



## **QUARTERLY REPORT**

September 2011 – February 2012

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

### Reporting period December 1, 2011 – February 29, 2012

- Group net sales amounted to MSEK 0.6 (114.5)
- Profit before tax amounted to MSEK -13.9 (73.7)
- Earnings per share after dilution were SEK -0.46 (2.51)
- The Group's liquid assets and short term investments amounted to MSEK 408 (474) as of February 29, 2012

### First half year, September 1, 2011 – February 29, 2012

- Group net sales amounted to MSEK 0.6 (259.0)
- Profit before tax amounted to MSEK -21.3 (172.0)
- Earnings per share after dilution were SEK -0.72 (5.88)

### Significant events during the reporting period December 1, 2011 – February 29, 2012

- Prevention study with Diamyd Medical's diabetes vaccine was fully recruited
- Medical's Phase III study was published in the New England Journal of Medicine

## CEO COMMENTS

It now only remains a few patients until we can announce that our US Phase II study in cancer pain with the drug candidate NP2 Enkephalin is fully enrolled and we continue our focused work to include the last patients in the study. We see that there is a large group of patients who are in need of more effective pain relief, and we assess the future market potential for NP2 Enkephalin to be very good. The main reason why the recruitment still takes long time is the difficulty of identifying patients suffering from severe cancer pain, yet not too ill to be able to, to be willing to, and to have the strength to participate in the study throughout the follow-up period. Based on previous experience, we estimate that it will take about two months after the last patient is included until we can present the first results.

In parallel with wrapping up the recruitment, we are preparing the documentation for an out-licensing process of products from the NTDDS platform. We will await the results from the Phase II study with NP2 Enkephalin before we begin to seek partners actively, although we are continuously in contact with various stakeholders. With positive study results, we also intend to start clinical trials with the NTDDS based candidate drug NG2 GAD in other types of pain. In addition, the preclinical development of the drug candidate NN1 Neurotrophin is continuing in accordance with the grant from the US National Institutes of Health. NN1 Neurotrophin is also based on our patented NTDDS technology and is being developed for prevention of nerve damage from chemotherapy. There is a significant medical need within the cancer care to be able to expand the use of chemotherapy without causing these severe side effects and we see a big market potential also in this area.

In January the fiftieth and final participant was included in the Swedish prevention study with the diabetes vaccine Diamyd<sup>®</sup> where healthy children, who are at high risk of developing type 1 diabetes, are treated as a preventative measure. It is reassuring that the safety profile continues to look good, which is also important for how we should proceed with the development of Diamyd<sup>®</sup>. There is interest among research groups, with funding from research grants, to evaluate the treatment both in larger prevention studies and in combination with other drugs. The diabetes vaccine recently received extra attention when the scientific journal *The New England Journal of Medicine*, published our ended European Phase III study. The paper reports on several interesting exploratory analyzes. We have also seen some effect in the few patients who were followed up for 30 months before the study was closed due to lack of efficacy, and similar immunological effects as in the previous Phase II study.

We continue to ensure that the company's cash position of about 400 million SEK is used for value-creating activities. Fixed costs are continuously being reviewed and the number of employees in Stockholm has been reduced to a minimum. Our operations in Pittsburgh, managing the development of the NTDDS platform, are prioritized and continue with preserved staffing levels.

The pending Phase II study results will provide guidance going forward and a basis for the Board in their work to establish Diamyd Medical's strategic direction. In addition, the Board is continuously evaluating new business opportunities that can create value for the company. It is with hope and confidence I look forward to the coming months.

Stockholm, April 4, 2012

Peter Zerhouni  
President and CEO Diamyd Medical AB

## **SIGNIFICANT EVENTS DURING THE REPORTING PERIOD**

### **DECEMBER 1, 2011 – FEBRUARY 29, 2012**

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

**Diamyd Medical's Phase III study published in the New England Journal of Medicine.** An article with the results of Diamyd Medical's European Phase III study of the antigen-based diabetes therapy Diamyd® has in February 2012 been published in the scientific journal the New England Journal of Medicine. The published results were previously presented at the American Diabetes Association's 71st Scientific Sessions in San Diego, California, USA, on June 28, 2011. The title of the article is "GAD65 Antigen Therapy in Recently Diagnosed Type 1 Diabetes Mellitus". The authors are J. Ludvigsson, D. Krisky, R. Casas, T. Battelino, L. Castaño, J. Greening, O. Kordonouri, T. Otonkoski, P. Pozzilli, J-J. Robert, H.J. Veeze and J. Palmer.

## BUSINESS OVERVIEW

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

### Strategy, objectives and business concept

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

### Business model

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

### Operation areas

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

## PROJECT PORTFOLIO

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

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

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

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

### The NTDDS platform

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

***Mechanism of action***

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

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

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

***Drug candidates and clinical studies***

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

***NP2 Enkephalin***

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

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

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

#### *NG2 GAD*

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

#### *NE2 Endomorphin*

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

#### *NN1 Neurotrophin*

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

technology to deliver nerve-protecting substances to nerve cells before chemotherapy is started, chemotherapy induced neuropathy could be prevented. There is a great unmet medical need to be able to expand the use of chemotherapy without causing nerve cell damage.

