010	3 months Jun-Aug 2008/2009	12 months Sep-Aug 2009/2010	12 months Sep-Aug 2008/2009
<b>Cash flow from operations before changes in working capital</b>				
Operating profit/loss	72,541	-26,850	-2,962	-84,373
Interest received	1,032	-	1,402	2,204
Interest paid	-	-	-1	-266
Dividend received	410	-	410	385
Non-cash flow items	-	-	-	-
Depreciation	66	-17	224	128
Other non-cash flow items	-502	-1,182	-929	976
Income tax paid	-	-	-	-
<b>Net cash flow from operating activities before changes in working capital</b>	<b>73,547</b>	<b>-28,049</b>	<b>-1,856</b>	<b>-80,946</b>
Increase (-) decrease (+) inventory	6	-2	9	-13
Increase (-) decrease (+) receivables	-15,321	2,593	-14,749	-2,621
Increase (+) decrease (-) liabilities	236,443	8,742	242,370	8,931
<b>Net cash flow from operating activities</b>	<b>294,675</b>	<b>-16,716</b>	<b>225,774</b>	<b>-74,649</b>
<b>Cash flow from investing activities</b>				
Purchase of intangible assets	-	-	-	-
Purchase of tangible assets	-22	-27	-700	-138
Purchase of financial assets	-	-	-	-
<b>Net cash flow from investing activities</b>	<b>-22</b>	<b>-27</b>	<b>-700</b>	<b>-138</b>
<b>Cash flow from financing activities</b>				
Option premiums	-	-	-	-
New share issue after issue expenses	1,768	-	238,861	28,090
<b>Cash flow from financing activities</b>	<b>1,768</b>	<b>-</b>	<b>238,861</b>	<b>28,090</b>
<b>Total cash flow for the period</b>	<b>296,421</b>	<b>-16,743</b>	<b>463,935</b>	<b>-46,697</b>
Cash and cash equivalents at beginning of period	205,035	54,430	37,287	81,890
Net foreign exchange difference	-124	-400	110	2,094
<b>Cash and cash equivalents at end of period</b>	<b>501,332</b>	<b>37,287</b>	<b>501,332</b>	<b>37,287</b>

## CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

KSEK	Share Capital	Other capital contributions	Reserves	Accumulated losses	Total
<b>Opening balance, September 1, 2008</b>	<b>10,902</b>	<b>424,115</b>	<b>271</b>	<b>-314,512</b>	<b>120,776</b>
<b><i>Comprehensive income</i></b>					
Net loss for the year	-	-	-	-81,945	-81,945
<b><i>Other comprehensive income</i></b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-81,945</b>	<b>-</b>
Translation gains/losses	-	-	-111	-	-111
<b>Total comprehensive income</b>	<b>-</b>	<b>-</b>	<b>-111</b>	<b>-81,945</b>	<b>-82,056</b>
<b><i>Transactions with owners</i></b>					
New share issue, before expenses	281	27,809	-	-	28,090
New share issue expenses	-	-	-	-	-
Employee options	-	-	-	3,907	3,907
<b>Total transactions with owners</b>	<b>281</b>	<b>27,809</b>	<b>-</b>	<b>3,907</b>	<b>31,997</b>
<b>Closing balance, August 31, 2009</b>	<b>11,183</b>	<b>451,924</b>	<b>160</b>	<b>-392,550</b>	<b>70,717</b>
<b>Opening balance, September 1, 2009</b>	<b>11,183</b>	<b>451,924</b>	<b>160</b>	<b>-392,550</b>	<b>70,717</b>
<b><i>Comprehensive income</i></b>					
Net loss for the period	-	-	-	-332	-332
<b><i>Other comprehensive income</i></b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-332</b>	<b>-332</b>
Translation gains/losses	-	-	-14	-	-14
<b>Total comprehensive income</b>	<b>-</b>	<b>-</b>	<b>-14</b>	<b>-332</b>	<b>-346</b>
<b><i>Transactions with owners</i></b>					
New share issue, after issue expenses	3,347	255,184	-	-	258,531
New share issue expenses	-	-19,670	-	-	-19,670
Employee options	-	-	-	5,551	5,551
<b>Total transactions with owners</b>	<b>3,347</b>	<b>235,514</b>	<b>-</b>	<b>5,551</b>	<b>244,412</b>
<b>Closing balance, August 31, 2010</b>	<b>14,530</b>	<b>687,438</b>	<b>146</b>	<b>-387,331</b>	<b>314,783</b>

