

# Quarterly report, Stockholm, April 14, 2011 September 1, 2010 – February 28, 2011

# Second quarter report for Diamyd Medical AB (publ.), fiscal year 2010/2011 (www.omxgroup.com ticker: DIAM B; www.otcqx.com ticker: DMYDY)

Second quarter, December 1, 2010 - February 28, 2011

- Group net sales for the second quarter were MSEK 114.5 (0.2)
- Profit before tax for the second quarter was MSEK 73.7 (-26.6)
- Earnings per share after dilution for the second quarter were SEK 2.51 (-0.2)

First half year, September 1, 2010 - February 28, 2011

- Group net sales for the first half year was MSEK 259.0 (1.4)
- Profit before tax for the first half year was MSEK 172.0 (-44.4)
- The Group's liquid assets amounted to MSEK 473.6 (200.1) as of February 28, 2011
- Earnings per share after dilution for the first half year were SEK 5.88 (-1.7)

Significant events during the reporting period December 1, 2010 – February 28, 2011

- Last patient completed the EU Phase III study of Diamyd<sup>®</sup> antigen based therapy for type 1 diabetes
- University of Florida Research Foundation initiated court case against Diamyd Medical
- Diamyd Medical started Phase II study in cancer pain
- The Diamyd share moved to NASDAQ OMX Stockholm Mid Cap list
- NASDAQ OMX Stockholm Disciplinary Committee imposed a penalty on Diamyd Medical AB for inadequate disclosure of information

# Significant events after the reporting period

• Diamyd results from Phase I clinical trial in cancer pain published in Annals of Neurology

# CEO COMMENTS

## All eyes on Diamyd

Diamyd Medical is currently experiencing an exceptionally intensive period with extremely high expectations on the company, both internally and externally. In mid-February, the last patient made the final visit in the 15-month main trial period in the company's European Phase III trial. Participants in the study are being treated with the antigen-based candidate drug Diamyd<sup>®</sup> or placebo to assess whether it is possible to preserve beta cell function and thus improve management of blood sugar control long term among children and adolescents with recent-onset type 1 diabetes. Extensive efforts are currently underway to compile and process all the data. This is a comprehensive and time-consuming undertaking and, as previously announced, we expect to be able to report the top line results from the study in the late spring.

This is a particularly important period; not just for Diamyd, but my immediate thoughts go to all the children and adolescents with diabetes participating in the study, as well as all the physicians and nurses performing the trial. We should also not lose sight of the great importance of the results for diabetes research worldwide. If we could show that it is possible to preserve beta cell function in recent-onset type 1 diabetes, it would represent a breakthrough that we have not seen since insulin was introduced in the 1920's.

Several important events have taken place in the past quarter. At year-end, Diamyd Medical (DIAM B) moved from the Small Cap list to the Mid Cap list on the NASDAQ OMX Stockholm. The interest in our company remains very high and we currently have more than 6,000 shareholders, which we are very proud of.

The pace is also quickening in the Pain business area. In January, we initiated a US Phase II trial aimed at testing the NP2 Enkephalin candidate drug's potential to relieve cancer pain. Some 32 patients with severe cancer pain are currently being enrolled in the study. Recently the interest in Diamyd's unique method of treating pain was further confirmed with the publication of the results of our Phase I trial with NP2 Enkephalin in the medical journal Annals of Neurology. As announced earlier, we also intend to launch a clinical study with the NG2 GAD candidate drug in patients with chronic neuropathic pain in 2011.

The upcoming period will possibly be the most significant in Diamyd's history when the results of the Phase III study are reported. We hope our results will be the main topic of conversation at the important diabetes meeting, the American Diabetes Association's 71st Scientific Sessions, which this year takes place in San Diego at the end of June. We have an incredibly exciting and intense time ahead of us.

Stockholm, April 14, 2011 Elisabeth Lindner President and CEO, Diamyd Medical AB

# SIGNIFICANT EVENTS DURING THE REPORTING PERIOD DECEMBER 1, 2010 – FEBRUARY 28, 2011

Last patient completed the EU Phase III study of Diamyd<sup>®</sup> antigen based therapy for type 1 diabetes. The last patient in the EU Diamyd Medical Phase III clinical study completed the 15-month visit in February. This important achievement in the Diamyd<sup>®</sup> Phase III program is now being followed by an intense period where the data from the more than 60 clinics throughout Europe and from the central laboratory is compiled and processed. The top line results are expected to be reported as planned, in late spring 2011.

University of Florida Research Foundation initiated court case against Diamyd Medical. The University of Florida Research Foundation (UFRF) filed a lawsuit in United States federal district court in Florida against Diamyd Medical claiming that UFRF is entitled to a percentage of the license fee paid to Diamyd Medical by Ortho-McNeil-Jansen Pharmaceuticals, Inc. (OMJPI). Diamyd Medical has licensed certain rights from UFRF, and these rights were among the rights that Diamyd Medical sublicensed to OMJPI.

**Diamyd Medical started Phase II study in cancer pain.** The Phase II clinical trial, with the candidate drug NP2 Enkephalin, started in January 2011 the recruitment of approximately 32 subjects with severe cancer pain. Their pain scores and concomitant pain medication usage will be followed. It is a multi-center, randomized, double-blind, placebo controlled study designed to provide a statistical evaluation of pain relief. 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.

**The Diamyd share moved to NASDAQ OMX Stockholm Mid Cap list.** 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. The Mid Cap segment includes companies with a market capitalization of between EUR 150 million and EUR 1 billion.