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

### ***Pain***

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

### ***Neuropathy (nerve cell damage)***

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

## The GAD platform

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

### *Mechanism of action*

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

### *Drug candidates and clinical studies*

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

Diamyd<sup>®</sup> for the treatment of recently diagnosed type 1 diabetes and LADA have been evaluated in several clinical trials. In 2008, Diamyd Medical launched two parallel Phase III studies with Diamyd<sup>®</sup>, one in Europe and the other in the US. Each study included approximately 330 patients recently diagnosed with type 1 diabetes. Results from the European Phase III study, announced in May 2011, showed that Diamyd<sup>®</sup> did not meet the primary efficacy endpoint of preserving beta cell function, as measured by meal-stimulated C-peptide, although a small positive effect was seen. Furthermore, Diamyd<sup>®</sup> was well tolerated, as demonstrated by a similar number of adverse events in the Diamyd<sup>®</sup> treated groups as well as in the placebo treated group. Based on the findings the Company decided, in June 2011, not to complete the follow-up period of the European Phase III study of Diamyd<sup>®</sup> and to also initiate the closure of the parallel US Phase III study. The results from the Phase III study were published in the New England Journal of Medicine in February 2012.

The Phase III studies were launched after the Company reported positive results from a 30-month Phase II study of 70 children and adolescents with type 1 diabetes. Diamyd Medical has also completed a randomized, double-blind, placebo controlled Phase II study with 47 LADA patients, in which various doses of Diamyd<sup>®</sup> were tested. A five-year follow-up of the participants showed that the risk a LADA patient will need to begin insulin treatment is significantly reduced after treatment with Diamyd<sup>®</sup> compared to placebo treatment.

### *Diamyd<sup>®</sup> - Prevention of type 1 diabetes*

In type 1 diabetes, the autoimmune attack and the destruction of blood sugar-regulating beta cells in the pancreas start long before the symptoms arise. Treatment with Diamyd<sup>®</sup> as a preventive measure is intended to intervene in the autoimmune process at an early stage, before the destruction of the

beta cell function has led to the appearance of overt symptoms, and thus prevent the disease from developing.

Diamyd<sup>®</sup> is since 2009 being evaluated in a Swedish researcher-initiated Phase II study, DiAPREV-IT. The study is double-blind and placebo-controlled and includes a total of 50 children aged four and older who through analysis of diabetes markers, so-called auto-antibodies, in the blood are demonstrated to be at high risk of developing type 1 diabetes. Half of the children receive two injections of Diamyd<sup>®</sup>, and the remaining half receive placebo (inactive substance). The children will be monitored for a total of five years by means of sampling and glucose tolerance tests to evaluate the beta cell function, a measure of the body's own ability to regulate blood sugar levels. The last participant was enrolled in the study in January 2012. The first results are expected to be compiled in 2015, three years after the last participant is enrolled. The study is being conducted by a research group at Lund University and is led by Dr. Helena Elding Larsson, a pediatrician in Malmö and researcher at Lund University. The study is funded by research grants, but Diamyd Medical has participated in the design of the study and can utilize the study results.

### ***Diabetes***

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

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

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

## FINANCIAL INFORMATION

**Net sales** – The Group's net sales for the second quarter were MSEK 0.6 (114.5). The Group's net sales for the first half year were MSEK 0.6 (259.0). The Group's net sales for the corresponding periods last year include remuneration for research services and part of an upfront payment received in connection with previously signed agreement with Ortho-Mc Neil-Janssen Pharmaceuticals, Inc.

**Costs** – Costs were MSEK 17.3 (45.2) in the second quarter. The costs for the first half year were MSEK 33.2 (92.9). The decrease in costs, compared to the same periods last year, is mainly attributable to the winding up of the Phase III program with the GAD65-based drug candidate Diamyd<sup>®</sup> and lower personnel costs. The decrease in personnel costs is attributable to having fewer employees compared to the corresponding periods last year and the exercise of employee options during the same periods last year. This fiscal year returned employee options have had a positive effect of 1.7 MSEK on personnel costs.

**Result** – Loss before tax for the first quarter was MSEK -13.9 (73.7). Loss before tax for the first half year was MSEK -21.3 (172.0).

**Financial position and liquidity** – The Group's liquid assets and short term investments were MSEK 408 (474) as of February 29, 2012. The liquid assets consist of bank account balances and interest bearing investments with an initial term to maturity of less than three months. Short term investments consist of interest bearing investments with an initial term to maturity of three to six months. During the first quarter MUS\$ 2, corresponding amount MSEK 12.8, was paid in compensation to the University of Florida Research Foundation, which has had a negative effect on the cash flow.

**Investments** – Investments in tangible assets for the second quarter were MSEK 0 (0.2). Investments in tangible assets for the first half year were MSEK 0 (0.4).

**Change in equity** – As of February 29, 2012, the Company's equity amounted to MSEK 439 (529), resulting in a solidity of 94 (95) percent.

**Organization** – The average number of employees during the first half year was 21 (27). At the end of the period the number of employees was 16 (32).

**Parent Company** – Investments for the the first half year were MSEK 0 (0). The Parent Company's net loss for the second quarter amounted to MSEK -9.9 (74.5). Net loss for the first half year amounted to -8.9 (174.0) MSEK.

