DIAMYD MEDICAL

Annual Report 2022/2023

Precision medicine for autoimmune diabetes

Contents

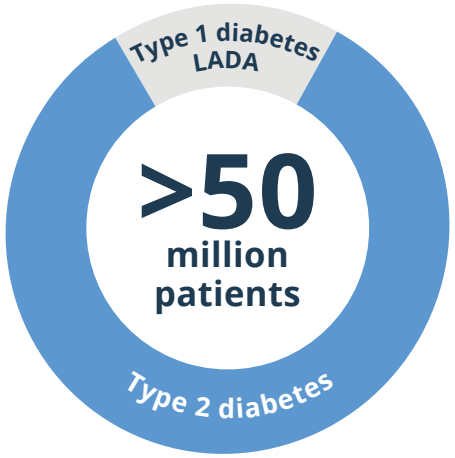
Diamyd Medical – an overview

Diamyd Medical develops precision medicine therapies for type 1 diabetes and other forms of autoimmune diabetes. The Diamyd® immunotherapy is currently being assessed in the DIAGNODE-3 trial, a registrational Phase III trial that is taking place at approximately 60 clinics across Europe and the US.

Diamyd Medical is a growing diabetes company that develops therapies for the treatment of autoimmune diabetes. The Company operates through its head office in Stockholm and has its own production facility in Umeå. The facility in Umeå is currently being prepared for the manufacture of GAD65, the active compound in Diamyd®. Diamyd® is an antigen-specific immunotherapy to preserve endogenous insulin production in patients with type 1 diabetes and also, potentially, with latent autoimmune diabetes in adults (LADA).

A previously completed meta-analysis and clinical trials show significant efficacy of Diamyd® in a genetically defined subpopulation of patients newly diagnosed with type 1 diabetes. About 40% of the total population with type 1 diabetes belongs to this genetic cohort. A registrational Phase III trial with Diamyd®, DIAGNODE-3, is currently taking place at approximately 60 clinics across Europe and the US.

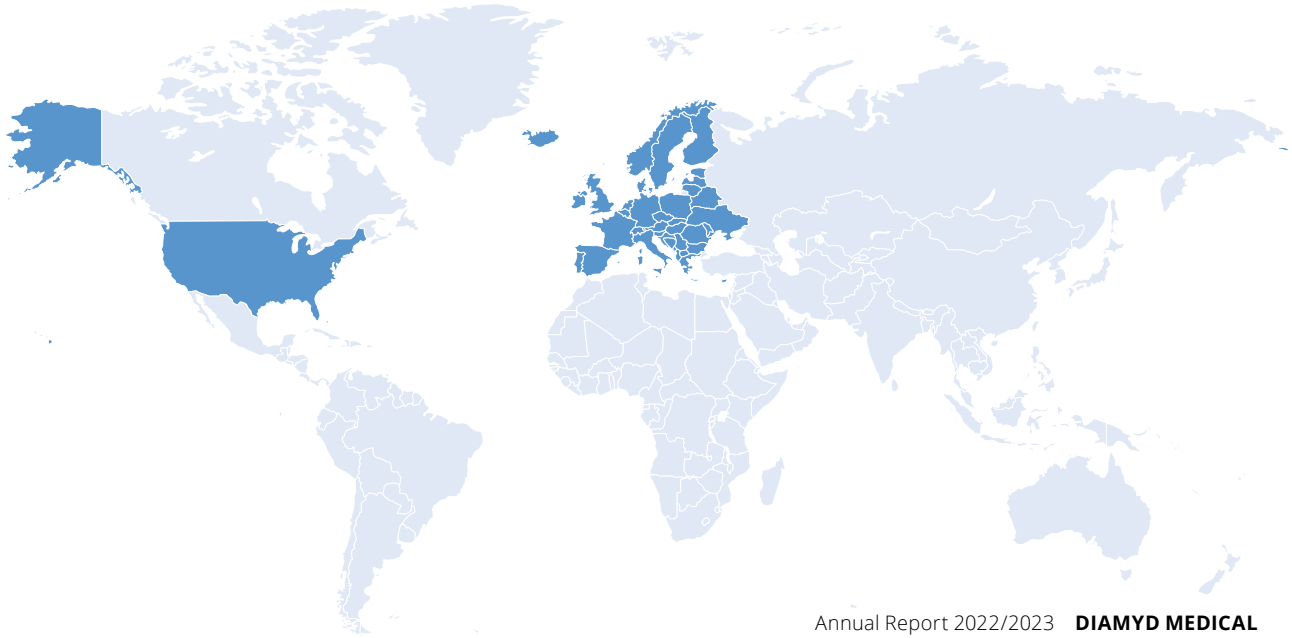
AUTOIMMUNE DIABETES



Of the 537 million[1)] who suffer from diabetes today more than 10% have autoimmune diabetes.

[1)] *IDF Diabetes Atlas 2021 - 10th edition*

ONGOING TRIALS IN EUROPE AND THE US



Steps towards the goal

Milestones along the path to approval and launch of the precision medicine therapy with Diamyd®

2019

ANALYSIS

Meta-analysis of earlier trials shows efficacy of Diamyd® in a genetically defined subpopulation with type 1 diabetes.

2020

MANUFACTURE

Start for establishment of own GAD65 manufacturing in Umeå.

PUBLICATION

The peer-reviewed medical journal Diabetologia publishes a meta-analysis of the efficacy of Diamyd® in a genetically defined subpopulation with type 1 diabetes.

ANALYSIS

Earlier prevention trials and a pilot study support the efficacy of Diamyd® in children at risk of type 1 diabetes who carry the HLA DR3-DQ2 genotype.

RESULTS

Topline results from the Phase IIb DIAGNODE-2 trial show the significant efficacy of Diamyd® in a genetically defined subpopulation with type 1 diabetes.

2021

ANALYSIS

Updated meta-analysis includes the results from DIAGNODE-2, providing further support for the efficacy of Diamyd® in a genetically defined subpopulation with type 1 diabetes.

PUBLICATION

The peer-reviewed medical journal Diabetes Care publishes results from the Phase IIb DIAGNODE-2 trial demonstrating the efficacy of Diamyd® in a genetically defined subpopulation with type 1 diabetes.

PATENT

A European patent is granted for the use of GAD65 to prevent or treat autoimmune diabetes in a genetically defined subpopulation.

2022

CLINICAL TRIAL

Intitation of the Phase III DIAGNODE-3 trial, where Diamyd® is given to type 1 diabetes patients who carry the HLA DR3-DQ2 genotype.

RESULTS

Primary endpoints for safety and tolerability are met and support the efficacy of Diamyd® in the Phase II GADinLADA clinical trial in LADA patients who carry the HLA DR3-DQ2 genotype.

COLLABORATION

Diamyd Medical joins the Critical Path Institute, an international organization with a Type 1 Diabetes consortium (T1DC).

PUBLICATIONS

The peer-reviewed medical journal Diabetes, Obesity and Metabolism publishes results from the updated meta-analysis of previous Diamyd® trials.

The peer-reviewed Journal of Endocrinology and Metabolism publishes results based on DIAGNODE-2 showing how Diamyd® improves glycemic control.

2023

REGULATORY

The FDA authorizes initiation of the Phase III DIAGNODE-3 trial in the US. The trial commences in the US later in the year.

CLINICAL TRIAL

Initiation of the DiaPrecise trial is approved by the Medical Products Agency and the Swedish Ethical Review Authority. The trial is assessing the safety of Diamyd® in children at risk of type 1 diabetes who carry the HLA DR3-DQ2 genotype.

COLLABORATION

Diamyd Medical and JDRF enter into a four-year research and development collaboration, including funding of MUSD 5 to Diamyd Medical for the Phase III DIAGNODE-3 trial.

PUBLICATION

The peer-reviewed medical journal Diabetes, Obesity and Metabolism publishes results from the GADinLADA trial, which show safety and support for efficacy in a genetically defined subpopulation with LADA.

The year in brief

Significant events during the financial year

- **FDA approved initiation of the DIAGNODE-3 trial in the US** – In November 2022, the FDA lifted the partial clinical hold on the Phase III DIAGNODE-3 trial to evaluate the precision medicine and antigen-specific immunotherapy Diamyd® in individuals newly diagnosed with type 1 diabetes. Following the FDA's decision, the initiation of DIAGNODE-3 in the US was approved.
- **Precision medicine patent for prevention and treatment of autoimmune diabetes granted for Eurasia** – The patent was granted by the Eurasian Patent Office and will remain valid until 2035. The patent primarily protects the use of a GAD autoantigen for treating or preventing autoimmune diabetes in individuals who carry the HLA DR3-DQ2 genotype. GAD is the active ingredient in the antigen-specific immunotherapy Diamyd® which is being evaluated in the confirming Phase III DIAGNODE-3 trial.
- **Initiation of the DiaPrecise trial approved by the Medical Products Agency and the Swedish Ethical Review Authority**
  DiaPrecise is an open-label prevention trial with the antigen-specific immunotherapy Diamyd®. The trial is assessing the safety, feasibility and immune response of intralymphatic injections of Diamyd® in children at risk of type 1 diabetes, who also carry the HLA DR3-DQ2 genotype. DiaPrecise is part of the AI for the Sustainable Prevention of Autoimmune in Society (ASSET) program, coordinated by Diamyd Medical and funded by the Swedish Agency for Innovation Systems (VINNOVA).
- **Diamyd Medical and JDRF formed a collaboration for DIAGNODE-3** – Diamyd Medical and JDRF, the leading global organization for research and advocacy in type 1 diabetes, entered into a four-year research and development collaboration, including funding of MUSD 5 to Diamyd Medical to support the ongoing Phase III trial with the precision medicine antigen-specific immunotherapy Diamyd®.
- **Topline results from the ReGenerate trial** – The trial assessing treatment with the GABA-based compound Remygen® met the primary safety endpoint. However, there was no clear support for a sustained treatment effect on increasing endogenous insulin production measured as C peptide, or the prevention of hypoglycemia (low blood sugar) in individuals with lifelong type 1 diabetes.
- **Rights issue raised MSEK 75** – Diamyd Medical implemented a rights issue that raised proceeds of about MSEK 75 for the Company less issue expenses. 8,351,941 Class B shares were subscribed by exercising subscription rights, and 503,434 Class B shares without subscription rights.