NASDAQ OMX Stockholm Disciplinary Committee imposed a penalty on Diamyd Medical AB for inadequate disclosure of information. In a letter dated November 5, 2010 to the Disciplinary Committee of NASDAQ OMX Stockholm, NASDAQ OMX Stockholm AB requested that the Disciplinary Committee issue a decision on disciplinary action regarding Diamyd Medical AB's disclosure of information. Diamyd Medical AB received the Disciplinary Committee's decision on December 15, 2010, instructing Diamyd Medical AB to pay an administrative penalty of SEK 576,000, corresponding to three annual fees.

# SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

**Diamyd results from Phase I clinical trial in cancer pain published in Annals of Neurology.** The Phase I clinical trial results evaluating the safety and efficacy of the candidate drug NP2 Enkephalin to treat intractable cancer pain were published in the medical journal Annals of Neurology.

# **BUSINESS OVERVIEW**

Diamyd Medical is a Swedish pharmaceutical company focusing on the development of pharmaceuticals for the treatment of autoimmune diabetes and pain. The Group consists of the Parent Company Diamyd Medical AB (publ) and three wholly-owned subsidiaries: Diamyd Therapeutics AB, Diamyd Diagnostics AB and Diamyd, Inc. The Company's headquarters is in Stockholm, Sweden, and it 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).

## Vision and objectives

Diamyd Medical's vision is to be able to prevent and cure autoimmune diabetes and its complications. The objective for the Company's development in the field of autoimmune diabetes is, at the first stage, to preserve the natural ability of newly diagnosed type 1 diabetes patients to control blood glucose by treatment with the drug candidate Diamyd<sup>®</sup>. The next stage is to prevent the development of type 1 diabetes through preventive treatment of people at high risk of developing the disease.

#### **Business concept and strategy**

Diamyd Medical's business concept is to bring in candidate products in the preclinical and clinical phases, and to refine them through development. The products are then to be commercialized, either independently or with a partner. Diamyd aims to build a small pharmaceutical company with its own development operations and sales and marketing organization in the Nordic countries: a Nordic small pharma company.

## **Outsourcing model**

Diamyd is managed according to an outsourcing model, where some of its 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. Diamyd does not perform basic research internally. This model generates lower operating expenses because expert services and new development projects are sought externally. This enables the Company to develop in a flexible manner while maintaining its focus on results and quality.

## Partnerships and acquisitions

Partnerships with other pharmaceutical companies are part of the Company's strategy, both to partner proprietary 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 antigen-based candidate therapy Diamyd<sup>®</sup> for the treatment and prevention of autoimmune diabetes. 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 US 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 |
|-------|----------|---------------------|-----------------|-------------------|
|       | S        | Diamyd <sup>®</sup> | Type 1 diabetes | Phase III         |
| Area  | Diabetes | Diamyd <sup>®</sup> | LADA            | Phase II          |
| s Ard |          | Diamyd <sup>®</sup> | Prevention      | Phase II          |
| iness |          | NP2 Enkephalin      | Cancer pain     | Phase II          |
| Bus   | Pain     | NG2 GAD             | Diabetes pain   | Preclinical       |
|       |          | NE2 Endomorphin     | Chronic 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 without ability to control blood sugar at all and the entire insulin requirement must be provided by exogenously 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 against 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, thus intervening in the autoimmune attack and preserving the ability to control blood sugar in autoimmune diabetes patients. The Diamyd<sup>®</sup> safety profile, which has been encouraging so far, is of great importance since a large proportion of newly diagnosed type 1 diabetes patients are children and adolescents.

It is estimated that about 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 newly diagnosed 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, the potential market is estimated to be considerably larger.

Diamyd<sup>®</sup> is currently being developed for three primary therapeutic indications: newly diagnosed 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<sup>®</sup> 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 newly diagnosed 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 placebo injections. 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.

Both the European and US Phase III studies are fully recruited. The European study enrolled its last patient in November 2009 and the last patient completed the 15-month visit in February 2011. This means all patients have completed the main 15 month study period in the trial. Study data are now being collected from the slightly more than 60 participating clinics throughout Europe and from the central laboratory, which carried out all the analyses. All data will be compiled and when all of this has been completed, the database will be locked. The trial will eventually be unblinded after which Diamyd Medical will be able to begin reporting study results in late spring 2011. The US Phase III study DiaPrevent enrolled its last patient in December 2010. The Company expects to complete the main study period of this study during the spring of 2012.

The Company has reported positive results from a similar 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, in this case the body's own capacity to control blood glucose compared to placebo. 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 journal *The New* 

*England Journal of Medicine*. The study has now been extended in order to follow the patients for a total of seven years to confirm the long-term effect 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 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 usually 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 disease primarily affects adults and does not require insulin treatment immediately, LADA patients are often diagnosed with type 2 diabetes. The Company estimates that about 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 in 47 LADA patients, which showed that treatment with Diamyd<sup>®</sup> significantly reduced the risk that LADA patients would need insulin treatment, still after 5 years, when compared to treatment with placebo. Only 14 percent of the patients in the group that received 20 µg of Diamyd<sup>®</sup> needed insulin after 5 years, vs. 64 percent in the placebo group. No serious side effects related to the treatment were reported in the study.

# Diamyd<sup>®</sup> - Prevention

In type 1 diabetes, the autoimmune attack and the destruction of blood sugar-regulating beta cells in the pancreas start long before the symptoms appear. If the autoimmune attack could be halted at an early stage, before the destruction of the beta cell function has led to the appearance of symptoms, it would be possible to prevent the disease from developing at all. Earlier studies have shown that Diamyd<sup>®</sup> is most effective when administered early in the course of the disease in patients with newly diagnosed type 1 diabetes. If these results can be confirmed by larger studies, the next logical step is to extend testing of Diamyd<sup>®</sup> to individuals who are at high risk of developing diabetes, thus preventing the disease before it manifests.