**Shares** – The total number of shares in Diamyd Medical as of February 29, 2012 was 29,579,133.

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

| KSEK   | Note | 3 months<br>Dec-Feb<br>2011/2012 | 3 months<br>Dec-Feb<br>2010/2011 | 6 months<br>Sep-Feb<br>2011/2012 | 6 months<br>Sep-Feb<br>2010/2011 | 12 months<br>sep-aug<br>2010/2011 |
|--|------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|-----------------------------------|
| <b>OPERATING INCOME</b>                                      |      |                                  |                                  |                                  |                                  |                                   |
| Net sales  | 1, 2 | 582                              | 114,510                          | 636                              | 258,982                          | 280,752                           |
| Other operating income                                       |      | 1,562                            | 2,512                            | 4,140                            | 2,512                            | 7,511                             |
| <b>Total operating income</b>                                |      | <b>2,144</b>                     | <b>117,022</b>                   | <b>4,776</b>                     | <b>261,494</b>                   | <b>288,263</b>                    |
| <b>OPERATING EXPENSES</b>                                    |      |                                  |                                  |                                  |                                  |                                   |
| Raw materials and consumables                                |      | -                                | -6                               | -                                | -7                               | -7                                |
| External research and development costs                      |      | -8,793                           | -23,716                          | -16,491                          | -45,385                          | -95,976                           |
| External patent and license expenses                         |      | -651                             | -525                             | -388                             | -1,124                           | -15,957                           |
| Personnel  | 3    | -2,891                           | -9,346                           | -7,635                           | -24,308                          | -48,794                           |
| Other external expenses                                      | 3    | -3,521                           | -5,046                           | -7,099                           | -8,156                           | -15,762                           |
| Other operating expenses                                     |      | -1,351                           | -6,477                           | -1,351                           | -13,725                          | -                                 |
| Depreciation, equipment                                      |      | -127                             | -86                              | -261                             | -161                             | -428                              |
| <b>Total operating expenses</b>                              |      | <b>-17,334</b>                   | <b>-45,202</b>                   | <b>-33,225</b>                   | <b>-92,866</b>                   | <b>-176,924</b>                   |
| <b>OPERATING PROFIT/LOSS</b>                                 |      | <b>-15,190</b>                   | <b>71,820</b>                    | <b>-28,449</b>                   | <b>168,628</b>                   | <b>111,339</b>                    |
| Net Financial Income/Expense                                 | 4    | 1 318                            | 1,833                            | 7,196                            | 3,353                            | -9,496                            |
| <b>Profit/Loss before taxes</b>                              |      | <b>-13,872</b>                   | <b>73,653</b>                    | <b>-21,253</b>                   | <b>171,981</b>                   | <b>101,843</b>                    |
| Taxes  |      | 240                              | 639                              | -71                              | 639                              | 727                               |
| <b>NET PROFIT/LOSS FOR THE PERIOD</b>                        |      | <b>-13,632</b>                   | <b>74,292</b>                    | <b>-21,324</b>                   | <b>172,620</b>                   | <b>102,570</b>                    |
| <b>Other comprehensive income for the period</b>             |      |                                  |                                  |                                  |                                  |                                   |
| Translation gains/losses                                     |      | 151                              | 110                              | -50                              | 154                              | 120                               |
| <b>Other comprehensive income for the period, net of tax</b> |      | <b>151</b>                       | <b>110</b>                       | <b>-50</b>                       | <b>154</b>                       | <b>120</b>                        |
| <b>TOTAL COMPREHENSIVE INCOME FOR THE PERIOD</b>             |      | <b>-13,481</b>                   | <b>74,402</b>                    | <b>-21,374</b>                   | <b>172,774</b>                   | <b>102,690</b>                    |
| Earnings per share before dilution, SEK                      |      | -0.46                            | 2.53                             | -0.72                            | 5.89                             | 3.48                              |
| Earnings per share after dilution, SEK                       |      | -0.46                            | 2.51                             | -0.72                            | 5.88                             | 3.48                              |
| Number of shares per closing day                             |      | 29,579,133                       | 29,579,133                       | 29,579,133                       | 29,579,133                       | 29,579,133                        |
| Average number of shares before dilution                     |      | 29,579,133                       | 29,458,400                       | 29,579,133                       | 29,320,280                       | 29,449,348                        |
| Average number of shares after dilution                      |      | 29,579,133                       | 29,560,823                       | 29,579,133                       | 29,374,322                       | 29,477,301                        |