CEO comments

The discovery of insulin 100 years ago was a medical revolution for mankind. A previously condemned patient group could now be treated. Following this ground-breaking milestone, decades of scientific research and innovation have resulted in the approval of the first disease-modifying drug for type 1 diabetes in the United States. We now see an unprecedented increase in investments in the field of diabetes, and the understanding of the causes of the disease, its course and how we can change the underlying disease has reached new heights. We are in a groundbreaking era where concrete progress is being made to realize the vision of curing and preventing type 1 diabetes.

At Diamyd Medical, we are proud to be at the forefront of this development with our antigen-specific immunotherapy, Diamyd®. Our registrational trial DIAGNODE-3 (www.diagnode-3.com) and the industry partnership with JDRF (www.jdrf.org), the leading patient organization for type 1 diabetes in the United States and leading funder of research in the field, constitute the heart of our development. DIAGNODE-3 is the first precision medicine Phase 3 trial in type 1 diabetes and the JDRF partnership underscores the importance of the study. We look forward with excitement to reaching new milestones in 2024, both in terms of patient recruitment and interim analysis in DIAGNODE-3.

Within the framework of the ASSET project (www.asset.healthcare), supported by the Swedish innovation agency VINNOVA (www.vinnova.se), we are very happy about our newly established collaboration with DiaUnion (www.diaunion.org) to conduct DiaPrecise, the first precision medicine prevention study with Diamyd®. DiaUnion is a center of excellence for research on autoimmune diabetes and related autoimmune diseases, and in DiaPrecise, DiaUnion will be responsible for the screening of study participants. Our goal is for Diamyd® to be established as a leading preventive treatment for individuals at high risk of developing type 1 diabetes. The collaboration within ASSET and with DiaUnion are central to achieving the goal.

In line with our clinical investment, we also look forward to large-scale production in our facility in Umeå. This facility is fundamental in our endeavor to become a fully integrated biotech company, and the ownership of a facility for biological pharmaceutical manufacturing represents significant value for the company in the face of future commercial production and new manufacturing initiatives. This is completely in the spirit of the times, not least for strategic reasons - that Sweden should have the potential to be self-sufficient in pharmaceutical production.

When I now look ahead, I do so with full awareness that our success is driven not only by scientific research, but also by the strong support and trust we receive from you, our shareholders. In these times of economic uncertainty and challenging financial markets, it is particularly difficult to finance capital intensive projects. We are deeply grateful for your trust. We continue to work towards a commercial breakthrough for Diamyd®.

Stockholm, November 8, 2023

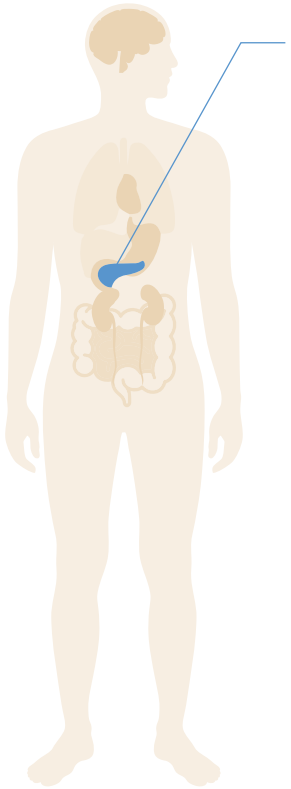
ULF HANNELIUS
President & CEO Diamyd Medical AB

"Our registrational trial DIAGNODE-3 and the industry partnership with JDRF, the leading patient organization for type 1 diabetes in the United States and leading funder of research in the field, constitute the heart of our development."

About diabetes

Diabetes is a group of metabolic diseases characterized by elevated levels of glucose in the blood, due to the body's inability to produce or respond to insulin.

HOW THE BODY PRODUCES INSULIN



PANCREAS

The pancreas has two main functions. The first is to produce digestive enzymes and bicarbonate. The second is to produce the two hormones insulin and glucagon, which are important for the body's metabolism and to help regulate blood sugar levels.

Insulin, glucagon and other hormones are produced by small clusters of cells known as islets. Insulin and glucagon circulate in the blood and help the body's cells to regulate blood sugar levels.

Diabetes is characterized by elevated levels of glucose in the blood due to the body's inability to produce the hormone insulin. There are different types of diabetes:

- Autoimmune diabetes (10-20% of diabetes patients)
  - LADA (latent autoimmune diabetes in adults)
  - Type 1 diabetes
- Type 2 diabetes (80-90% of diabetes patients)

Autoimmune diabetes – the body stops producing insulin

Type 1 diabetes and LADA are forms of autoimmune diabetes, which means the body's own immune system, for an unknown reason, destroys pancreatic beta cells, which are the cells that produce insulin and thereby regulate blood sugar. Type 1 diabetes most often occurs in children and adolescents, while LADA develops in adults and has a slower disease progression. The disease process starts long before the individual feels any symptoms. The progression of the disease can be divided into three stages:

Stage 1: Two or more beta-cell specific auto-antibodies (part of the immune system) have developed but do not yet have any measurable effect on blood sugar.

Stage 2: The autoimmune destruction continues and the body's ability to regulate blood sugar deteriorates.

Stage 3: The body's ability to regulate blood sugar is severely impaired and the patient shows clinical symptoms of diabetes. This is the clinical diagnosis of type 1 diabetes.

Type 2 diabetes – the body stops responding to insulin

Type 2 diabetes is the most common form of diabetes. In contrast to autoimmune diabetes, type 2 diabetes is often characterized by insulin resistance, which means the insulin does not have the same capacity to regulate blood sugar levels in the body, and endogenous insulin production is impaired. Type 2 diabetes mainly affects adults, although a growing number of children are also developing the disease.

Causes

The cause of diabetes remains unknown. With regard to autoimmune diabetes, elevating risk factors have been identified, such as a family history of diabetes, genetics and certain viral infections. The causes of type 2 diabetes are a combination of factors such as family history, lifestyle and environment.

Diagnosis

Type 1 diabetes is usually diagnosed when only a limited proportion of a person's own ability to produce insulin remains. The patient must then immediately begin insulin therapy, otherwise the disease is life-threatening. Type 1 diabetes may also be diagnosed before any clinical symptoms appear by checking a blood test for the occurrence of specific auto-antibodies, including antibodies against GAD65. LADA patients are also characterized by the presence of antibodies against GAD65, which means LADA patients can also be diagnosed with an antibody test.

Complications

People with diabetes often develop complications that can impact several organs in the body and lead to great suffering and premature death. Life expectancy is lower for patients with diabetes compared with healthy individuals, particularly when diagnosed at an early age.

Severe complications primarily include serious hypoglycemia and ketoacidosis. Hypoglycemia is a condition with dangerously low blood sugar levels, which can lead to severe hypoglycemic coma, brain damage and even death. Ketoacidosis is a condition caused by a deficiency of insulin where large amounts of ketone metabolites are released as the cells break down fats and proteins due to the absence of glucose, which leads to a reduction in the blood's pH level. This is a life-threatening condition that requires intensive care.

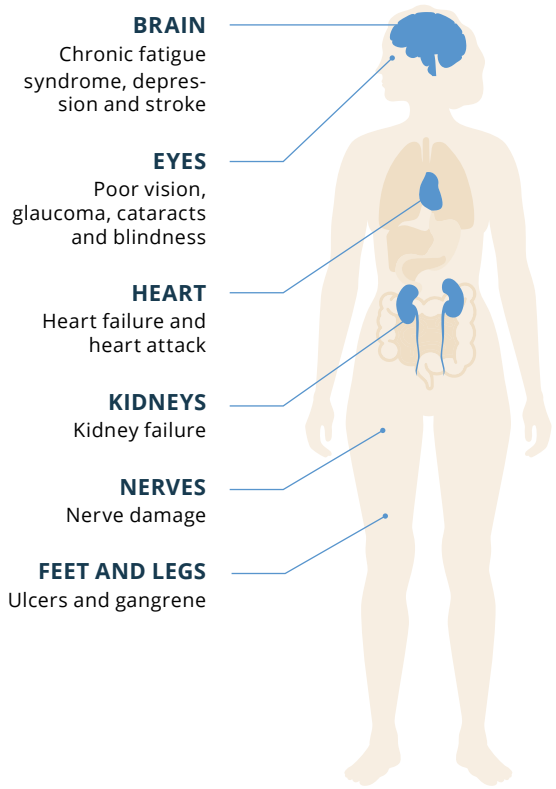
Consistently elevated blood sugar levels cause long-term diabetes complications:

- cardiovascular disease, such as heart attack, stroke and impaired blood circulation
- nephropathy (kidney disease), such as kidney failure, which may require dialysis or a kidney transplant
- neuropathy (nerve disease), such as the loss of feeling and severe pain in parts of the body, and impotence
- retinopathy (eye disease), such as vision loss and, in some cases, also blindness

Treatment

Blood sugar levels must be kept in balance to reduce the risk of acute and long-term diabetes complications. Blood sugar levels are maintained by administering insulin several times each day. With regard to type 2 diabetes patients, dietary and lifestyle changes may prevent and control the disease progression but the progressive disease often requires permanent medication using tablets or insulin therapy.

HOW THE BODY IS DAMAGED BY DIABETES



Market trend

Diabetes is one of the most common diseases in the world and approaching epidemic proportions. The disease causes serious physical and psychological distress and is a global economic burden. The unmet need for new drugs that can reduce these consequences is therefore great.

Approximately 540 million people aged 20-79 years are affected by diabetes [1]. This figure is expected to reach 780 million by 2045.

The most common form of diabetes is type 2, which is caused by age or obesity, and currently accounts for about 80% of all diabetes prevalence. About 10% of patients with diabetes have type 1, and 10% have LADA.

In 2021, diabetes was responsible for an estimated 6.7 million deaths [1]. There is no cure for diabetes yet and the mainstay of treatment is either exogenous insulin or improved insulin sensitivity. In addition to human pain and suffering, the total annual costs of diabetes are at least USD 966 billion, an increase of 316% over the past 15 years [1]. Most of these costs are attributable to long-term diabetes complications, such as cardiovascular problems, kidney damage and nerve damage.

Health economic assessments show that even a slightly positive effect on slowing the disease progression for individuals living with type 1 diabetes could be translated into major economic value [2]. Research shows that a small amount of preserved endogenous insulin production in these individuals could reduce 60-80% of long-term diabetic complications, such as cardiovascular problems.