## PARENT COMPANY INCOME STATEMENT

KSEK	Note	3 months Jun-Aug 2009/2010	3 months Jun-Aug 2008/2009	12 months Sep-Aug 2009/2010	12 months Sep-Aug 2008/2009
<b>OPERATING INCOME</b>					
Net sales	2	112,039	-	112,039	-
Other operating income		1,403	-	3,267	4,048
<b>Total operating income</b>		<b>113,442</b>	<b>-</b>	<b>115,306</b>	<b>4,048</b>
<b>Operating expenses</b>					
Personnel		-297	-142	-589	-274
Other external expenses		-19,385	-4,317	-29,207	-16,896
Other operating expenses		-	-662	-	-
<b>Total operating expenses</b>		<b>-19,682</b>	<b>-5,121</b>	<b>-29,796</b>	<b>-17,170</b>
<b>OPERATING PROFIT/LOSS</b>		<b>93,760</b>	<b>-5,121</b>	<b>85,510</b>	<b>-13,122</b>
<b>Financial income and expenses</b>					
Result from group participation		-13,709	-25,184	-81,308	-71,828
Dividend from other bonds		410	-	410	385
Interest income and similar items		2,152	1,040	2,499	2,554
Interest expense and similar items		-	-525	-	-245
<b>Total financial income and expenses</b>		<b>-11,147</b>	<b>-24,669</b>	<b>-78,399</b>	<b>-69,134</b>
<b>Profit/Loss before tax</b>		<b>82,613</b>	<b>-29,790</b>	<b>-7,111</b>	<b>-82,256</b>
Taxes		-1,957	-	-1,957	-
<b>NET PROFIT/LOSS FOR THE PERIOD</b>		<b>80,656</b>	<b>-29,790</b>	<b>5,154</b>	<b>-82,256</b>



## PARENT COMPANY'S BALANCE SHEET

KSEK	Note	Aug 31 2010	Aug 31 2009
<b>ASSETS</b>			
<b>Non-current assets</b>			
<i>Intangible assets</i>			
Acquired research and development		16,627	16,627
<i>Financial assets</i>			
Shares in Group companies		1,200	1,200
Receivables at Group companies		20,612	3,970
Other long-term bond holdings		21,418	21,418
Financial instruments available for sale		9,260	-
<b>Total non-current assets</b>		<b>69,117</b>	<b>43,215</b>
<b>Current assets</b>			
Other receivables		152	200
Prepaid expenses and accrued income		15,591	1,117
Financial assets that can be sold	4	-	7,841
<b>Total trade and other receivables</b>		<b>15,743</b>	<b>9,158</b>
Liquid assets		478,882	26,138
<b>Total current assets</b>		<b>494,652</b>	<b>35,296</b>
<b>TOTAL ASSETS</b>		<b>563,742</b>	<b>78,511</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>			
<b>Shareholders' equity</b>			
<b>Restricted equity</b>			
Issued capital		14,530	11,183
Statutory reserve		96,609	96,609
<b>Non-restricted equity</b>			
Share premium reserve non-restricted		337,442	101,928
Profit or loss brought forward		-138,767	-56,576
Net profit/loss for the period		5,154	-82,256
<b>Total shareholders' equity</b>		<b>314,968</b>	<b>70,888</b>
Liabilities to subsidiary		17,515	5,625
<b>Current liabilities</b>			
Trade payables		298	977
Prepaid income and accrued expenses	6	230,961	1,021
<b>Total current liabilities</b>		<b>231,259</b>	<b>1,998</b>
		-	-
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>563,742</b>	<b>78,511</b>
Assets pledged		-	157
Contingent liabilities		-	-

## Notes

### Accounting principles

This interim report was prepared as per IAS 34, Interim Financial Reporting. For a more detailed description of the accounting principles used by the Group, reference is made to the most recent annual report. The interim report has been adjusted to the revised standard IAS 1, *Presentation of Financial Statements*, which has meant new titles for the financial statements, as well as some changes to how they are arranged. As of September 1, 2009, the Group applies IFRS 8, *Operating Segments*. The effects are described in more detail under Note 1 – Segment results.