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

| KSEK  | Note | Feb 29<br>2012 | Feb 28<br>2011 | Aug 31<br>2011 |
|---|------|----------------|----------------|----------------|
| <b>ASSETS</b>                                       |      |                |                |                |
| <b>Non-current assets</b>                           |      |                |                |                |
| Intangible assets                                   |      | 16,627         | 16,627         | 16,627         |
| Tangible assets                                     |      | 2,011          | 1,005          | 2,224          |
| Financial assets                                    |      | 29,835         | 29,527         | 29,241         |
| <b>Total non-current assets</b>                     |      | <b>48,473</b>  | <b>47,159</b>  | <b>48,092</b>  |
| <b>Current assets</b>                               |      |                |                |                |
| Inventory   |      | 5              | 15             | 5              |
| Trade receivables                                   |      | 37             | 14,296         | 15,179         |
| Other receivables                                   |      | 3,860          | 3,854          | 15,240         |
| Prepaid expenses and accrued income                 |      | 5,450          | 15,341         | 5,445          |
| Short term investments                              |      | 231,941        | 297,501        | 277,859        |
| Liquid assets                                       |      | 176,529        | 176,130        | 157,782        |
| <b>Total current assets</b>                         |      | <b>417,822</b> | <b>507,137</b> | <b>471,510</b> |
| <b>TOTAL ASSETS</b>                                 |      | <b>466,295</b> | <b>554,296</b> | <b>519,602</b> |
| <b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>         |      |                |                |                |
| <b>Shareholders' equity</b>                         |      |                |                |                |
| Share capital                                       |      | 14,790         | 14,790         | 14,790         |
| Other capital contributions                         |      | 724,737        | 724,737        | 724,737        |
| Other reserves                                      |      | 216            | 300            | 266            |
| Accumulated losses including results for the period |      | -300,504       | -210,859       | -278,819       |
| <b>Total shareholders' equity</b>                   |      | <b>439,239</b> | <b>528,968</b> | <b>460,974</b> |
| <b>Non-current liabilities</b>                      |      |                |                |                |
| Other liabilities                                   |      | 738            | -              | -              |
| <b>Total non-current liabilities</b>                |      | <b>738</b>     | <b>-</b>       | <b>-</b>       |
| <b>Current liabilities</b>                          |      |                |                |                |
| Trade payables                                      |      | 8,353          | 9,504          | 9,182          |
| Other payables                                      |      | 1,322          | 1,781          | 15,323         |
| Prepaid income and accrued expenses                 |      | 16,643         | 14,043         | 34,123         |
| <b>Total current liabilities</b>                    |      | <b>26,318</b>  | <b>25,328</b>  | <b>58,628</b>  |
| <b>TOTAL EQUITY AND LIABILITIES</b>                 | 5    | <b>466,295</b> | <b>554,296</b> | <b>519,602</b> |

## CONSOLIDATED STATEMENT OF CASH FLOW

| KSEK   | Note | 3 months<br>Dec-Feb<br>2011/2012 | 3 months<br>Dec-Feb<br>2010/2011 | 6 months<br>Sep-Feb<br>2011/2012 | 6 months<br>Sep-Feb<br>2010/2011 | 12 months<br>Sep-Aug<br>2010/2011 |
|--|------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|-----------------------------------|
| <b>Cash flow from operations before changes in working capital</b>               |      |                                  |                                  |                                  |                                  |                                   |
| Operating profit/loss  |      | -15,190                          | 71,820                           | -28,449                          | 168,628                          | 111,339                           |
| Interest received  |      | 3,257                            | 2,137                            | 7,810                            | 2,734                            | 4,568                             |
| Interest paid  |      | -28                              | -8                               | -42                              | -11                              | -8,329                            |
| Dividend received  |      | -                                | -                                | -                                | -                                | 410                               |
| <i>Non-cash flow items</i>   |      |                                  |                                  |                                  |                                  |                                   |
| Depreciation   |      | 127                              | 86                               | 261                              | 161                              | 428                               |
| Other non-cash flow items  | 6    | 191                              | -94,274                          | -299                             | -211,401                         | -210,015                          |
| <b>Net cash flow from operating activities before changes in working capital</b> |      |                                  |                                  |                                  |                                  |                                   |
|  |      | <b>-11,643</b>                   | <b>-20,239</b>                   | <b>-20,719</b>                   | <b>-39,889</b>                   | <b>-101,599</b>                   |
| Increase (-) decrease (+)  |      |                                  |                                  |                                  |                                  |                                   |
| inventory  |      | 0                                | 3                                | 0                                | 1                                | 10                                |
| Increase (-) decrease (+)  |      |                                  |                                  |                                  |                                  |                                   |
| receivables  |      | 11,412                           | 6,770                            | 25,614                           | -11,625                          | -13,689                           |
| Increase (+) decrease (-)  |      |                                  |                                  |                                  |                                  |                                   |
| liabilities  |      | -3,284                           | -12,077                          | -32,701                          | -13,098                          | 21,251                            |
| <b>Net cash flow from operating activities</b>                                   |      |                                  |                                  |                                  |                                  |                                   |
|  |      | <b>-3,515</b>                    | <b>-25,543</b>                   | <b>-27,806</b>                   | <b>-64,611</b>                   | <b>-94,027</b>                    |
| <b>Cash flow from investing activities</b>                                       |      |                                  |                                  |                                  |                                  |                                   |
| Increase (-) decrease (+) short  |      |                                  |                                  |                                  |                                  |                                   |
| term investments   |      | 25,935                           | 34,810                           | 45,918                           | -297,501                         | -277,859                          |
| Purchase of tangible assets  |      | -41                              | -156                             | -42                              | -379                             | -1,928                            |
| Sale of equipment  |      | 16                               | -                                | 16                               | -                                | -                                 |
| <b>Net cash flow from investing activities</b>                                   |      |                                  |                                  |                                  |                                  |                                   |
|  |      | <b>25,910</b>                    | <b>34,654</b>                    | <b>45,892</b>                    | <b>-297,880</b>                  | <b>-279,787</b>                   |
| <b>Cash flow from financing activities</b>                                       |      |                                  |                                  |                                  |                                  |                                   |
| New share issue after issue  |      |                                  |                                  |                                  |                                  |                                   |
| expenses   |      | -                                | 21,837                           | -                                | 37,559                           | 37,559                            |
| <b>Cash flow from financing activities</b>                                       |      |                                  |                                  |                                  |                                  |                                   |
|  |      | <b>-</b>                         | <b>21,837</b>                    | <b>-</b>                         | <b>37,559</b>                    | <b>37,559</b>                     |
| <b>Total cash flow for the period</b>  |      |                                  |                                  |                                  |                                  |                                   |
|  |      | <b>22,395</b>                    | <b>30,948</b>                    | <b>18,086</b>                    | <b>-324,932</b>                  | <b>-336,255</b>                   |
| Cash and cash equivalents at   |      |                                  |                                  |                                  |                                  |                                   |
| beginning of period  |      | 155,872                          | 145,341                          | 157,782                          | 501,332                          | 501,332                           |
| Net foreign exchange difference  |      |                                  |                                  |                                  |                                  |                                   |
|  |      | -1,738                           | -159                             | 661                              | -270                             | -7,295                            |
| <b>Cash and cash equivalents at end of period</b>                                |      |                                  |                                  |                                  |                                  |                                   |
|  |      | <b>176,529</b>                   | <b>176,130</b>                   | <b>176,529</b>                   | <b>176,130</b>                   | <b>157,782</b>                    |

## CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

| KSEK                                      | Share<br>Capital | Other<br>capital<br>contri-<br>butions | Reserves   | Accu-<br>mulated<br>losses | Total          |
|---|------------------|--|------------|----------------------------|----------------|
| <b>Sep 1, 2010 – Aug 31, 2011</b>         |                  |  |            |                            |                |
| <b>Opening balance, September 1, 2010</b> | <b>14,530</b>    | <b>687,438</b>                         | <b>146</b> | <b>-387,331</b>            | <b>314,783</b> |
| <b>Comprehensive income</b>               |                  |  |            |                            |                |
| Net loss for the period                   | -                | -                                      | -          | 102,570                    | 102,570        |
| Translation gains/losses                  | -                | -                                      | 120        | -                          | 120            |
| <b>Total comprehensive income</b>         | <b>-</b>         | <b>-</b>                               | <b>120</b> | <b>102,570</b>             | <b>102,690</b> |
| <b>Transactions with owners</b>           |                  |  |            |                            |                |
| New share issue                           | 260              | 37,299                                 | -          | -                          | 37,559         |
| New share issue expenses                  | -                | -                                      | -          | -                          | -              |
| Employee options                          | -                | -                                      | -          | 5,942                      | 5,942          |
| <b>Total transactions with owners</b>     | <b>260</b>       | <b>37,299</b>                          | <b>-</b>   | <b>5,942</b>               | <b>43,501</b>  |
| <b>Closing balance, August 31, 2011</b>   | <b>14,790</b>    | <b>724,737</b>                         | <b>266</b> | <b>-278,819</b>            | <b>460,974</b> |
| <b>Sep 1, 2010 – Feb 28, 2011</b>         |                  |  |            |                            |                |
| <b>Opening balance, September 1, 2010</b> | <b>14,530</b>    | <b>687,438</b>                         | <b>146</b> | <b>-387,331</b>            | <b>314,783</b> |
| <b>Comprehensive income</b>               |                  |  |            |                            |                |
| Net loss for the period                   | -                | -                                      | -          | 172,620                    | 172,620        |
| Translation gains/losses                  | -                | -                                      | 154        | -                          | 154            |
| <b>Total comprehensive income</b>         | <b>-</b>         | <b>-</b>                               | <b>154</b> | <b>172,620</b>             | <b>172,774</b> |
| <b>Transactions with owners</b>           |                  |  |            |                            |                |
| New share issue                           | 260              | 37,299                                 | -          | -                          | 37,559         |
| New share issue expenses                  | -                | -                                      | -          | -                          | -              |
| Employee options                          | -                | -                                      | -          | 3,852                      | 3,852          |
| <b>Total transactions with owners</b>     | <b>260</b>       | <b>37,299</b>                          | <b>-</b>   | <b>3,852</b>               | <b>41,411</b>  |
| <b>Closing balance, 28 February 2011</b>  | <b>14,790</b>    | <b>724,737</b>                         | <b>300</b> | <b>-210,859</b>            | <b>528,968</b> |
| <b>Sep 1, 2011 – Feb 29, 2012</b>         |                  |  |            |                            |                |
| <b>Opening balance, September 1, 2011</b> | <b>14,790</b>    | <b>724,737</b>                         | <b>266</b> | <b>-278,819</b>            | <b>460,974</b> |
| <b>Comprehensive income</b>               |                  |  |            |                            |                |
| Net loss for the period                   | -                | -                                      | -          | -21,324                    | -21,324        |
| Translation gains/losses                  | -                | -                                      | -50        | -                          | -50            |
| <b>Total comprehensive income</b>         | <b>-</b>         | <b>-</b>                               | <b>-50</b> | <b>-21,324</b>             | <b>-21,374</b> |
| <b>Transactions with owners</b>           |                  |  |            |                            |                |
| New share issue                           | -                | -                                      | -          | -                          | -              |
| New share issue expenses                  | -                | -                                      | -          | -                          | -              |
| Employee options                          | -                | -                                      | -          | -361                       | -361           |
| <b>Total transactions with owners</b>     | <b>-</b>         | <b>-</b>                               | <b>-</b>   | <b>-361</b>                | <b>-361</b>    |
| <b>Closing balance, February 29, 2012</b> | <b>14,790</b>    | <b>724,737</b>                         | <b>216</b> | <b>-300,504</b>            | <b>439,239</b> |