A small-scale Swedish study of Diamyd<sup>®</sup>, encompassing 50 children from the age of 4 at high risk of developing type 1 diabetes, has been in progress since 2009. Half of the children are being treated with two Diamyd<sup>®</sup> injections and half are receiving placebo. The purpose of the study is to evaluate whether treatment with Diamyd<sup>®</sup> as a preventive measure could delay or halt disease progression, thus preventing the children from developing clinical symptoms of type 1 diabetes. The study is being conducted by a research group at Lund University and is led by Helena Elding Larsson, pediatrician in Malmö and 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 Company's project portfolio in the Pain business area consists of candidate drugs in clinical and preclinical phases that use the Company's proprietary NTDDS (Nerve Targeting Drug Delivery System) platform to administer drugs to the nervous system for the treatment of

chronic pain, such as cancer pain and diabetes pain. Research and development on the NTDDS platform is primarily performed by the Company's subsidiary Diamyd, Inc. in Pittsburgh in the US.

NTDDS represents a new class of pharmaceutical products that delivers gene-based drugs to nerve cells, providing a local effect in the cells targeted by the treatment. NTDDS carrying the gene for a painkilling substance such as human Enkephalin, is injected into the skin over the painful area, and is transported along the local peripheral nerve fibers to the spinal cord where the drug exerts its effect by stopping the transmission of pain signals from the peripheral nerves to the nerves of the spinal cord. NTDDS uses the nerve cell's own processes for continually producing the painkilling substance locally on site at the spinal cord. As the drug is gene-based, one treatment can produce a long-term therapeutic effect. NTDDS has several advantages over other pain-relieving therapies, as it acts locally (the treatment does not enter the bloodstream), reducing the risk of side effects. The risk of side effects is also reduced compared to other gene therapy technologies since the NTDDS is not integrated into the chromosomes of the host cell and does not induce an immune reaction.

Apart from its use in pain relief, the NTDDS platform is also targeting several other diseases of the peripheral and central nervous systems, such as peripheral neuropathy – a condition for which there is currently no effective treatment. Local treatment using the NTDDS platform to deliver growth factors could prove very important clinically if it is able to protect nerve cells and stimulate their regeneration. Peripheral neuropathy is a common complication of diabetes. Reduced feeling in the body's extremities and erectile dysfunction (impotence) are examples of the consequences of neuropathy in people with diabetes.

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 in the Pain business area. It makes the target nerve cells produce the opioid Enkephalin locally for the treatment of pain.

NP2 has been evaluated in a clinical Phase I study for the treatment for chronic cancer pain. The study was designed as an open-label, dose-escalation study in patients with intractable pain from malignant cancer and constitutes a safety study for the entire NTDDS platform. Although the trial was not primarily designed to study efficacy, substantial and sustained reduction in pain scores was observed. No drug-related Serious Adverse Events have been reported by any patient included in the trial. The Phase I study has formed the basis for future studies of other drug candidates using the NTDDS platform targeting other diseases and conditions.

Based on the Phase I observations, in January 2011 the Company started a Phase II trial of NP2 Enkephalin in the US. The trial will recruit approximately 32 subjects with severe cancer pain and follow their pain scores and concomitant pain medication usage. It is a multi-center, placebo-controlled study designed to provide a statistical evaluation of pain relief. The trial has a four-week double-blind main study period after which all patients will be offered up to two additional doses of active NP2 Enkephalin in an open-label study extension.

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, in these studies, could 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.

## NG2 GAD

The NG2 GAD candidate drug, using the NTDDS platform, 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 a result of, for example, diabetes and spinal cord injury. Preclinical studies of NG2 GAD are in progress and these are being funded by grants from the United States Department of Veterans Affairs. The Company plans to start clinical trials in 2011. It should also be possible to use the NTDDS platform with GAD in the treatment of several other diseases.

# NE2 Endomorphin

The candidate drug NE2 Endomorphin is a therapy under development for the treatment of neuropathic pain, where the opioid Endomorphin is conveyed to the pain area locally 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 also 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**

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 medicinal 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. 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

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

#### **Risks regarding intellectual property rights**

There are no guarantees that the Company will develop products that can be patented, or that 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.

## **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.

# FINANCIAL PERFORMANCE

**Net sales** – The Group's net sales for the second quarter were MSEK 114.5 (0.2). Last fiscal year Diamyd received an upfront payment of MSEK 327.3 in connection to the signing of the agreement with 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. The Group's operating income for the first half year was MSEK 259.0 (1.4). The Group's operating income for the first half year also contains remuneration for research services of MSEK 28.6 from OMJPI.

**Costs** – Costs were MSEK 45.2 (27.8) in the second quarter. The cost for the first half year was MSEK 92.9 (58.6). 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 and an increase in personnel costs.

**Result** – Profit before tax for the second quarter was MSEK 73.7 (-26.6). Profit before tax for the first half year was MSEK 172.0 (-44.4).

**Financial position and liquidity** – The Group's liquid assets were MSEK 473.6 (200.1) as of February 28, 2011.

**Investments** – Investments in tangible assets for the second quarter were MSEK 0.2 (0.2). Investments in tangible assets for the first half year were MSEK 0.4 (0.2).