[1] *IDF Diabetes Atlas 2021 – 10th edition*

[2] *JDRF. Modeling the Total Economic Value of Novel Type 1 Diabetes 2020.*

The market for Diamyd Medical

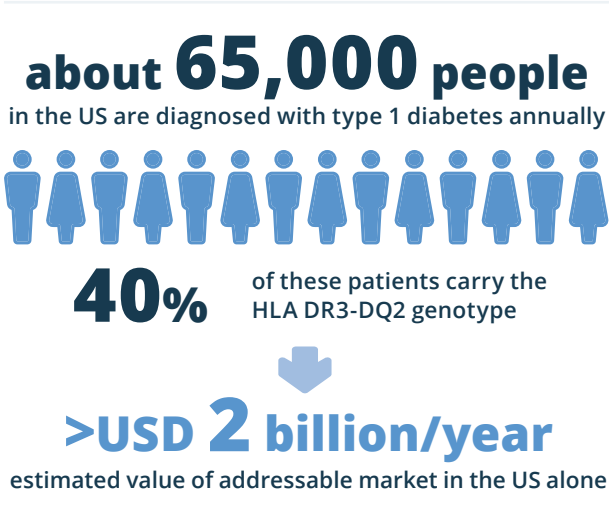
The antigen-specific immunotherapy Diamyd® is being developed to preserve the body's ability to produce insulin in patients newly diagnosed with type 1 diabetes. In 2021, about 184,000 children and young people worldwide were diagnosed with type 1 diabetes. If all age groups are included, more than 500,000 are diagnosed with type 1 diabetes every year. At least as many are diagnosed with LADA each year. About 40% of individuals with type 1 diabetes or LADA are assessed to belong to a genetically defined subpopulation that carry the HLA DR3-DQ2 genotype, which trials have shown respond positively to treatment with Diamyd®.

The addressable market for Diamyd® in Europe and the US is estimated to be well over USD 2 billion annually based on expected pricing. If the use of Diamyd® could be broadened to treat the other form of autoimmune diabetes, LADA, the addressable market for Diamyd® would be even larger. Diamyd® has also shown positive indications for diagnostic delay in individuals at increased risk of developing type 1 diabetes, which further increases the market size.

A broadening towards other antigens and genotypes has the potential to address most of the market for autoimmune diabetes.

In recent years, several major business transactions and regulatory milestones have been achieved in diabetes. In 2022, the FDA approved Teplizumab as the first type 1 diabetes disease-modifying drug. In 2023, the FDA also approved the first cell therapy for type 1 diabetes, Lantidra, for a small cohort of patients living with severe type 1 diabetes.

In March 2023, Sanofi announced a takeover bid for Provention Bio, the company that developed Teplizumab, valuing the company at USD 2.9 billion. In 2019, Vertex Pharmaceuticals acquired cell therapy company Semma Therapeutics for MUSD 950 and in 2022, acquired ViaCyte for MUSD 320. In 2023, Eli Lilly placed a bid on cell therapy developer Sigilon Therapeutics, valuing the company at up to MUSD 500.



Manufacturing

A new biomanufacturing facility is under development in Umeå whose primary purpose will be the manufacture of recombinant GAD65, the active ingredient in Diamyd®.

The long-term goal is that the facility, in addition to producing enough GAD65 to meet the market demand for Diamyd®, will also be a key player in the production of biological compounds for other drug projects.

The 2,200 square-meter production facility, which includes clean rooms, laboratories, storerooms and office space, will facilitate full control, predictability and scalability of the manufacturing technology for the active ingredient in Diamyd®. Employees at the facility are experts in areas such as cell cultivation and protein purification, which is paving the way for future implementations of precision medicine in type 1 diabetes.

Diamyd Medical has chosen Cytiva's FlexFactory, a configurable single-use platform for the manufacturing process based on a baculovirus-insect cell expression system.

Small-scale experimental production of GAD65 has been established at the manufacturing facility and large-scale production is being set up with the aim of having an operational facility in 2024. Additional biomanufacturing projects will be evaluated to make full use of the site, platform, analytical laboratory and competencies.

Business strategy

The foundation for Diamyd Medical's business strategy is to develop, produce and sell drugs that preserve and stimulate endogenous insulin production. The drugs currently under development primarily target patients who are newly diagnosed with type 1 diabetes. Upon commercialization of Diamyd®, the Company intends to produce and sell via license agreements with one or more major players, and through in-house production and sales in selected markets.

Drug development

The current mainstay of treatment for type 1 diabetes is subcutaneous deliveries of insulin by injection or pump therapy, combined with continuous glucose monitoring. However, drug development is under way on multiple fronts to increase patient benefits and reduce healthcare costs.

Diamyd Medical primarily focuses on developing antigen-specific immunotherapy through Diamyd®. Antigen-specific immunotherapy is a treatment targeting the disease's underlying causes and is designed to reprogram the body's own immune system so that the insulin-producing cells are no longer attacked by the immune system. Diamyd® has the potential to significantly increase patient benefits and reduce healthcare costs by slowing the disease progression, improving glycemic control and preventing short and long-term complications. In extensive clinical trials in children and adults, Diamyd® has demonstrated excellent safety and shown a significantly positive effect in a genetically defined subpopulation that carries the HLA DR3-DQ2 genotype, corresponding to about 40% of all individuals with type 1 diabetes in Europe and the US.

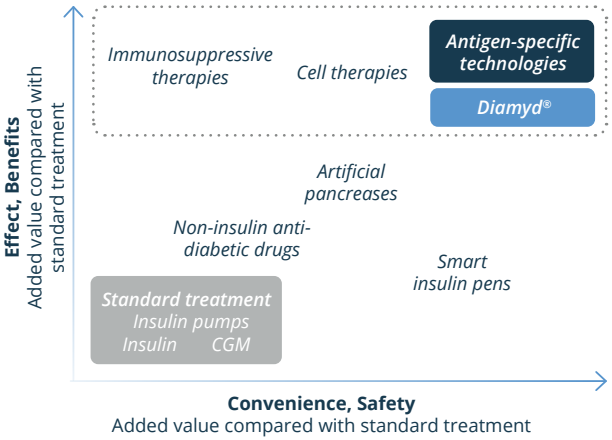
Diamyd Medical is also developing the GABA-based drug Remygen®, which is designed to stimulate the body's ability to recreate insulin-producing beta cells and prevent hypoglycemia – a severe drop in blood sugar. Remygen® could potentially be used to treat patients with type 1 diabetes, type 2 diabetes and LADA.

Diamyd Medical's clinical development program with Diamyd® also includes booster injections of Diamyd®, treatment of children at risk of type 1 diabetes and treatment of patients diagnosed with LADA.

Market position

Only one disease-modifying treatment for autoimmune diabetes has been approved in the US to date: the anti-CD3 monoclonal antibody Teplizumab (Tzield), which was approved by the FDA in autumn 2022. Teplizumab delays the onset of type 1 diabetes in people with stage 2 of the disease. Upon approval, Diamyd Medical's investigational drug Diamyd® is expected to penetrate the market quickly due to (1) the major unmet medical need among type 1 diabetes patients, (2) the precision medicine approach, which is based on only giving Diamyd® to patients who carry the HLA DR3-DQ2 genotype, and (3) the ease and safety of the treatment delivery. Diamyd Medical's clinical development program will enable the Company to broaden its offering for patients with type 1 diabetes.

Market position of Diamyd®



Existing patents

As part of an exclusive license from the University of California, Los Angeles (UCLA), Diamyd Medical has patent protection in the US until 2032 for the use of GAD65 to treat diabetes, known as a pharmaceutical patent. In addition, the Company has been granted a patent for Europe and Eurasia for the prevention and treatment of autoimmune diabetes in individuals who carry the HLA DR3-DQ2 genotype. The patent is valid until 2035, and patents are pending in several countries. The patent application also contains patent claims for HLA DR4-DQ8 alone, and in combination with HLA DR3-DQ2, for the prevention and treatment of autoimmune diabetes with insulin-based antigen.

The Company has also been granted patents for intralymphatic administration of Diamyd® in Europe, Japan, Russia, Israel, Australia, Canada and China, and patents are pending in several other countries.

The patents are a key form of protection for Diamyd®, especially the intralymphatic route of administration that has demonstrated positive results in the Phase IIb DIAGNODE-2 trial and in the international Phase III DIAGNODE-3 trial, which is currently being evaluated.

As a biologic drug, Diamyd® has been granted a 12-year period of market exclusivity in the US and 10 years in Europe, independent of patent protection. Diamyd® has been granted orphan drug designation in the US which comes with several benefits including a 7-year period of market exclusivity and lower regulatory costs.

In-house manufacturing

Diamyd Medical is establishing a manufacturing facility in Umeå as part of the Company's ambition to be an integrated pharmaceutical company in selected markets. The facility will produce GAD65, the active pharmaceutical compound in the investigational drug Diamyd®. The long-term goal is that the facility, in addition to producing enough GAD65 to meet the market demand for Diamyd®, will also be a key player in the production of biological compounds for other drug projects. The 2,200 square-meter facility in Umeå comprises clean rooms, laboratories, storerooms and offices. Pharmaceutical production must comply with the international Good Manufacturing Practice (GMP) system, which describes the minimum standards for manufacturing and control. Diamyd Medical is now working actively to build up the quality systems required to meet the GMP standards and the activities are designed to meet demands from both EU and other markets. Diamyd Medical has chosen Cytiva's configurable single-use bioprocess manufacturing platform FlexFactory for the process that is based on a baculovirus-insect cell expression system. Small-scale experimental GAD65 production has now been established and large-scale production is being set up with the aim of having an operational facility in 2024. The property where manufacturing is being established is fully owned by Diamyd Medical through its subsidiary Diamyd Biomanufacturing AB.

STRATEGIC HOLDINGS

Diamyd Medical has a number of strategic holdings aimed at strengthening and broadening the Company's research in the treatment of type 1 diabetes. Diamyd Medical is the largest shareholder of NextCell Pharma AB with a holding of 12.5%, and the company develops stem cell therapies with the investigational drug ProTrans, which has shown significant efficacy in the treatment of type 1 diabetes in a Phase II trial.

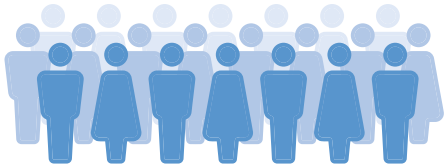
Alongside of clinical trials, NextCell Pharma also runs Sweden's first family cord blood bank – Cellaviva. Diamyd Medical also owns 25% of MainlyAI AB, a deeptech company focused on helping businesses to speed up their AI deployment to become more sustainable.

DIAGNODE-3

DIAGNODE-3 is a Phase III trial that is ongoing in Europe and the US.