## PARENT COMPANY INCOME STATEMENT

| KSEK                                       | Note | 3 months<br>Dec-Feb<br>2011/2012 | 3 months<br>Dec-Feb<br>2010/2011 | 6 months<br>Sep-Feb<br>2011/2012 | 6 months<br>Sep-Feb<br>2010/2011 | 12 months<br>Sep-Aug<br>2010/2011 |
|--|------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|-----------------------------------|
| <b>OPERATING INCOME</b>                    |      |                                  |                                  |                                  |                                  |                                   |
| Net sales                                  | 2    | -                                | 113,934                          | -                                | 258,406                          | 280,110                           |
| Other operating income                     |      | -                                | -                                | -                                | -                                | -                                 |
| <b>Total operating income</b>              |      | -                                | <b>113,934</b>                   | -                                | <b>258,406</b>                   | <b>280,110</b>                    |
| <b>Operating expenses</b>                  |      |                                  |                                  |                                  |                                  |                                   |
| Personnel                                  |      | -                                | -345                             | -                                | -345                             | -785                              |
| Other external expenses                    |      | -12,030                          | -16,059                          | -16,251                          | -37,109                          | -68,913                           |
| Other operating expenses                   |      | -701                             | -5,605                           | -163                             | -12,361                          | -220                              |
| <b>Total operating expenses</b>            |      | <b>-12,731</b>                   | <b>-22,009</b>                   | <b>-16,414</b>                   | <b>-49,815</b>                   | <b>-69,918</b>                    |
| <b>OPERATING PROFIT/LOSS</b>               |      | <b>-12,731</b>                   | <b>91,925</b>                    | <b>-16,414</b>                   | <b>208,591</b>                   | <b>210,192</b>                    |
| <b>Financial income and expenses</b>       |      |                                  |                                  |                                  |                                  |                                   |
| Result from group participation            |      | 1,277                            | -19,349                          | 361                              | -38,129                          | -74,234                           |
| Dividend from holdings                     |      | -                                | -                                | -                                | -                                | 410                               |
| Interest income and similar items          |      | 1,525                            | 1,946                            | 7,201                            | 3,551                            | 6,678                             |
| Interest expense and similar items         |      | -                                | -                                | -15                              | -                                | -13,900                           |
| <b>Total financial income and expenses</b> |      | <b>2,802</b>                     | <b>-17,403</b>                   | <b>7,547</b>                     | <b>-34,578</b>                   | <b>-81,046</b>                    |
| <b>Profit/Loss before tax</b>              |      | <b>-9,929</b>                    | <b>74,522</b>                    | <b>-8,867</b>                    | <b>174,013</b>                   | <b>129,146</b>                    |
| Taxes                                      |      | -                                | -                                | -                                | -                                | -53,547                           |
| <b>NET PROFIT/LOSS FOR THE PERIOD</b>      |      | <b>-9,929</b>                    | <b>74,522</b>                    | <b>-8,867</b>                    | <b>174,013</b>                   | <b>75,599</b>                     |

## PARENT COMPANY'S BALANCE SHEET

| KSEK  | Note | Feb 29<br>2012 | Feb 29<br>2011 | Aug 31<br>2011 |
|---|------|----------------|----------------|----------------|
| <b>ASSETS</b>                               |      |                |                |                |
| <b>Non-current assets</b>                   |      |                |                |                |
| <i>Intangible assets</i>                    |      |                |                |                |
| Acquired research and development           |      | 16,627         | 16,627         | 16,627         |
| <i>Financial assets</i>                     |      |                |                |                |
| Shares in Group companies                   |      | 1,200          | 1,200          | 1,200          |
| Receivables at Group companies              |      | 8,807          | 62,115         | 8,687          |
| Other long-term bond holdings               |      | 29,241         | 21,419         | 29,241         |
| Financial instruments available for sale    |      | -              | 8,109          | -              |
| <b>Total non-current assets</b>             |      | <b>55,875</b>  | <b>109,470</b> | <b>55,755</b>  |
| <b>Current assets</b>                       |      |                |                |                |
| Trade receivables                           |      | -              | 13,788         | 15,107         |
| Other receivables                           |      | 1,331          | 183            | 13,562         |
| Prepaid expenses and accrued income         |      | 4,597          | 13,493         | 4,919          |
| <b>Total trade and other receivables</b>    |      | <b>5,928</b>   | <b>27,464</b>  | <b>33,588</b>  |
| Short term investments                      |      | 231,941        | 297,501        | 277,859        |
| Liquid assets                               |      | 152,695        | 143,327        | 143,228        |
| <b>Total current assets</b>                 |      | <b>390,564</b> | <b>468,292</b> | <b>454,675</b> |
| <b>TOTAL ASSETS</b>                         |      | <b>446,439</b> | <b>577,762</b> | <b>510,430</b> |
| <b>SHAREHOLDERS' EQUITY AND LIABILITIES</b> |      |                |                |                |
| <b>Shareholders' equity</b>                 |      |                |                |                |
| <b>Restricted equity</b>                    |      |                |                |                |
| Issued capital                              |      | 14,790         | 14,790         | 14,790         |
| Statutory reserve                           |      | 96,609         | 96,609         | 96,609         |
| <b>Non-restricted equity</b>                |      |                |                |                |
| Share premium reserve non-restricted        |      | 374,741        | 369,256        | 374,741        |
| Profit or loss brought forward              |      | -202,488       | -124,279       | -277,726       |
| Net profit/loss for the period              |      | -8,867         | 174,013        | 75,599         |
| <b>Total shareholders' equity</b>           |      | <b>274,785</b> | <b>530,389</b> | <b>284,013</b> |
| Liabilities to subsidiary                   | 7    | 162,720        | 47,142         | 224,934        |
| <b>Current liabilities</b>                  |      |                |                |                |
| Trade payables                              |      | 5,325          | 205            | 1,091          |
| Other payables                              |      | 3,271          | -              | 392            |
| Prepaid income and accrued expenses         |      | 338            | 26             | -              |
| <b>Total current liabilities</b>            |      | <b>8,934</b>   | <b>231</b>     | <b>1,483</b>   |
| <b>TOTAL EQUITY AND LIABILITIES</b>         |      | <b>446,439</b> | <b>577,762</b> | <b>510,430</b> |
| 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 performance measurement that is followed up is the operating result.