### Note 1 – Segment results

As of September 1, 2009, the Group is applying IFRS 8, Operating Segments, which has meant a change to how the Group reports its segmentation. This standard requires that disclosures are made from management's perspective, which means that the reporting shall correspond to how it is presented internally. CEO has been identified as the CODM (Chief Operating Decision Maker). The Group is organized in and is managed from geographical regions that correspond to the operating segments for which information is given and is followed up internally at the operational level. The Group has identified which segments are followed up through the Company's internal reporting; as a result, the Company is presenting its segments divided by country. Since this constitutes an altered accounting principle, the comparative figures in the segment reporting have been recalculated. The outcome measurement being followed up is the operating results, i.e, the profit/loss before financial income and expenses.

Segment results	2009-09-01 - 2010-08-31			2008-09-01 - 2009-08-31		
	Sweden	USA	Group	Sweden	USA	Group
KSEK						
Total segment income	143,054	10,495	153,549	4,871	7,433	12,304
Sales between segments	-14,583	-7,608	-22,191	-22	-6,882	-6,904
Total income	128,471	2,887	131,358	4,849	551	5,400
Operating loss	-3,250	287	-2,963	-85,013	640	-84,373
Financial income			2,278			2,435
Financial expenses			-1			-250
Total financial income and expenses			2,277			2,185
Dividends			410			385
Loss before tax			-276			-81,803
Income tax			-56			-142
Net loss for the period			-332			-81,945

*Not 2 – Distribution of net sales*

	<b>Group</b>		<b>Patent Company</b>	
	<b>2009/2010</b>	<b>2008/2009</b>	<b>2009/2010</b>	<b>2008/2009</b>
Revenues from research collaboration agreement	97,494	-	97,494	-
Research services	14,545	-	14,545	-
Other services	990	1,105	-	-
<b>Total</b>	<b>113,029</b>	<b>1,105</b>	<b>112,039</b>	<b>-</b>

Diamyd Medical AB has in June, 2010, signed an agreement with Ortho-McNeil-Janssen Pharmaceuticals, Inc. to develop and commercialize Diamyd<sup>®</sup>. The agreement relates to the development and commercialization of the antigen-based therapy Diamyd<sup>®</sup> for the treatment and prevention of autoimmune diabetes. Diamyd Medical received an upfront payment of MSEK 327.3 in connection to the closing of the agreement. The amount is periodized according to Diamyd Medical's interpretation of IAS 18. Periodization will be made until February, 2011, when the 15-month study period for the European study is ended.

The agreement also states that parties will equally share costs for the development program until results from the ongoing EU Phase III study, expected in the first half of 2011. Per August 31, 2010, this amounts to MSEK 14.5 in research services.

*Note 3 – Related-party transactions*

During the year companies represented by immediate family members of the Chairman of the Board were retained as consultants. Total compensation for web services during the year amounted to KSEK 650 (760) excluding VAT. Prizing has been set by the arm's length principle. Total compensation to immediate family members of the Chairman amounted to a total of KSEK 2,684 (991) during the year. No other members of the Board of Directors, key executives, or their immediate family members have been directly or indirectly involved in any business transaction with the Company that is or was unusual in its character or terms and conditions and took place during the year. Neither has the Company given any loans, provided any guarantees or surety to or for the benefit of any member of the Board of Directors, key executives or auditors in the Company.

<b>KSEK</b>	<b>12 months</b>	<b>12 months</b>
	<b>Sep-Aug</b>	<b>Sep-Aug</b>
	<b>2009/2010</b>	<b>2008/2009</b>
Salaries	2,684	991
Consultant fees	650	760

*NOTE 4 – Financial assets available for sale*

In fiscal 2007/2008 the Company invested in a convertible promissory note in Protein Sciences Corporation, Meriden CT, USA. As the convertible has not been converted as of December 31, 2008 the promissory note continues at an interest rate of 5% for an undetermined period. The initial assessment was that the promissory note would be settled within 12 months. However on the balance date the assessment is that the payment will be made, but since Protein Sciences is a development company, the payment is considered not to take place within 12 months, and therefore the asset is being reclassified as a non-current asset.