The first patient received their first intralymphatic injection of Diamyd® in May 2022. The trial will involve about 330 individuals aged 12-29 years who are newly diagnosed with type 1 diabetes and carry the HLA DR3-DQ2 genotype. DIAGNODE-3 is being carried out in approximately 60 clinics across Europe and the US. Diamyd Medical and JDRF, the leading global organization for research and advocacy in type 1 diabetes, have signed a four-year research and development collaboration to support DIAGNODE-3.

ANTIGEN-SPECIFIC IMMUNOMODULATION



Patients with type 1 diabetes and the HLA DR3-DQ2 genotype

Patients receive intralymphatic injections of Diamyd® on three occasions over a two-month period

Participants at the investigator meeting in September 2023 before the start-up of DIAGNODE-3 in the US.

Navigating the market

With her extensive experience in the biotech industry, Dr. Karin Rosén, a Doctor of Medicine from Lund University who has been living and working in the US for many years, is contributing valuable insights into how Diamyd® can be launched successfully as a treatment for diabetes.

Market trends and challenges

Global demand for innovative therapies for type 1 diabetes treatments has increased recently, and one example is Sanofi's acquisition of Provention Bio, whose Tzield immunotherapy has been approved by the FDA.

In order to succeed with a potential marketing authorization, an analysis of the complex factors that influence a launch is crucial, especially the differences between the US and European healthcare sectors.

"The conditions vary and an understanding of market trends is important, which requires knowledge of the complexities of the healthcare system," explains Karin Rosén. "Market research and health economic assessments are key elements in the lead-up to regulatory approval," she says.

The US healthcare system presents challenges, however, with insurance companies and other players affecting reimbursement structures and thereby the pricing of drugs.

Pricing strategies must be based on the value that innovative therapies can generate. Pricing statistics for high-cost drugs could be a key parameter in this context. One example is Tzield, which costs about USD 200,000 per treatment in the US.

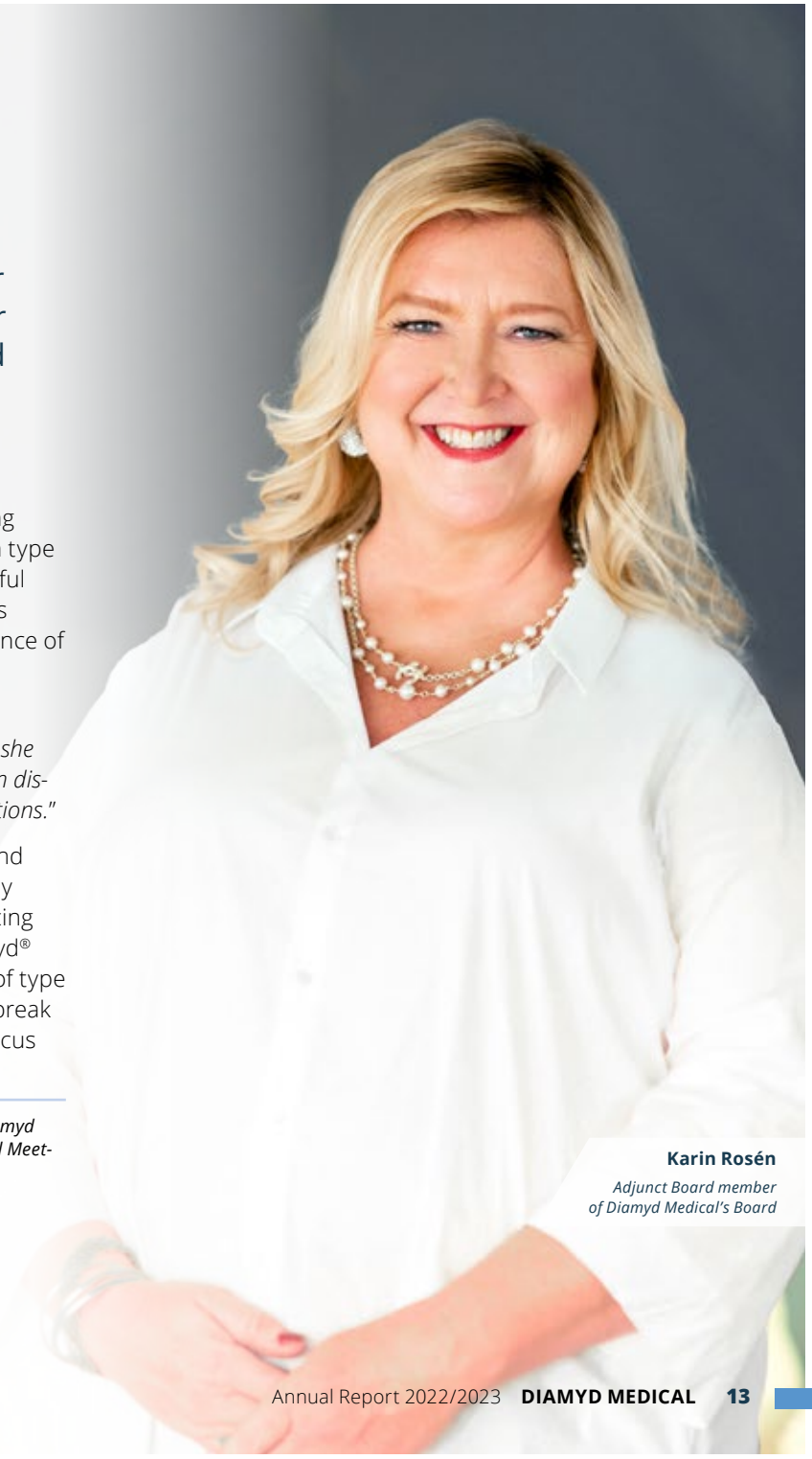
Patient-centered care

Diamyd Medical's partnership with JDRF, a leading global organization for research and advocacy in type 1 diabetes, presents opportunities for a successful launch and access to awareness of patient needs worldwide. Karin Rosén emphasizes the importance of engaging various stakeholders.

"In addition to the treating doctors, reaching out to patients is crucial, including patient organizations," she says. "Patients are increasingly becoming involved in disease diagnosis and discussions about treatment options."

Along with understanding regional differences and market trends, a precision medicine care strategy is also valuable for achieving the goal of introducing a breakthrough treatment. In this context, Diamyd® could have a significant effect on the treatment of type 1 diabetes in both Europe and the US, and also break new ground in innovative diabetes care with a focus on the patient's needs.

It has been proposed that Karin Rosén, Adjunct member of Diamyd Medical's Board, be elected to the Board at the Annual General Meeting (AGM) on November 30, 2023.



Karin Rosén
Adjunct Board member of Diamyd Medical's Board

Clinical development

Diamyd Medical's drug treatment is designed to preserve endogenous insulin production, reduce the risk of diabetic complications, simplify treatment and reduce the burden of social costs related to diabetes. Diamyd® is currently undergoing a Phase III clinical trial for type 1 diabetes and Phase I/II clinical trial for children.

About Diamyd®

Diamyd® is an antigen-specific immunotherapy for preserving the body's ability to produce insulin in autoimmune diabetes (type 1 diabetes and LADA). Clinical data from about 1,000 individuals who received active treatment support good safety and significant treatment efficacy in a genetically defined subpopulation. The investigational drug is based on the active ingredient GAD65, a protein produced by the insulin-producing beta cells. The effect is achieved by reprogramming antigen-specific immune cells by injecting low doses of Diamyd® into superficial lymph nodes. In 2022, the Phase III DIAGNODE-3 trial was initiated to evaluate Diamyd® in patients newly diagnosed with type 1 diabetes who also carry the HLA DR3-DQ2 genotype. A Phase I/II trial is also ongoing to evaluate Diamyd® in children at higher risk of being diagnosed with type 1 diabetes and who carry the HLA DR3-DQ2 genotype. Diamyd® has previously undergone a Phase I/II trial to evaluate Diamyd® in patients with LADA, which showed positive results.

About Remygen®

Remygen® is an immunomodulation therapy in the form of a tablet for both forms of autoimmune diabetes (type 1 and LADA) and type 2 diabetes. Remygen® is a formulation of GABA (gamma-aminobutyric acid), best known for its role as a neurotransmitter in the central nervous system. In clinical trials, GABA has been shown to stimulate the release of the glucose-regulating hormones insulin and glucagon, and the hormonal response to hypoglycemia (low blood sugar levels). Preclinical studies have presented strong evidence that GABA stimulates the formation and function of the cells that produce insulin and glucagon in the pancreas. During the year, the Phase I/II ReGenerate-1 clinical trial of Remygen® was concluded, and showed that Remygen® met the primary safety endpoint but there is no clear support for a sustained treatment effect on increased endogenous insulin production.

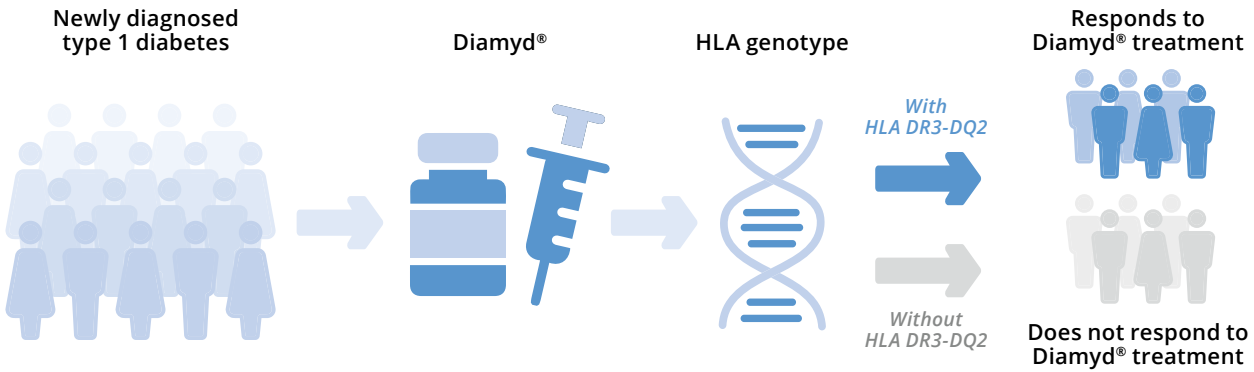
ONGOING TRIALS

Trial	Type	Indication	Product	Participants	Sponsor	Status
DIAGNODE-3	Phase III	Newly diagnosed type 1 diabetes, carrying the HLA DR3-DQ2 genotype	Diamyd®	330	Diamyd Medical	About 50 clinics in Europe have been initiated in the trial and the trial commenced in the US in summer 2023. The patients will be followed for 24 months. Industry partnership with the US patient organization JDRF.
DiaPrecise	Phase I/II	Children at risk of type 1 diabetes, carrying the HLA DR3-DQ2 genotype	Diamyd®	10-16	Diamyd Medical	The trial commenced in the fourth quarter of the 2023 calendar year and is taking place in partnership with Lund University and DiaUnion.