**Change in equity** – As of February 28, 2011, the Company's equity amounted to MSEK 529.0 (229.0), resulting in a solidity of 95 (91) percent.

**Personnel** – The Group had 32 (17) employees as of February 28, 2011, of whom 10 (7) were men and 22 (10) were women.

**Parent Company** – Investments for the period were MSEK 0 (0). The Parent Company's net profit for the second quarter amounted to MSEK 74.5 (-26.2). The net profit for the first half year amounted to MSEK 174.0 (-44.6).

The Parent Company's income statement for the first half year has been charged with MSEK 38.1 (37.2) in shareholders' contributions that the Parent Company provided to its subsidiary during the period to finance research and development.

**Shares** – The total number of shares in Diamyd Medical as of February 28, 2011 was 29,579,133.

# CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

|  |       | 3 months                | 3 months   | 6 months                | 6 months   | 12 months                |
|--|-------|-------------------------|------------|-------------------------|------------|--------------------------|
|  |       | Dec-Feb                 | Dec-Feb    | Sep-Feb                 | Sep-Feb    | Sep-Aug                  |
| KSEK   | Note  | 2010/2011               | 2009/2010  | 2010/2011               | 2009/2010  | 2009/2010                |
| OPERATING INCOME                                 |       |                         |            |                         |            |                          |
| Net sales  | 1 0   | 114 510                 | 164        | 250 002                 | 1,449      | 113,028                  |
|  | 1, 2  | 114,510                 | 785        | 258,982                 | 2          | ,                        |
| Other operating income<br>Total operating income | -     | 2,512<br><b>117,022</b> | 949        | 2,512<br><b>261,494</b> | 12,731     | 18,330<br><b>131,358</b> |
| Total operating income                           |       | 117,022                 | 545        | 201,494                 | 14,180     | 151,550                  |
| OPERATING EXPENSES                               |       |                         |            |                         |            |                          |
| Raw materials and consumables                    |       | -6                      | -          | -7                      | -          | -26                      |
| External research and development<br>costs       |       | -23,716                 | -17,982    | -45,385                 | -33,102    | -80,845                  |
| External patent and license                      |       | -23,710                 | -17,302    | -40,000                 | -55,102    | -00,040                  |
| expenses   |       | -525                    | -344       | -1,124                  | -722       | -2,916                   |
| Personnel  | 3     | -9,346                  | -5,610     | -24,308                 | -13,522    | -31,215                  |
| Other external expenses                          | 3     | -5,046                  | -3,371     | -8,156                  | -10,435    | -19,095                  |
| Other operating expenses                         | 4     | -6,477                  | -490       | -13,725                 | -746       | -                        |
| Depreciation, equipment                          | _     | -86                     | -          | -161                    | -38        | -224                     |
| Total operating expenses                         | -     | -45,202                 | -27,797    | -92,866                 | -58,565    | -134,321                 |
|  |       |                         |            |                         |            |                          |
| <b>OPERATING PROFIT/LOSS</b>                     |       | 71,820                  | -26,848    | 168,628                 | -44,385    | -2,963                   |
| FINANCIAL INCOME AND<br>EXPENSES                 |       |                         |            |                         |            |                          |
| Dividend from other bonds                        |       | -                       | -          | -                       | -          | 410                      |
| Financial income                                 |       | 1,841                   | 286        | 3,364                   | 40         | 2,278                    |
| Financial expenses                               | -     | -8                      | -          | -11                     | -9         | -1                       |
| Total financial income and expenses              |       | 1,833                   | 286        | 3,353                   | 31         | 2,687                    |
| Profit/Loss before taxes                         |       | 73,653                  | -26,562    | 171,981                 | -44,354    | -276                     |
| Taxes  |       | 639                     | -9         | 639                     | -9         | -56                      |
|  |       |                         |            |                         |            |                          |
| NET PROFIT/LOSS FOR THE<br>PERIOD                |       | 74,292                  | -26,571    | 172,620                 | -44,363    | -332                     |
| Other comprehensive income for the period        |       |                         |            |                         |            |                          |
| Translation gains/losses                         |       | 110                     | -10        | 154                     | -2         | -14                      |
| Other comprehensive income for                   |       | 110                     | 10         | 104                     | 2          | 1-7                      |
| the period, net of tax                           |       | 110                     | -10        | 154                     | -2         | -14                      |
| TOTAL COMPREHENSIVE<br>INCOME FOR THE PERIOD     |       | 74,402                  | -26,581    | 172,774                 | -44,365    | -346                     |
| Earnings per share before dilution, S            | EK    | 2.53                    | -0.2       | 5.89                    | -1.7       | -0.01                    |
| Earnings per share after dilution, SE            |       | 2.51                    | -0.2       | 5.88                    | -1.7       | -0.01                    |
| Number of shares per closing day                 |       | 29,579,133              | 28,660,988 | 29,579,133              | 28,660,988 | 29,060,277               |
| Average number of shares before dil              | ution | 29,458,400              | 28,654,968 | 29,320,280              | 26,181,196 | 27,595,347               |
| Average number of shares after diluti            |       | 29,560,823              | 28,654,968 | 29,374,322              | 26,181,196 | 27,595,347               |
|  |       |                         |            |                         |            |                          |