*Not 5 – Liquid assets*

MSEK 447.5 of Diamyd's liquid assets consists of commercial papers and bank deposits up to three months in counterparties with high credit-worthiness.

*Note 6 – Prepaid income and accrued expenses*

	Group		Parent Company	
	2009/2010	2008/2009	2009/2010	2008/2009
Accrued vacation pay	-356	-279	-	-
Accrued social security expenses	-1,174	-245	-47	-
Accrued social security expenses on employee option programs	-3,034	-636	-	-
Accrued expenses, clinical trials	-9,920	-2,524	-	-
Other expenses	-1,603	-1,989	-1,108	-1,021
Prepaid Income*	-229,806	-	-229,806	-
<b>Total</b>	<b>-245,893</b>	<b>-5,673</b>	<b>-230,961</b>	<b>-1,021</b>

\*Up-front payment.

*Note 7 – Equity and liabilities*

All Group debts are non-interest-bearing.

Key figures	3 months	3 months	12 months	12 months
	Jun-Aug	Jun-Aug	Sep-Aug	Sep-Aug
	2009/2010	2008/2009	2009/2010	2008/2009
Earnings per share before dilution, SEK	2.58	-1.33	-0.01	-3.73
Earnings per share after dilution, SEK	2,55	-1,33	-0,01	-3,73
Shareholders' equity per share, SEK	10.8	3.2	10.8	3.2
Cash flow per share, SEK	10.2	-0.7	-16.8	-2.1
Dividend, SEK	-	-	-	-
Share price, SEK	119.5	44.3	119.5	44.3
Closing share price/shareholders' equity per share, SEK	11.2	14.0	10.5	13.8
P/E ratio, times	46.3	Neg	Neg	Neg
Return on equity, %	27.2	-35.1	-0.2	-85.7
Solidity, %	55	79	55	79
Average number of employees	24	14	19	14
Research and Development Costs, MSEK	-24.3	-17.3	-80.8	-47.2
Investment in fixed assets, KSEK	-	-	-	-
Number of shares	29,060,277	22,364,944	29,060,277	22,364,944
Average number of shares before dilution	29,043,587	22,364,944	27,595,347	22,001,696
Average number of shares after dilution	29,453,480	22,364,944	27,595,347	22,001,696

Key figures have, with regards to historical share price, been adjusted to the split that was executed in January, 2010, meaning that each share has been divided into two shares. The Key figures that have been adjusted are Earnings per share, Shareholders' equity per share, Cash flow per share and Share price.

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

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

**Stockholm, October 22, 2010**

**The Board of Diamyd Medical AB (publ,)**

Anders Essen-Möller, Chairman of the Board

Lars Jonsson, Board Member

Sam Lindgren, Board Member

Henrik Bonde, Board Member

Maria-Teresa Essen-Möller, Board Member

Göran Pettersson, Board Member

Elisabeth Lindner, President and CEO

**Financial Calendar**

Annual report, November 25, 2010

Annual General Meeting, December 9, 2010

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

**About Diamyd Medical**

Diamyd Medical is a Swedish pharmaceutical company focusing on the development of pharmaceuticals for the treatment of autoimmune diabetes and pain. The Diabetes business area consists of the antigen-based candidate drug Diamyd<sup>®</sup> for the treatment and prevention of autoimmune diabetes. Phase III studies of Diamyd<sup>®</sup> are currently in progress in Europe and the US. In 2010 the Company signed an agreement with Ortho-McNeil-Janssen Pharmaceuticals, Inc., for the development and commercialization of Diamyd<sup>®</sup>. The Pain business area consists of development projects that use the Company's proprietary NTDDS (Nerve Targeting Drug Delivery System) platform to administer drugs directly to the nervous system to treat chronic pain. A Phase I study of the candidate drug NP2 Enkephalin for cancer pain is ongoing, and the Company plans to initiate a Phase II study.

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

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*The document contains certain statements about the Company's operating environment and future performance. These statements should only be seen as reflective of prevailing interpretations. No guarantees can be made that these statements are free from errors.*