Ongoing clinical trials

DIAGNODE-3 – Diamyd®

DIAGNODE-3 is a placebo-controlled Phase III trial designed to confirm the topline results from the Phase IIb clinical trial, DIAGNODE-2, where significant treatment efficacy for Diamyd® was observed in members of a genetically defined subpopulation. In the earlier trial, those who received active treatment maintained more than 50% of their endogenous insulin production compared with placebo treatment. DIAGNODE-3 is also based on a large published meta-analysis of three trials with Diamyd®



Topline results from the Phase IIb DIAGNODE-2 trial showed the significant treatment efficacy of Diamyd® in a genetically defined subpopulation of individuals with type 1 diabetes, corresponding to about 40% of the patient population. The results confirm previous meta-analysis findings based on earlier Phase III and Phase II trials published in the peer-reviewed medical journal Diabetologia. The treatment is currently being tested in the Phase III DIAGNODE-3 trial.

in more than 500 individuals newly diagnosed with type 1 diabetes. The Phase III trial began in 2022, and the first patient received their first intralymphatic injection of Diamyd® in May. The trial will involve about 330 individuals aged 12-29 years who are newly diagnosed with type 1 diabetes and carry the HLA DR3-DQ2 genotype (about 40% of the total population). The participants will be followed for 24 months. The trial is taking place in eight European countries and the US. Diamyd Medical and JDRF, the leading global organization for research and advocacy in type 1 diabetes, have signed a four-year research and development collaboration to support DIAGNODE-3.

DiaPrecise – Diamyd®
DiaPrecise is an open-label Phase I/II clinical trial where Diamyd® is administered directly into lymph nodes in children aged 8 to 18 who are at higher risk of being diagnosed with type 1 diabetes and also carry the HLA DR3-DQ2 genotype. The aim of the trial is to assess the safety and feasibility of two or three intralymphatic injections with Diamyd®, the effect on the immune system, and clinical parameters such as endogenous insulin production and glycemic control. DiaPrecise is the first prevention trial with a precision medicine focus, and part of the AI for the Sustainable Prevention of Autoimmune in Society (ASSET) program, which is coordinated by Diamyd Medical. ASSET is funded by the Swedish Agency for Innovation Systems (VINNOVA). The trial is being conducted in partnership with Lund University and DiaUnion.

Trials completed during the year

DIAGNODE-B – Diamyd®
DIAGNODE-B was an open-label, investigator-initiated Phase IIb clinical trial, in which Diamyd® was administered directly into lymph nodes in type 1 diabetes patients who carry the HLA DR3-DQ2 genotype and had previously been treated with intralymphatic injections of Diamyd® in either the DIAGNODE-1 or DIAGNODE-2 trial. The aim of the trial was to assess the safety of a booster (fourth/fifth) injection with Diamyd®, as well as the effect on the immune system and endogenous insulin production. The results showed that the primary endpoints for safety and tolerability were met after 12 months from the booster injection, as well as support for a mild disease progression up to eight years from a type 1 diabetes diagnosis.

ReGenerate-1 – Remygen®
ReGenerate-1 was an open-label investigator-initiated Phase I/II clinical trial involving a total of 35 individuals who have had type 1 diabetes for longer than five years with low to non-existing residual insulin production. The trial comprised two studies – an initial safety and dose-escalation study with six patients, and the actual main study comprising a total of 35 patients, who were followed for up to nine months depending on their dose expansion cohort. Topline results from the trial showed that the primary safety endpoint was met, however there is no clear support for a sustained treatment effect on increased endogenous insulin production.

International collaboration

Research partnerships are ongoing to support innovation and progress that, with the help of big data analytics, can streamline clinical development in type 1 diabetes treatment. Diamyd Medical currently participates in several international academic partnerships, including the Critical Path Institute's Trial Outcome Markers Initiative.

In addition to contributing to progress and broader dialog with regulators, Diamyd Medical's involvement creates major opportunities for networking with opinion leaders and raising awareness of immunotherapy. The Company is also strengthening its presence at scientific conferences on key areas such as human genetics and diabetes.

Diamyd Medical has also entered into a four-year research and development collaboration with JDRF, the leading global organization for research and advocacy in type 1 diabetes. Within the context of this collaboration, the Company will receive funding of MUSD 5 to support the ongoing Phase III trial with the precision medicine antigen-specific immunotherapy Diamyd®. The funding is provided by JDRF's Industry Discovery & Development Partnership program, which is focused on the commercialization of therapeutics and/or devices to cure, treat and/or prevent type 1 diabetes and its complications.

Diamyd Medical has entered into a collaboration with DiaUnion, a center of excellence for research into autoimmune diabetes and related autoimmune diseases, to identify participants for the DiaPrecise trial.

COMPLETED TRIALS

Trial	Type	Indication	Product	Participants	Sponsor	Results	Completion
ReGenerate-1	Phase I/II	Type 1 diabetes	Remygen®	35	Uppsala University	Remygen® met the primary safety endpoint but there was no clear support for a sustained treatment effect on increased endogenous insulin production.	2023
GADinLADA	Phase I/II	Newly diagnosed LADA	Diamyd®	15	NTU Trondheim	The trial showed positive results and the participants remained insulin-independent 12 months after the treatment.	2022
DIAGNODE-2	Phase IIb	Newly diagnosed type 1 diabetes, carrying the HLA DR3-DQ2 genotype	Diamyd®	109	Diamyd Medical	The trial showed positive results and significant treatment efficacy for Diamyd® was observed among the participants.	2021
Meta-analysis	N/A	Newly diagnosed type 1 diabetes, carrying the HLA DR3-DQ2 genotype	Diamyd®	521	Diamyd Medical	Retrospective meta-analysis of three earlier clinical trials showed significant impact of the HLA genotype on the clinical effect of Diamyd®. Laid the foundation for the precision medicine focus for Diamyd®.	2020
DIAGNODE-1	Phase I/II	Newly diagnosed type 1 diabetes	Diamyd®	12	Linköping University	The trial showed positive results and the participants showed a decrease in the need for exogenous insulin and close to normal blood sugar levels.	2018

Advancing Precision Medicine in Type 1 Diabetes

The DIAGNODE-3 study has taken a step to the US. Dr. Jason Gaglia, a Clinical Investigator at the Joslin Diabetes Center and Dr. Tom Donner, Director of The Johns Hopkins Diabetes Center provide their perspectives on the study and its potential impact.

Innovative Drug Delivery

Jason Gaglia, a clinical investigator at Joslin Diabetes Center, summarises the clinical trial DIAGNODE-3.

Precision Medicine through Antigen-Specific Therapy

The treatment regime in the DIAGNODE-3 trial, using the antigen-specific therapy Diamyd®, distinguishes it from the type 1 diabetes research. The approach offers enhanced safety and personalization, aligning with the concept of precision medicine as it tailors' treatment to individual needs.

*"We are looking forward to having the DIAGNODE-3 trial be an option for our patients,"*Gaglia explains. *"The immune system is at the core of type 1 diabetes, so it is important to explore if this treatment delivery approach will be beneficial."*

Crucial Roles of Pioneering Institutions

Joslin Diabetes Center and The Johns Hopkins Diabetes Center play essential roles in advancing diabetes research. Dr. Tom Donner underscores their significance, emphasizing the confidence patients have in academic institutions' leading research.

"We offer patients opportunities to participate in clinical trials, potentially improving their health and our understanding of type 1 diabetes", Dr. Donner notes.

"The study DIAGNODE-3 focuses on desensitizing the immune system through presenting GAD65, the active component in Diamyd®. This approach holds potential benefits for type 1 diabetes patients seeking alternatives to full insulin replacement therapy."

Patient-Centric Approach

Dr. Donner has actively reached out to endocrinologists in the Washington DC area to refer patients to the study. He reports a positive response stating:

"This study is easy to endorse. We believe that the treatment regime has a potential to slowing down the autoimmunity and the destruction of insulin-producing cells. There's no immunosuppression, and the side effects are minimal. The benefits far outweigh any potential risks from participating in a clinical trial."

Jason Gaglia
Section Head of Joslin Diabetes Center
Principal Investigator, DIAGNODE-3

Thomas Walter Donner
Director of The Johns Hopkins Diabetes Center
Principal Investigator, DIAGNODE-3

Sustainability

As part of the life sciences sector, Diamyd Medical is contributing to the social transition to long-term sustainable business. Significant parts of the Company's activities are affected by the UN's 2030 Agenda and the Sustainable Development Goals (SDGs), which cover the entire pharmaceutical value chain from research and development to manufacturing, distribution and administration.

The aim of the SDGs is to contribute to the social, economic and environmental dimensions of sustainable development and they should be achieved by all of the world's countries by 2030. Due to the way that drugs are designed and manufactured, the production process, distribution and use of the drugs have a negative impact on the local environment and our water.

The activities that Diamyd Medical conducts that have an environmental impact range from the manufacture of recombinant GAD protein at the production facility in Umeå to the handling of drugs, and analyses of samples from clinical trial participants at clinics in Europe and the US.

Drug treatments are vital for human health and well-being. Therefore, there is a need to weigh the positive and negative effects of new drugs on the SDGs against the impact of existing treatment methods on patient health and quality of life.

Clinical trials allow patients to access new drugs and treatments before they are widely available, and increase the knowledge of healthcare professionals. Diamyd Medical believes that the research and innovation conducted by the Company is contributing to patient safety and a modern healthcare system, where employees are also offered opportunities for professional development and varied tasks.

International collaboration

Diamyd Medical and JDRF entered into a research and development collaboration, including funding of MUSD 5.

JDRF supports and promotes disease-modifying therapies that slow or reverse the progression of type 1 diabetes. The organization's program for industrial discoveries and development is focused on commercializing therapies for treatment, cure and prevention of type 1 diabetes and its complications.

The collaboration is supporting the ongoing Phase III DIAGNODE-3 trial with the precision medicine antigen-specific immunotherapy Diamyd® and promoting the commercial preparations.

Clinical trial optimization

One of the challenges when designing clinical trials for potential disease-modifying therapies for new-onset type 1 diabetes is often the difficulty in defining clinically meaningful effects in trial settings. Diamyd Medical is involved in various partnerships with the aim of exploring new opportunities to optimize the selection of participants in clinical trials to prevent type 1 diabetes.