| KOEK  | Nata | Feb 28   | Feb 28   | Aug 31   |
|---|------|----------|----------|----------|
| KSEK  | Note | 2011     | 2010     | 2010     |
| ASSETS  |      |          |          |          |
| Non-current assets                                  |      |          |          |          |
| Intangible assets                                   |      | 16,627   | 16,627   | 16,627   |
| Tangible assets                                     |      | 1,005    | 569      | 855      |
| Financial assets                                    |      | 29,527   | 21,418   | 30,678   |
| Total non-current assets                            |      | 47,159   | 38,614   | 48,160   |
| Current assets                                      |      |          |          |          |
| Inventory   |      | 15       | 24       | 17       |
| Trade receivables                                   |      | 14,296   | 1,281    | 1,721    |
| Other receivables                                   |      | 3,854    | 1,233    | 1,768    |
| Prepaid tax   |      | -        | 611      | -        |
| Prepaid expenses and accrued income                 |      | 15,341   | 2,272    | 16,195   |
| Financial assets that can be sold                   |      | -        | 7,178    | -        |
| Liquid assets                                       |      | 473,631  | 200,134  | 501,332  |
| Total current assets                                |      | 507,137  | 212,733  | 521,033  |
| TOTAL ASSETS  |      | 554,296  | 251,347  | 569,193  |
| SHAREHOLDERS' EQUITY AND LIABILITIES                |      |          |          |          |
| Shareholders' equity                                |      |          |          |          |
| Share capital                                       |      | 14,790   | 14,330   | 14,530   |
| Other capital contributions                         |      | 724,737  | 649,558  | 687,438  |
| Other reserves                                      |      | 300      | 158      | 146      |
| Accumulated losses including results for the period |      | -210,859 | -435,086 | -387,331 |
| Total shareholders' equity                          |      | 528,968  | 228,960  | 314,783  |
| Current liabilities                                 |      |          |          |          |
| Trade payables                                      |      | 9,504    | 9,485    | 7,083    |
| Other payables                                      |      | 1,781    | 647      | 1,434    |
| Prepaid income and accrued expenses                 |      | 14,043   | 12,255   | 245,893  |
| Total current liabilities                           |      | 25,328   | 22,387   | 254,410  |
| TOTAL EQUITY AND LIABILITIES                        | 5    | 554,296  | 251,347  | 569,193  |

# CONSOLIDATED STATEMENT OF FINANCIAL POSITION

|   | 3 months         | 3 months       | 6 months         | 6 months       | 12 months      |
|---|------------------|----------------|------------------|----------------|----------------|
|   | Dec-Feb          | Dec-Feb        | Sep-Feb          | Sep-Feb        | Sep-Aug        |
| KSEK                                      | 2010/2011        | 2009/2010      | 2010/2011        | 2009/2010      | 2009/2010      |
| KOEK                                      | 2010/2011        | 2003/2010      | 2010/2011        | 2003/2010      | 2003/2010      |
| Cash flow from operations before changes  |                  |                |                  |                |                |
| in working capital                        |                  |                |                  |                |                |
| Operating profit/loss                     | 71,820           | -26,848        | 168,628          | -44,386        | -2,962         |
| Interest received                         | 2,137            | 183            | 2,734            | 195            | 1,402          |
| Interest paid                             | -8               | -42            | -11              | -1             | -1             |
| Dividend received                         | -                | -              | -                | -              | 410            |
| Non-cash flow items                       |                  |                |                  |                |                |
| Depreciation                              | 86               | -4             | 161              | 38             | 224            |
| Other non-cash flow items                 | -94,274          | 361            | -211,401         | 1,397          | -929           |
| Net cash flow from operating activities   |                  |                |                  |                |                |
| before changes in working capital         | -20,239          | -26,268        | -39,889          | -42,757        | -1,856         |
|   | 0                | 0              |                  | 0              | 0              |
| Increase (-) decrease (+) inventory       | 3                | 2              | 1                | 2              | 9              |
| Increase (-) decrease (+) receivables     | 6,770            | 2,010          | -11,625          | 599            | -14,749        |
| Increase (+) decrease (-) liabilities     | -12,077          | -149           | -13,098          | 4,468          | 242,370        |
| Net cash flow from operating activities   | -25,543          | -24,404        | -64,611          | -37,688        | 225,774        |
| Cash flow from investing activities       |                  |                |                  |                |                |
| Purchase of tangible assets               | -156             | -151           | -379             | -239           | -700           |
| Net cash flow from investing activities   | -156             | -151           | -379             | -239           | -700           |
| Cash flow from financing activities       |                  |                |                  |                |                |
| New share issue after issue expenses      | 21,837           | 1,007          | 37,559           | 200,781        | 238,861        |
| Cash flow from financing activities       | 21,837<br>21,837 | 1,007<br>1,007 | 37,559<br>37,559 | <b>200,781</b> | <b>238,861</b> |
| cash now from financing activities        | 21,037           | 1,007          | 37,559           | 200,701        | ∠30,00 I       |
| Total cash flow for the period            | -3,862           | -23,548        | -27,431          | 162,854        | 463,935        |
| Cash and cash equivalents at beginning of |                  |                |                  |                |                |
| period                                    | 477,652          | 223,628        | 501,332          | 37,287         | 37,287         |
| Net foreign exchange difference           | -159             | 55             | -270             | -6             | 110            |
| Cash and cash equivalents at end of       |                  |                |                  |                |                |
| period                                    | 473,631          | 200,135        | 473,631          | 200,135        | 501,332        |