| Segment results 3 months     | 2011-12-01 – 2012-02-29 |         |        | 2010-12-01 – 2011-02-28 |         |        |         |
|------------------------------|-------------------------|---------|--------|-------------------------|---------|--------|---------|
|                              | KSEK                    | Sweden  | USA    | Group                   | Sweden  | USA    | Group   |
| Total net sales for segments |                         | 558     | 9,773  | 10,331                  | 125,317 | 4,378  | 129,317 |
| Inter-segment sales          |                         | -       | -9,749 | -9,749                  | -10,870 | -4,315 | -15,185 |
| Total net sales              |                         | 558     | 24     | 582                     | 114,447 | 63     | 114,510 |
| Operating result             |                         | -15,270 | 79     | -15,190                 | 74,487  | -2,667 | 71,820  |

  

| Segment results 6 months     | 2011-09-01 – 2012-02-29 |         |         | 2010-09-01 – 2011-02-28 |         |        |         |
|------------------------------|-------------------------|---------|---------|-------------------------|---------|--------|---------|
|                              | KSEK                    | Sweden  | USA     | Group                   | Sweden  | USA    | Group   |
| Total net sales for segments |                         | 558     | 13,161  | 13,719                  | 287,520 | 7,662  | 295,182 |
| Inter-segment sales          |                         | -       | -13,083 | -13,083                 | -28,601 | -7,599 | -36,200 |
| Total net sales              |                         | 558     | 78      | 636                     | 258,919 | 63     | 258,982 |
| Operating result             |                         | -27,963 | -486    | -28,449                 | 170,456 | -1,828 | 168,628 |

  

| Segment results 12 months    | 2010-09-01 – 2011-08-31 |         |         |         |
|------------------------------|-------------------------|---------|---------|---------|
|                              | KSEK                    | Sweden  | USA     | Group   |
| Total net sales for segments |                         | 330,905 | 17,039  | 347,944 |
| Inter-segment sales          |                         | -50,255 | -16,937 | -67,192 |
| Total net sales              |                         | 280,650 | 102     | 280,752 |
| Operating result             |                         | 113,149 | -1,810  | 111,339 |

*Note 2 – Distribution of net sales*

| Distribution of net sales 3 months             | Group      |                | Parent Company |                |
|--|------------|----------------|----------------|----------------|
|  | Dec-Feb    | Dec-Feb        | Dec-Feb        | Dec-Feb        |
|  | 2011/2012  | 2010/2011      | 2011/2012      | 2010/2011      |
| Revenues from research collaboration agreement | -          | 103,065        | -              | 103,065        |
| Research services                              | -          | 10,869         | -              | 10,869         |
| Other services                                 | 582        | 576            | -              | -              |
| <b>Total</b>                                   | <b>582</b> | <b>114,510</b> | <b>-</b>       | <b>113,934</b> |

| Distribution of net sales 6 months             | Group      |                | Parent Company |                |
|--|------------|----------------|----------------|----------------|
|  | Sep-Feb    | Sep-Feb        | Sep-Feb        | Sep-Feb        |
|  | 2011/2012  | 2010/2011      | 2011/2012      | 2010/2011      |
| Revenues from research collaboration agreement | -          | 229,806        | -              | 229,806        |
| Research services                              | -          | 28,600         | -              | 28,600         |
| Other services                                 | 636        | 576            | -              | -              |
| <b>Total</b>                                   | <b>636</b> | <b>258,982</b> | <b>-</b>       | <b>258,406</b> |

| Distribution of net sales 12 months            | Group     |                | Parent Company |                |
|--|-----------|----------------|----------------|----------------|
|  | Sep-Aug   | Sep-Aug        | Sep-Aug        | Sep-Aug        |
|  | 2010/2011 | 2010/2011      | 2010/2011      | 2010/2011      |
| Revenues from research collaboration agreement |           | 229,806        |                | 229,806        |
| Research services                              |           | 50,304         |                | 50,304         |
| Other services                                 |           | 642            |                | -              |
| <b>Total</b>                                   |           | <b>280,752</b> |                | <b>280,110</b> |