The Critical Path Institute (C-Path) combines industry, academia and patient cohorts to accelerate the development of type 1 diabetes treatments by using biomarkers and model-based tools for drug development. Diamyd

Employees

16 women

9 men

Management

4 women

3 men

Board

3 women

4 men

Employees with a PhD, %

12 of total

25

Medical contributes data from earlier clinical trials of Diamyd® and is an active voice in the decision-making process around C-Path's focus and goals.

Good health and access to drugs

In the VINNOVA-funded ASSET project, Diamyd Medical is working closely with players from industry and academia to promote the introduction of a national screening program for symptom-free autoimmune type 1 diabetes within the Swedish healthcare system.

A screening of the patient population would enable personalized diagnostic testing and treatment with, for example, precision medicine therapies. The aim of a national screening program would be to identify individuals in the early stages of the disease so that meaningful disease-modifying therapy can be offered.

Sustainable manufacturing

Production facilities give rise to greenhouse gas (GHG) emissions throughout their entire life cycle. As part of its production facility in Umeå, Diamyd Medical participated in the VINNOVA-funded ALISTAIR (Artificial Intelligence for Sustainable Production) project, which mapped Diamyd Medical's production process from a sustainability perspective, the manufacturing unit's energy consumption and opportunities for managing waste and recycling the components used during the manufacturing process. Opportunities for how data streams and artificial intelligence could be used in the future to continuously optimize sustainability aspects were also studied.

THE UN AND THE SDGS

Diamyd Medical's sustainability ambitions are based on the 2030 Agenda and the SDGs. The Company has evaluated how it can best respond to the 2030 Agenda and determined that it can make the biggest difference for the following SDGs.

GOOD HEALTH AND WELL-BEING

Diamyd Medical is dedicated to improving human health and well-being. The Company's main focus is to develop and manufacture drugs designed to reduce the complications of type 1 diabetes, which has a positive effect on quality of life and life expectancy for patients.

INDUSTRY, INNOVATION AND INFRASTRUCTURE

Research and development is a fundamental part of Diamyd Medical's business and forms part of Swedish manufacturing infrastructure. In-house drug development and production reduces the dependence on external contract manufacturers, while promoting regional innovation and creating jobs.

RESPONSIBLE CONSUMPTION AND PRODUCTION

When establishing the production facility in Umeå, the Company is striving to create the most sustainable production possible and to assess the environmental impact throughout the entire product life cycle, including production, consumption and waste management.

The Diamyd Medical share

Diamyd Medical's shares are traded in the Health Care segment of Nasdaq First North Growth Market (ticker: DMYD B, ISIN code: SE0005162880).

Share and share capital

At August 31, 2023, the number of shares in Diamyd Medical was 85,782,314, comprising 83,226,091 Class B shares (one-tenth of a vote per share) and 2,556,223 Class A shares (one vote per share). The rounded quotient value of both Class A and Class B shares was SEK 0.1014. The shares are denominated in Swedish kronor (SEK). At the end of the financial year (August 31, 2023), the share capital amounted to SEK 8,700,150.

Share performance

The last price paid at August 31, 2023 was SEK 9.79 (14.58), generating a market cap of MSEK 815 (1,084) for Diamyd Medical calculated on the number of Class B shares. During the financial year, the share price declined 33% (56). The highest price paid was SEK 21.50 (39.84). The lowest price paid was SEK 7.79 (10.40). The average share price was SEK 12.73 (19.49). During the financial year, 29,449,583 Class B shares (73,686,834) were traded on Nasdaq First North Growth Market for a total value of MSEK 377 (1,436).

New share issue

A rights issue was completed during the financial year based on the authorization granted by the AGM on December 1, 2022. The new issue increased the number of shares in the Company by 8,855,375 to 85,782,314, and the share capital by SEK 898,123 to SEK 8,700,150. The issue was fully registered with the Swedish Companies Registration Office on July 6, 2023.

Ownership structure

At August 31, 2023, the number of shareholders was 16,101 (16,519). The ten largest owners of Diamyd Medical held shares corresponding to 35.8% of the capital and 49.4% of the votes.

Dividend

The Board proposes that no dividend be paid for the 2022/2023 financial year.

Certified Adviser

All companies listed on Nasdaq First North Growth Market must have a Certified Adviser for guidance and support. Diamyd Medical's Certified Adviser is FNCA Sweden AB.

Share performance, 2022/2023

Data per share	2022/23	2021/22
Share price, August 31, SEK	9.8	14.6
Share performance, %	–33	–56
Equity per share, SEK	2.0	2.8
Result per share, SEK	–1.5	–1.4
Average no. of shares	78,285,572	76,530,657
No. of shares at August 31	85,782,314	76,926,939

Ownership structure by size of holding at August 31, 2023

Holding	No. of shareholders	Class A shares	Class B shares	Holding (%)	Votes (%)	Market cap (KSEK)
1 – 500	8,797		1,343,230	1.57	1.23	13,150
501 – 1,000	1,924		1,467,353	1.71	1.35	14,365
1,001 – 5,000	3,541		8,261,543	9.63	7.59	80,881
5,001 – 10,000	803		5,817,982	6.78	5.35	56,958
10,001 – 15,000	349		4,338,690	5.06	3.99	42,476
15,001 – 20,000	176		3,164,128	3.69	2.91	30,977
20,001 –	511	2,556,223	58,833,165	71.56	77.58	575,977
Total	**16,101**	**2,556,223**	**83,226,091**	**100**	**100**	**814,784**

Ten largest shareholders at August 31, 2023

Name	Class A shares	Class B shares	Holding (%)	Votes (%)
Försäkringsaktiebolaget, Avanza Pension		10,844,059	12.64	9.97
Lindkvist, Bertil		7,700,000	8.98	7.08
Nordnet Pensionsförsäkring AB		3,754,786	4.38	3.45
Essen-Möller, Anders	556,223	2,813,040	3.93	7.70
Essen-Möller, Maria-Teresa	400,000	963,998	1.59	4.56
Konstruktions och Försäljningsaktiebolag		906,250	1.06	0.83
Essen-Möller, Jon	400,000	402,987	0.94	4.05
Essen-Möller, Martin	400,000	298,513	0.81	3.95
Hillborg, Erika	400,000	263,537	0.77	3.92
Essenshaw, My	400,000	181,002	0.68	3.84
Total, ten largest owners	**2,556,223**	**28,128,172**	**35.77**	**49.35**
Other shareholders		55,097,919	64.23	50.65
Total	**2,556,223**	**83,226,091**	**100**	**100**

Source: Euroclear and Diamyd Medical AB

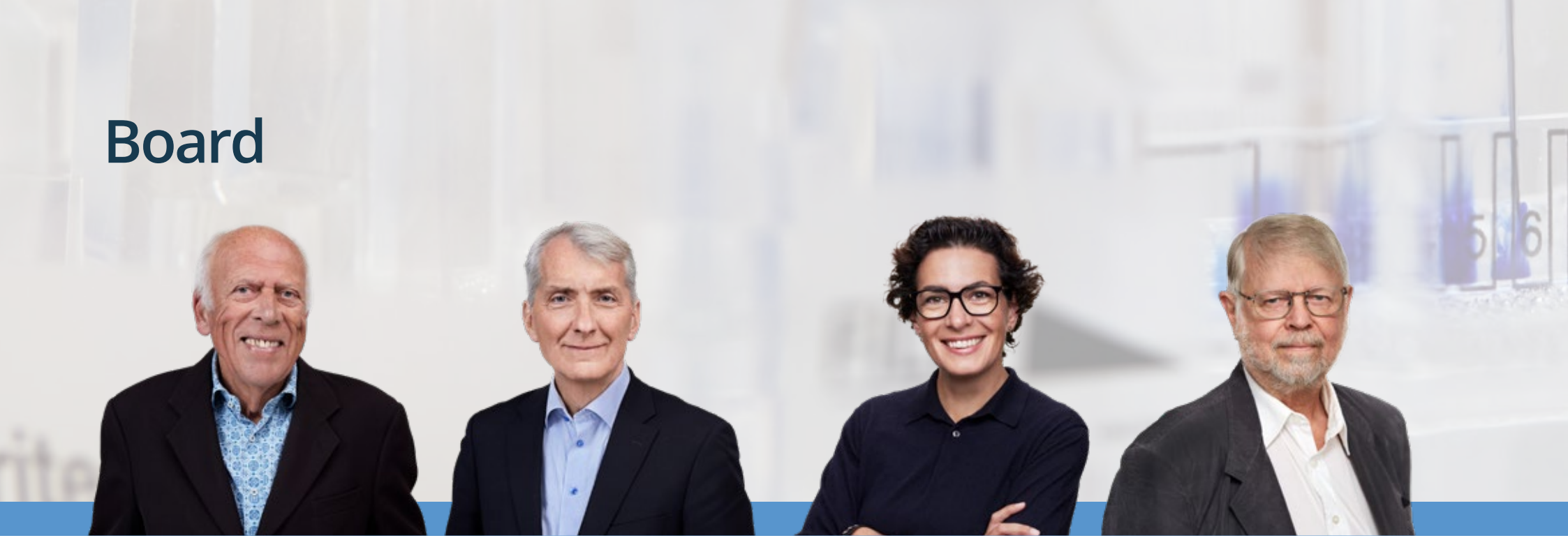
Share capital trend

Year	Transaction	Share capital (increase, SEK)	Class A shares (increase)	Class B shares (increase)	Share capital (accumulated, SEK)
1984	The Company was founded	1,000,000		1,000,000	1,000,000
2013	Split		479,292	8,380,419	1,000,000
2013	New share issue	1,000,000	479,292	9,380,419	2,000,000
2015	New share issue[1)]	10,142		100,000	2,010,142
2015	New share issue	202,846		2,000,000	2,212,988
2015	New share issue[1)]	30,427		300,000	2,243,415
2016	New share issue	747,805	319,528	7,053,612	2,991,220
2017	New share issue	2,573,706	852,074	24,523,919	5,564,926
2017	New share issue[1)]	119,642		1,179,635	5,684,568
2017	New share issue[1)]	28,978		285,714	5,713,545
2018	New share issue[2)]	1,301,852	426,037	12,409,855	7,015,397
2021	New share issue	243,414		2,400,000	7,258,812
2021	New share issue	543,215		5,357,143	7,802,027
2023	New share issue	898,123		8,855,375	8,700,151
Total		**8,700,150**	**2,556,223**	**83,226,091**	**8,700,150**

[1)] *Offset issues.*

[2)] *Warrant redemption scheme.*

Board



Anders Essen-Möller

Chairman
Born in 1941

MSc. Founder of Diamyd Medical and CEO 1996–2007. Independent of the Company, is a major owner. Also Chair of Diamyd Medical 2007-2015. Founder of Synectics Medical AB, which was divested to Medtronic, Inc. in 1996. Chairman of NextCell Pharma AB.