# CONSOLIDATED STATEMENT OF CASH FLOW

# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

| KSEK   | Share<br>Capital | Other<br>capital<br>contributions | Reserves | Accumulated<br>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    |
| Other comprehensive income   | -                | -                                 | -        | -332                  | -332    |
| Translation gains/losses   | -                | -                                 | -14      | -                     | -14     |
| Total comprehensive income   | -                | -                                 | -14      | -332                  | -346    |
|  |                  |                                   |          |                       |         |
| Transactions with owners   |                  |                                   |          |                       |         |
| New share issue, before expenses                                     | 3,347            | 255,184                           | -        | -                     | 258,531 |
| New share issue expenses   | -                | -19,670                           | -        | -                     | -19,670 |
| Employee options   | -                | -                                 | -        | 5,551                 | 5,551   |
| Total transactions with owners                                       | 3,347            | 235,514                           | -        | 5,551                 | 244,412 |
| Closing balance, August 31, 2010                                     | 14,530           | 687,438                           | 146      | -387,331              | 314,783 |
|  |                  |                                   |          |                       |         |
| Opening balance, September 1, 2009                                   | 11,183           | 451,924                           | 160      | -392,550              | 70,717  |
|  |                  |                                   |          |                       |         |
| Comprehensive income   |                  |                                   |          | 44.000                | 44.000  |
| Net loss for the period  | -                | -                                 | -        | -44,363               | -44,363 |
| Other comprehensive income   | -                | -                                 | -        | -44,363               | -44,363 |
| Translation gains/losses   | -                | -                                 | -2       | -                     | -2      |
| Total comprehensive income   | -                | -                                 | -2       | -44,363               | -44,365 |
| Transactions with owners<br>New share issue, after issue<br>expenses | 2 4 4 7          | 217 204                           |          |                       | 220 451 |
| New share issue expenses   | 3,147            | 217,304                           | -        | -                     | 220,451 |
|  |                  | -19,670                           | -        | 4 0 0 7               | -19,670 |
| Employee options<br>Total transactions with owners                   | -                | -                                 | -        | 1,827                 | 1,827   |
| Total transactions with owners                                       | 3,147            | 197,643                           | -        | 1,827                 | 202,608 |
| Closing balance, February 28, 2010                                   | 14,330           | 649,558                           | 158      | -435,086              | 228,960 |
| Opening balance, September 1, 2010                                   | 14,530           | 687,438                           | 146      | -387,331              | 314,783 |
|  |                  |                                   |          |                       |         |
| Comprehensive income   |                  |                                   |          | 470.000               | 470.000 |
| Net loss for the period  | -                | -                                 | -        | 172,620               | 172,620 |
| Other comprehensive income   | -                | -                                 | -        | 172,620               | 172,620 |
| Translation gains/losses   | •                | -                                 | 154      | -                     | 154     |
| Total comprehensive income   | -                | -                                 | 154      | 172,620               | 172,774 |
| Transactions with owners   |                  |                                   |          |                       |         |
| New share issue, after issue expenses                                | 260              | 37,299                            | -        | -                     | 37,559  |
| New share issue expenses   |                  |                                   | -        | -                     | -       |
| Employee options   | -                | -                                 | -        | 3,852                 | 3,852   |
| Total transactions with owners                                       | 260              | 37,299                            | -        | 3,852                 | 41,411  |
|  | 200              | 0.,200                            |          | 0,002                 | ,       |
| Closing balance, February 28, 2011                                   | 14,790           | 724,737                           | 300      | -210,859              | 528,968 |

# PARENT COMPANY INCOME STATEMENT

| KSEK                                | Note | 3 months<br>Dec-Feb<br>2010/2011 | 3 months<br>Dec-Feb<br>2009/2010 | 6 months<br>Sep-Feb<br>2010/2011 | 6 months<br>Sep-Feb<br>2009/2010 | 12 months<br>Sep-Aug<br>2009/2010 |
|-------------------------------------|------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|-----------------------------------|
|                                     |      |                                  |                                  |                                  |                                  |                                   |
|                                     | 2    | 440.004                          |                                  | 050 400                          |                                  | 440.000                           |
| Net sales                           | 2    | 113,934                          | -                                | 258,406                          | -                                | 112,039                           |
| Other operating income              |      |                                  | 202                              | -                                | 792                              | 3,267                             |
| Total operating income              |      | 113,934                          | 202                              | 258,406                          | 792                              | 115,306                           |
| Operating expenses                  |      |                                  |                                  |                                  |                                  |                                   |
| Personnel                           |      | -345                             | -292                             | -345                             | -292                             | -589                              |
| Other external expenses             |      | -16,059                          | -4,541                           | -37,109                          | -7,650                           | -29,207                           |
| Other operating expenses            |      | -5,605                           | -89                              | -12,361                          | -225                             | -                                 |
| Total operating expenses            |      | -22,009                          | -4,917                           | -49,815                          | -8,167                           | -29,796                           |
| OPERATING PROFIT/LOSS               |      | 91,925                           | -4,727                           | 208,591                          | -7,375                           | 85,510                            |
| Financial income and expenses       |      |                                  |                                  |                                  |                                  |                                   |
| Result from group participation     |      | -19,349                          | -21,759                          | -38,129                          | -37,209                          | -81,308                           |
| Dividend from other bonds           |      | -                                | -                                | -                                | -                                | 410                               |
| Interest income and similar items   |      | 1,946                            | 238                              | 3,551                            | 23                               | 2,499                             |
| Interest expense and similar items  |      | -                                | -                                | -                                | -8                               | -                                 |
| Total financial income and expenses |      | -17,403                          | -21,521                          | -34,578                          | -37,194                          | -78,399                           |
| Profit/Loss before tax              |      | 74,522                           | -26,238                          | 174,013                          | -44,569                          | 7,111                             |
| Taxes                               |      | -                                | -                                | -                                | -                                | -1,957                            |
| NET PROFIT/LOSS FOR THE PERIOD      |      | 74,522                           | -26,238                          | 174,013                          | -44,569                          | 5,154                             |