*Note 3 – Related-party transactions*

During the period companies represented by immediate family members of the Chairman of the Board were contracted as consultants. Total compensation during the period amounted to KSEK 456 (676) 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 268 (530) 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 period. Neither has the Company given any loans, provided any guarantees or surety to or for the benefit of any member of the Board of Directors, key executives or auditors in the Company.

| KSEK                                    | Sep-Feb<br>2011/2012 | Sep-Feb<br>2010/2011 | Sep-Aug<br>2010/2011 |
|---|----------------------|----------------------|----------------------|
| Purchase of intercompany services*      | 13,083               | 36,140               | 67,192               |
| Salaries to related parties             | 268                  | 530                  | 1,011                |
| Share-based payments to related parties | 156                  | 408                  | 639                  |
| Consultant fees to related parties      | 456                  | 676                  | 1,422                |

\*Transactions between subsidiaries

*Note 4 – Net Financial Income/Expense*

Net Financial Income/Expense for the first half year amounts to MSEK 7.2 and consists of interest income of MSEK 4.9 on liquid assets and short term investments and a positive exchange rate difference of MSEK 2.3.

*Note 5 – Equity and liabilities*

All Group debts are non-interest-bearing.

**Note 6 – Other non-cash flow items**

The previous year's amount includes part of accrued up-front payment.

**Note 7 – Liabilities to subsidiary**

The amount includes Group contribution to Diamyd Therapeutics AB accounted for last year.

| <b>Key figures</b>                              | <b>3 months<br/>Dec-Feb<br/>2011/2012</b> | <b>3 months<br/>Dec-Feb<br/>2010/2011</b> | <b>6 months<br/>Sep-Feb<br/>2011/2012</b> | <b>6 months<br/>Sep-Feb<br/>2010/2011</b> | <b>12 months<br/>Sep-Aug<br/>2010/2011</b> |
|---|---|---|---|---|--|
| Earnings per share before dilution, SEK         | -0.5                                      | 2.5                                       | -0.7                                      | 5.9                                       | 3.5  |
| Earnings per share after dilution, SEK          | -0.5                                      | 2.5                                       | -0.7                                      | 5.9                                       | 3.5  |
| Research and development costs, MSEK            | -8.8                                      | -23.7                                     | -16.5                                     | -45.4                                     | -96.0                                      |
| Shareholders' equity per share, SEK             | 14.8                                      | 18.0                                      | 14.8                                      | 18.0                                      | 15.7                                       |
| Cash flow per share, SEK                        | 0.8                                       | 1.1                                       | 0.6                                       | -11.1                                     | -11.4                                      |
| Return on equity, %                             | -3.1                                      | 15.5                                      | -4.7                                      | 40.9                                      | 26.4                                       |
| Solidity, %                                     | 94.2                                      | 95  | 94.2                                      | 95  | 89   |
| Share price per closing, SEK                    | 11.0                                      | 128.5                                     | 11.0                                      | 128.5                                     | 9.0  |
| Share price/shareholders' equity per share, SEK | 0.7                                       | 7.1                                       | 0.7                                       | 7.1                                       | 0.6  |
| Number of shares per closing                    | 29,579,133                                | 29,579,133                                | 29,579,133                                | 29,579,133                                | 29,579,133                                 |
| Average number of shares before dilution        | 29,579,133                                | 29,458,400                                | 29,579,133                                | 29,320,280                                | 29,449,348                                 |
| Average number of shares after dilution         | 29,579,133                                | 29,560,823                                | 29,579,133                                | 29,374,322                                | 29,477,301                                 |

**Significant risks and uncertainties**

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

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

**This interim report has been reviewed by the Company's auditors.**

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

**Stockholm, April 4, 2012**

Anders Essen-Möller, Chairman of the Board

Lars Jonsson, Board Member

Maria-Teresa Essen-Möller, Board Member

Christer Lindberg, Board Member

Joseph Janes, Board Member

Peter Zerhouni, President and CEO

**About Diamyd Medical**

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

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

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

**For more information, please contact:**

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



## **Report of Review of Interim Financial Information**

### **Introduction**

We have reviewed this report for the period September 1, 2011 to February 29, 2012 for Diamyd Medical AB (publ). The board of directors and the CEO are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Swedish Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

### **Scope of Review**

We conducted our review in accordance with the Swedish Standard on Review Engagements SÖG 2410, Review of Interim Report Performed by the Independent Auditor of the Entity. A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing, ISA, and other generally accepted auditing standards in Sweden. The procedures performed in a review do not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

### **Conclusion**

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, in accordance with IAS 34 and the Swedish Annual Accounts Act, regarding the Group, and with the Swedish Annual Accounts Act, regarding the Parent Company.

Stockholm, April 4, 2012

Öhrlings PricewaterhouseCoopers AB

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Eva Blom

Authorised Public Accountant