Holding in Diamyd Medical at August 31, 2023:
556,223 Class A shares, 2,813,040 Class B shares.
Holding in endowment policy: 1,203,250 Class B shares.

Erik Nerpin

Vice Chairman
Born in 1961

Bachelor of Laws, Master of Laws. Lawyer. Self-employed with Advokatfirman Nerpin AB. Independent of the Company and its principal owner. Board member of Diamyd Medical since 2012 and Chair 2015-2023. Chair of Kancera AB and Blasieholmen Investment Group AB. Board member of various companies, including Effnetplattformen AB.

Holding in Diamyd Medical at August 31, 2023:
58,731 Class B shares.

Maria-Teresa Essen-Möller

Board member
Born in 1970

MSc in Business Administration. Runs own consulting business. Prior experience includes Chief Commercial Officer at ScientificMed AB, CEO of Health Solutions AB and Digital Marketing Manager at Sanofi. Independent of the Company, but not independent of its principal owner. Board member of Diamyd Medical since 2009.

Holding in Diamyd Medical at August 31, 2023:
400,000 Class A shares, 963,998 Class B shares.

Torbjörn Bäckström

Board member
Born in 1948

Specialist physician in gynecology and obstetrics. CEO of Umecrine AB. Independent of the Company and its principal owner. Board member since 2017. Head of Neurosteroid Research Centre in Umeå and Senior Professor at the Department of Clinical Science, Obstetrics and Gynecology at Umeå University.

Holding in Diamyd Medical at August 31, 2023:
1,000 Class B shares via company.

Mark Atkinson

Board member
Born in 1961

PhD. Professor of Diabetes Research, Department of Pathology, Immunology and Laboratory Medicine, University of Florida, USA. American Diabetes Association Eminent Scholar for Diabetes Research. Director, UF Diabetes Institute, University of Florida. Independent of the Company and its principal owner. Board member since 2018.

Holding in Diamyd Medical at August 31, 2023:
16,750 Class B shares.

Karin Hehenberger

Board member
Born in 1972

M.D., PhD, Karolinska Institute, post-doc at Joslin Diabetes Center, Harvard Medical School. Founder and CEO of Lyfebulb, Board member of 3B Future Health Ventures Scientific Advisory board, Board member of AADI pharmaceuticals, Board member of Anacardio AB, Board member of Rolf Luft Foundation for Diabetes Research, Board member of American Diabetes Association NY/NJ Community Board. Independent of the Company and its principal owner. Board member since 2021.

Holding in Diamyd Medical at August 31, 2023:
10,000 Class B shares.

Karin Rosén

Adjunct Board member
Born in 1967

MD, PhD, Lund University. More than 20 years of experience in senior positions in Global Clinical Development and US & Global Medical Affairs with Horizon Therapeutics, GlaxoSmithKline, Aimmune Therapeutics and Genentech (a member of the Roche Group). Independent of the Company and the principal owners. Adjunct Board member since March 2023.

Holding in Diamyd Medical at August 31, 2023:
-

Management

Ulf Hannelius

Chief Executive Officer
Born in 1975

PhD in Molecular Biology from Karolinska Institute in Stockholm and MBA from the Stockholm School of Economics. Prior experience from business development in the biotech and medtech industries, and from academic research in the fields of genetics and molecular biology. Chair of Diamyd Biomanufacturing AB, Board member of MainlyAI AB. Joined Diamyd Medical in 2015, CEO since 2016.

Holding in Diamyd Medical at August 31, 2023:
237,500 Class B shares.

Anna Styrud

Chief Financial Officer
Born in 1961

MSc in Business Administration from Uppsala University. Prior experience includes CFO of Vasakronan and various positions in finance and accounting in the real estate and engineering industries. Board member of Diamyd Biomanufacturing AB. Anna Styrud joined Diamyd Medical in 2010.

Holding in Diamyd Medical at August 31, 2023:
137,499 Class B shares.

Martina Widman

Chief Operating Officer
Born in 1981

MSc in Mechanical Engineering from the Royal Institute of Technology in Stockholm, with a specialization in biomedical engineering. Prior experience of clinical activities in the pharmaceutical industry. Joined Diamyd Medical in 2008.

Holding in Diamyd Medical at August 31, 2023:
12,500 Class B shares.

Anton Lindqvist

Chief Scientific Officer
Born in 1980

MSc in Molecular Biotechnology from Uppsala University. Research experience from University of Pittsburgh, Uppsala University, the Royal Institute of Technology and Karolinska Institutet. Prior experience in managing technical development at several biotech companies. Anton Lindqvist joined Diamyd Medical in 2013.

Holding in Diamyd Medical at August 31, 2023:
-

Maja Johansson

Chief Operating Officer, Manufacturing Site
Born in 1962

PhD in Biochemistry from Umeå University and Associate Professor in Neuroendocrinology. Prior experience from working in biotech companies. Board member of Diamyd Biomanufacturing AB. Maja Johansson joined Diamyd Medical in 2020.

Holding in Diamyd Medical at August 31, 2023:
2,500 Class B shares.

Eva Karlström

Chief Regulatory Affairs Officer
Born in 1964

Pharmacist from Uppsala University. Prior experience of regulatory affairs in the pharmaceutical industry from AstraZeneca. Eva Karlström joined Diamyd Medical in August 2020.

Holding in Diamyd Medical at August 31, 2023:
-

Christoph Nowak

Chief Medical and Business Officer
Born in 1986

PhD in molecular epidemiology from Uppsala University, MD from University of Oxford (UK), combined Bachelor-Master in Psychology from Braunschweig University (Germany). Prior experience includes Assistant Professor at Karolinska Institutet and physician at Raigmore Hospital in Inverness (Scotland). Christoph Nowak joined Diamyd Medical in 2021.

Holding in Diamyd Medical at August 31, 2023:
8,910 Class B shares.
Holding in endowment policy: 597 Class B shares

Auditors

The Company's auditors are BDO Mälardalen AB, Box 24193, SE-104 51 Stockholm, Sweden. Johan Pharmanson (born in 1964) is Auditor in Charge.

Contents

Directors' Report

The Board of Directors and Chief Executive Officer of Diamyd Medical AB, with its registered office in Stockholm, Sweden, Corporate Registration Number 556242-3797, hereby present their financial statements for the financial year of September 1, 2022–August 31, 2023.

INTRODUCTORY INFORMATION

This annual report encompasses the Group (the "Group", "Company" or "Diamyd Medical"), which includes Diamyd Medical AB, Corp. Reg. No. 556242-3797, and the subsidiary Diamyd Biomanufacturing AB, Corp. Reg. No. 559041-0931. Personnel are employed by the Parent Company. Services billed in the Group are based on resource utilization. The Group was formed on October 31, 2021 when Diamyd Medical AB acquired all of the shares in Mark och Schakt Fastigheter i Umeå AB, later renamed Diamyd Properties AB and subsequently Diamyd Biomanufacturing AB. Diamyd Medical's Class B shares have been traded on Nasdaq First North Growth Market under the DMYD ticker since May 2013. The Company's Certified Adviser is FNCA Sweden AB.

ACTIVITIES

Diamyd Medical develops precision medicine drugs for type 1 diabetes. Diamyd® is an antigen-specific immunotherapy for preserving the body's ability to produce insulin. DIAGNODE-3, a Phase III trial is actively enrolling patients with new-onset type 1 diabetes in eight European countries and has been initiated in the US. A large-scale meta-analysis and the Company's European Phase IIb DIAGNODE-2 trial, where Diamyd® was administered directly into a lymph node in children and young adults newly diagnosed with type 1 diabetes, have shown a statistically significant effect on endogenous insulin retention for 15 months in a large genetically defined subpopulation. A biomanufacturing facility is being set up in Umeå for the manufacture of recombinant GAD65, the active ingredient in the antigen-specific immunotherapy Diamyd®. Diamyd Medical is also developing the GABA-based investigational drug Remygen® as a therapy for regeneration of endogenous insulin production and to improve hormonal response to hypoglycemia.

Diamyd Medical's strategy and business model are based on commercializing and entering into licensing agreements for Diamyd® and Remygen®. By advancing therapies with the Company's investigational drugs, the conditions for concluding agreements with industry partners and licensing agreements to commercialize the Company's values, are strengthened.

Clinical development

Diamyd® and Remygen® are investigational drugs that target the mechanisms underlying diabetes: the loss or dysfunction of insulin-producing beta cells in the pancreas.

Diamyd® is an antigen-specific immunotherapy precision medicine drug for the treatment of autoimmune diabetes (type 1 diabetes and LADA). Clinical data provides strong support for the potential of the Diamyd® diabetes vaccine to suppress or halt the autoimmune destruction of insulin-producing beta cells in individuals who carry the HLA DR3-DQ2 genotype. The effect is achieved by reprogramming antigen-specific immune cells by injecting low doses of Diamyd® into superficial lymph nodes. By preserving endogenous insulin secretion, Diamyd® has the potential to make a significant difference to the patient's daily life and reduce the complications of type 1 diabetes. Topline results from the Phase IIb DIAGNODE-2 trial showed significant treatment efficacy for Diamyd® in a genetically defined subpopulation. A Phase III DIAGNODE-3 trial is ongoing.

Remygen® is an oral regenerative and immunomodulation therapy for the treatment of autoimmune and type 2 diabetes. By stimulating the formation of insulin-producing cells, Remygen® has the potential to slow the disease progression in autoimmune and type 2 diabetes. Based on clinical data, Remygen® also has the potential to improve the hormonal response to hypoglycemia.

Clinical trials

Intralymphatic immunotherapy with Diamyd®

DIAGNODE-3 is a Phase III trial that includes about 330 people aged 12-29 who are newly diagnosed with type 1 diabetes and carry the genetically defined HLA DR3-DQ2 haplotype. This patient population is based on clinical safety and efficacy results from the Phase IIa and IIb trials, DIAGNODE-1 and DIAGNODE-2, as well as the large-scale meta-analysis of data extrapolated from more than 600 people in earlier Phase II and

Phase III trials with Diamyd®. Another subpopulation based on HLA genotypes is included in the trial in order to evaluate the potential cohort of super-responders who are HLA DR3-DQ2 positive, but HLA DR4-DQ8 negative.