# PARENT COMPANY'S BALANCE SHEET

| KSEK   | Note      | Feb 28<br>2011 | Feb 28<br>2010 | Aug 31<br>2010 |
|--|-----------|----------------|----------------|----------------|
| ASSETS   |           |                |                |                |
| Non-current assets                                 |           |                |                |                |
| Intangible assets                                  |           |                |                |                |
| Acquired research and development                  |           | 16,627         | 16,627         | 16,627         |
| Financial assets                                   |           |                |                |                |
| Shares in Group companies                          |           | 1,200          | 1,200          | 1,200          |
| Receivables at Group companies                     |           | 62,115         | 4,948          | 20,612         |
| Other long-term bond holdings                      |           | 21,419         | 21,418         | 21,418         |
| Financial instruments available for sale           |           | 8,109          | -              | 9,260          |
| Total non-current assets                           |           | 109,470        | 44,193         | 69,117         |
| Current assets                                     |           |                |                |                |
| Other receivables                                  |           | 13,788         | -              | -              |
| Prepaid expenses and accrued income                |           | 183            | 1,022          | 152            |
| Financial assets that can be sold                  |           | 13,493         | 1,043          | 15,591         |
| Total trade and other receivables                  | . <u></u> | -              | 7,178          | -              |
|  |           | 27,464         | 9,243          | 15,743         |
| Liquid assets                                      |           | 440,828        | 179,573        | 478,882        |
| Total current assets                               |           | 468,292        | 188,816        | 494,625        |
| TOTAL ASSETS                                       |           | 577,762        | 233,009        | 563,742        |
| SHAREHOLDERS' EQUITY AND LIABILITIES               |           |                |                |                |
|  |           |                |                |                |
| Shareholders' equity                               |           |                |                |                |
| Restricted equity                                  |           |                | 4.4.000        |                |
| Issued capital                                     |           | 14,790         | 14,330         | 14,530         |
| Statutory reserve Non-restricted equity            |           | 96,609         | 96,609         | 96,609         |
| Share premium reserve non-restricted               |           | 369,256        | 299,561        | 337,442        |
| Profit or loss brought forward                     |           | -124,279       | -137,005       | -138,767       |
| Net profit/loss for the period                     |           | 174,013        | -44,569        | 5,154          |
| Total shareholders' equity                         |           | 530,389        | 228,926        | 314,968        |
| Liabilities to subsidiary                          |           | 47,142         | -              | 17,515         |
| Current lickilities                                |           |                |                |                |
| Current liabilities                                |           | 205            | 740            | 200            |
| Trade payables Prepaid income and accrued expenses |           | 205            | 742<br>116     | 298            |
| Total current liabilities                          |           | - 26           | 3,225          | -<br>230,961   |
|  |           | 231            | 4,083          | 230,301        |
| TOTAL EQUITY AND LIABILITIES                       | 5         | 577,762        | 233,009        | 563,742        |
|  |           |                |                |                |
| Assets pledged                                     |           | -              | -              | -              |
| Contingent liabilities                             |           | -              | -              | -              |

## Notes

# Accounting principles

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

# Note 1 – Segment results

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

| Segment results              | 2010- <sup>-</sup> | 2010-12-01 – 2011-02-28 |         |         | 2009-12-01 - 2010-02-28 |         |  |  |
|------------------------------|--------------------|-------------------------|---------|---------|-------------------------|---------|--|--|
| KSEK                         | Sweden             | USA                     | Group   | Sweden  | USA                     | Group   |  |  |
| Total net sales for segments | 125,317            | 4,378                   | 129,695 | 138     | 2,233                   | 2,371   |  |  |
| Inter-segment sales          | -10,870            | -4,315                  | -15,185 | -39     | -2,168                  | -2,207  |  |  |
| Total net sales              | 114,447            | 63                      | 114,510 | 99      | 65                      | 164     |  |  |
| Operating result             | 74,487             | -2,667                  | 71,820  | -19,319 | -7,529                  | -26,848 |  |  |

| Segment results              | 2010-09-01 – 2011-02-28 |        |         | 2009-09-01 - 2011-02-28 |        |         |  |
|------------------------------|-------------------------|--------|---------|-------------------------|--------|---------|--|
| KSEK                         | Sweden                  | USA    | Group   | Sweden                  | USA    | Group   |  |
| Total net sales for segments | 287,520                 | 7,662  | 295,182 | 138                     | 3,752  | 3,890   |  |
| Inter-segment sales          | -28,601                 | -7,599 | -36,200 | -39                     | -2,402 | -2,441  |  |
| Total net sales              | 258,919                 | 63     | 258,982 | 99                      | 1,350  | 1,449   |  |
| Operating result             | 170,456                 | -1,828 | 168,628 | -44,481                 | 96     | -44,385 |  |

#### Segment results

2009-09-01 - 2010-08-31

| KSEK                         | Sweden  | USA    | Group   |
|------------------------------|---------|--------|---------|
| Total net sales for segments | 127,350 | 7,914  | 135,219 |
| Inter-segment sales          | -14,583 | -7,608 | -22,191 |
| Total net sales              | 112,722 | 306    | 113,028 |
| Operating result             | -3,250  | 287    | -2,963  |

## Note 2 – Distribution of net sales

|  | Gro                   | oup       | Parent Company   |           |  |
|--|-----------------------|-----------|------------------|-----------|--|
|  | Dec-Feb Dec-Feb Dec-I |           | eb Dec-Feb Dec-F |           |  |
|  | 2010/2011             | 2009/2010 | 2010/2011        | 2009/2010 |  |
| Revenues from research collaboration agreement | 103,065               | -         | 103,065          | -         |  |
| Research services                              | 10,869                | -         | 10,869           | -         |  |
| Other services                                 | 576                   | 164       | -                | -         |  |
| Total  | 114,510               | 164       | 113,934          | -         |  |

|   | Gre       | oup       | Patent Company |                |  |
|---|-----------|-----------|----------------|----------------|--|
|   | Sep-Feb   | Sep-Feb   | Sep-Feb        | Sep-Feb        |  |
|   | 2010/2011 | 2009/2010 | 2010/2011      | 2009/2010      |  |
| Revenues from research collaboration<br>agreement | 229,806   | -         | 229,806        | -              |  |
| Research services                                 | 28,600    | -         | 28,600         | -              |  |
| Other services                                    | 576       | 1,449     | -              | -              |  |
| Total   | 258,982   | 1,449     | 258,406        | -              |  |
|   |           | Group     |                | Patent Company |  |
|   |           | Sep-Aug   |                | Sep-Aug        |  |
|   |           | 2009/2010 |                | 2009/2010      |  |
| Revenues from research collaboration<br>agreement |           | 97,494    |                | 97,494         |  |
| Research services                                 |           | 14,545    |                | 14,545         |  |
| Other services                                    |           | 990       |                | -              |  |
| Total   |           | 113,029   |                | 112,039        |  |

Diamyd Medical AB signed in June, 2010 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 at the closing of the agreement.

# Note 3 - Related-party transactions

During the first half year companies represented by immediate family members of the Chairman of the Board were contracted as consultants. Total compensation during the period amounted to KSEK 676 (264) excluding VAT and was attributable to IT-services. Pricing has been set by the arm's length principle. Total compensation to immediate family members of the Chairman amounted to a total of KSEK 530 (675) during the period. 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 quarter. 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.

|                                     | Sep-Feb   | Sep-Feb   | Sep-Aug   |
|-------------------------------------|-----------|-----------|-----------|
| KSEK                                | 2010/2011 | 2009/2010 | 2009/2010 |
| Purchase of intercompany services * | 36,140    | 2,441     | 22,192    |
| Salaries                            | 530       | 675       | 2,684     |
| Share-based payments                | 408       | 402       | 726       |
| Consultant fees                     | 676       | 264       | 650       |

\* Transactions between subsidiaries

#### Note 4 – Other operating expenses

Other operating expenses amounted to KSEK -13,725 and consisted of exchange rate differences. Diamyd'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 5 – Equity and liabilities

All Group debts are non-interest-bearing.

| Key figures  | 3 months<br>Dec-Feb<br>2010/2011 | 3 months<br>Dec-Feb<br>2009/2010 | 6 months<br>Sep-Feb<br>2010/2011 | 6 months<br>Sep-Feb<br>2009/2010 | 12 months<br>Sep-Aug<br>2009/2010 |
|--|----------------------------------|----------------------------------|----------------------------------|----------------------------------|-----------------------------------|
| Earnings per share before dilution, SEK                    | 2.53                             | -0.2                             | 5.89                             | -1.7                             | -0.01                             |
| Earnings per share after dilution, SEK                     | 2.51                             | -0.2                             | 5.88                             | -1.7                             | -0.01                             |
| Shareholders' equity per share, SEK                        | 18.0                             | 8.7                              | 18.0                             | 8.7                              | 10.8                              |
| Cash flow per share, SEK                                   | -0.1                             | -11.5                            | -0.8                             | 6.2                              | 16.8                              |
| Dividend, SEK  | -                                | -                                | -                                | -                                | -                                 |
| Share price, SEK   | 128.5                            | 113.0                            | 128.5                            | 113.0                            | 119.5                             |
| Closing share price/shareholders'<br>equity per share, SEK | 7.1                              | 12.9                             | 7.1                              | 12.9                             | 10.5                              |
| P/E ratio, times   | Pos                              | Neg                              | Pos                              | Neg                              | Neg                               |
| Return on equity, %  | 15.5                             | -18.6                            | 40.9                             | -29.6                            | -0.2                              |
| Solidity, %  | 95                               | 91                               | 95                               | 91                               | 55                                |
| Average number of employees                                | 29                               | 15                               | 28                               | 15                               | 19                                |
| Research and Development Costs,<br>MSEK                    | -23.7                            | -18.0                            | -45.4                            | -33.1                            | -80.8                             |
| Investment in fixed assets, KSEK                           | -                                | -                                | -                                | -                                | -                                 |
| Number of shares per closing                               | 29,579,133                       | 28,660,988                       | 29,579,133                       | 28,660,988                       | 29,060,277                        |
| Average number of shares before dilution                   | 29,458,400                       | 28,654,968                       | 29,320,280                       | 28,181,196                       | 27,595,347                        |
| Average number of shares after<br>dilution                 | 29,560,823                       | 28,654,968                       | 29,374,322                       | 28,181,196                       | 27,595,347                        |

# **Financial Calendar**

Quarterly report 3, July 1, 2011

Financial statement, October 13, 201

# 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 face the Parent Company and the companies in the Group.

# Stockholm, April 14, 2011

# The Board of Diamyd Medical AB (publ.)

| 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             |                            |

Elisabeth Lindner, President and CEO

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 II study of the candidate drug NP2 Enkephalin for cancer pain is ongoing in the US.

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.

# **For more information, please contact:** Elisabeth Lindner, President and CEO, + 46 8 661 0026

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.