The trial is taking place at around 60 clinics across Europe and the US. After an initial month in which all trial participants receive vitamin D, the individuals are randomized 2:1, i.e. two out of three trial participants receive three intralymphatic injections of Diamyd® and one in three receive the corresponding placebo at one month intervals, with one primary reading 24 months after trial start. The design provides, based on efficacy data from previous studies on the HLA-restricted patient population, a high probability of reaching the primary endpoints; preservation of stimulated C-peptide and lower HbA1c. The Principal Investigator of the trial is Professor Johnny Ludvigsson from Linköping University. The sponsor of the trial is Diamyd Medical.

DiaPrecise is an open-label clinical trial where Diamyd® (GAD-alum) is administered directly into lymph nodes in 10 to 16 children aged 8 to 18 years who are at high risk of being diagnosed with clinical type 1 Diabetes (known as stage 1 or stage 2 type 1 Diabetes), and who also carry the genetically defined haplotype HLA DR3-DQ2, associated with clinical response to Diamyd®. The aim of the trial is to assess the safety and feasibility of two or three intralymphatic injections with Diamyd®, the effect on the immune system, and clinical parameters such as endogenous insulin production and glycemic control. The Principal Investigator of DiaPrecise is Dr. Markus Lundgren, Researcher at the Department of Clinical Sciences at Lund University and consultant pediatrician at Kristianstad hospital, Sweden. The sponsor of the trial is Diamyd Medical.

In-house manufacturing of GAD65

A new biomanufacturing facility is being set up in Umeå, the Capital of Västerbotten County in Sweden. The primary purpose is the manufacture of recombinant GAD65, the active pharmaceutical ingredient in the investigational medicine Diamyd®, an antigen-specific immuno therapy currently in late-stage clinical development. The long-term goal is that the facility, in addition to producing enough GAD65 to meet the market demand for Diamyd®, will also be a key player in the production of biological compounds for other drug projects. The 2,200 square-meter facility, which includes clean rooms, laboratories, storerooms and office space, will facilitate full control, predictability and scalability of the manufacturing technology for the active ingredient in Diamyd®. Diamyd Medical has chosen Cytiva's configurable single-use bioprocess manufacturing platform FlexFactory for the process that is based on a baculovirus-insect cell expression system. Small-scale experimental production of GAD65 has been established at the manufacturing facility and large-scale production is being set up with the aim of having an operational facility in 2024. Additional biomanufacturing projects will be evaluated to make full use of the site, platform, analytical laboratory and competencies.

ASSET (AI for Sustainable Prevention of Autoimmunity in the Society)

In September 2021, a five-year project started in sustainable precision health, to which the Swedish governmental innovation agency VINNOVA is providing MSEK 40 in financing. The project is led by Diamyd Medical. The objective of the project is to develop and study new algorithms based on artificial intelligence (AI) for preventive precision medicine treatments for type 1 diabetes and other autoimmune diseases. The innovation environment also includes MainlyAI AB, Lund University, Sahlgrenska University Hospital, the National Diabetes Register and the Leading Health Care Foundation. In parallel, ASSET will study the healthcare system implications/effects in terms of organizational, economic, and legal prerequisites and consequences of applying the suggested precision health approach in the Swedish healthcare system. Diamyd Medical's share of the five-year grant is approximately MSEK 18.

Shares and participations in other companies

Diamyd Medical is the largest owner of NextCell Pharma AB. NextCell Pharma AB, listed on Nasdaq First North Growth Market, develops stem cell therapies and runs a cord blood bank for privately banked stem cells in umbilical cord blood and other sources of stem cells under the company's secondary name of Cellaviva. At August 31, 2023, Diamyd Medical's share of capital and voting rights in the Company was approximately 12.5%, recognized as about MSEK 15.4 in the Parent Company. Diamyd Medical also owns 25% of the shares in the AI company MainlyAI AB. At August 31, the carrying amount was MSEK 1.3.

SIGNIFICANT EVENTS DURING THE FINANCIAL YEAR

- In November 2022, the U.S. Food and Drug Administration (FDA) lifted the partial clinical hold on the Phase III DIAGNODE-3 trial in the US. Following the FDA's decision, the initiation of DIAGNODE-3 in the US was approved.
- In April 2023, Diamyd Medical and JDRF, the leading global organization for research and advocacy in type 1 diabetes, entered into a four-year research and development collaboration including funding of MUSD 5 to Diamyd Medical to support its ongoing Phase III trial with the precision medicine antigen-specific immunotherapy Diamyd®. The grant will be funded under JDRF's Industry Discovery & Development Partnership program, which is focused on the commercialization of therapeutics and/or devices to cure, treat and/or prevent type 1 diabetes and its complications.

- In May 2023, the topline results were announced from Uppsala University Hospital's ReGenerate-1 trial evaluating Diamyd Medical's Remygen®. The trial met the primary safety endpoint. No clear support was observed for a sustained treatment effect on increasing endogenous insulin production measured as C peptide, or the prevention of hypoglycemia (low blood sugar) by improving the protective counterregulatory hormonal response. A potential trend for an immediate effect, e.g. directly following ingestion of Remygen®, on improving counterregulatory hormonal responses was observed in the higher dose groups.
- On May 24, 2023, the Board of Directors of Diamyd Medical, based on the authorization granted by the Company's AGM held on December 1, 2022, resolved on a rights issue of a maximum of 19,231,734 Class B shares, corresponding to approximately MSEK 163 (the "Rights Issue"). The subscription price in the Rights Issue was set at SEK 8.50 per share. Shareholders in Diamyd Medical on the record date had, for each four (4) held shares, regardless of share class, preferential right to subscribe for one (1) new Class B share in the Rights Issue. External guarantors had also provided guarantee commitments subject to customary conditions which, in aggregate, amounted to approximately MSEK 115.2. The Board of Directors of Diamyd Medical resolved to convene an Extraordinary General Meeting (EGM) to decide on an amendment of the Articles of Association. Initially, the Board of Directors proposed that subscribers to the new issue would, in addition to shares, also receive warrants free of charge This proposal was later withdrawn, partly because the registration procedure regarding the prospectus risked being delayed and thus also the intended timeline.
- On June 5, Nasdaq Stockholm decided to stop the trading in subscription rights in Diamyd Medical's Rights Issue. The trading halt was linked to the issue structure (including the new issue of Class B shares and issue of warrants) that Diamyd Medical announced in a press release on May 24.
- On June 13, Diamyd Medical announced its decision to refrain from enforcing the underwriting agreements entered into with a number of external investors in connection with the Rights Issue. The reason is that there was substantial uncertainty as to whether the underwriting agreements were fully legally binding and could be enforced by the Company. In light of this, Diamyd Medical decided to extend the subscription period in the Rights Issue and to draw up a supplementary prospectus.
- Diamyd Medical announced the outcome in the Company's Rights Issue of Class B shares, for which the subscription period ended on June 27, 2023. 8,351,941 Class B shares, corresponding to approximately 43% of the Rights Issue, have been subscribed for with subscription rights. Additionally, applications were received for the subscription of 503,434 Class B shares without subscription rights, corresponding to approximately 3% of the shares offered. In aggregate, the subscriptions with subscription rights and the applications for subscription without subscription rights correspond to approximately 46% of the shares offered. Thus, the Company will receive issue proceeds from the rights issue of approximately MSEK 75 before the deduction of issue expenses.

SIGNIFICANT EVENTS AFTER THE END OF THE FINANCIAL YEAR

- The Board of Directors of Diamyd Medical AB has, subject to approval from an Extraordinary General Meeting, resolved on a rights issue of a maximum of 28,594,104 units, corresponding to approximately MSEK 243. The subscription price in the rights issue was set at SEK 8.50 per unit. Each unit consists of one (1) share, of either Class A or B, one (1) free-of-charge series TO3 warrant for the corresponding share class and one (1) free-of-charge series TO4 warrant for the corresponding share class. An Extraordinary General Meeting on October 10, 2023 approved the rights issue.
- Preliminary results from the open-label DIAGNODE-B clinical trial provided additional support for the safety and feasibility of intralymphatic booster injections of Diamyd®, showing only a small decline in stimulated endogenous insulin production one year following the additional injection and up to eight years from type 1 diabetes diagnosis.
- A retrospective follow-up study of two prior randomized placebo-controlled trials (DiAPREV-IT and DiAPREV-IT2) indicated numerical benefits, although not statistically significant, favoring treatment with only two subcutaneous injections of Diamyd® on reducing the incidence of type 1 diabetes diagnosis (stage 3) in healthy children at risk of type 1 diabetes (stage 1 or stage 2) carrying the HLA DR3-DQ2 haplotype. The study, encompassing a total of 76 children, of whom 40 carried the HLA DR3-DQ2 haplotype, had a maximum follow-up time of 13 years and was performed by Professor Helena Elding Larsson (Lund University and Skåne University Hospital).
- On October 31, 2023, Diamyd Medical announced that the outcome of the Company's rights issue of units, for which the subscription period ended on October 31, 2023, indicated that 8,215,848 units, corresponding to approximately 29% of the rights issue, had been subscribed for with unit rights. Additionally, applications were received for the subscription of 949,834 units without unit rights, corresponding to approximately 3% of the rights issue. In aggregate, the subscriptions with unit rights and the applications for subscription without unit rights correspond

to approximately 32% of the units offered. Thus, the rights issue will provide the Company with issue proceeds of approximately MSEK 78 before the deduction of issue expenses.

FINANCIAL INFORMATION, GROUP

Revenues

Revenues amounted to MSEK 3.7 (2.6). See also Note 3.

Research and development costs

Research and development (R&D) costs is the largest cost item in the Company and amounted to KSEK –69,909 (–75,567), or about 56% (63) of total operating expenses. R&D costs mainly comprise costs for the Phase III DIAGNODE-3 trial and the establishment of GAD65 manufacturing at the facility in Umeå.

Earnings

The Company posted a loss of MSEK –116.1 (–103.5) for the year.

Financial position

At August 31, 2023, cash and cash equivalents and short-term investments amounted to MSEK 127.5 (159.7). Equity amounted to MSEK 169.4 (214.4).

Result from shares and participations

At August 31, 2023, Diamyd Medical had an ownership interest of approximately 12.5% in NextCell Pharma AB. The carrying amount of the holding in the Parent Company amounted to MSEK 15.4 after impairment of approximately MSEK 11.8, based on the difference between cost and market value at August 31, 2023. The share of capital and voting rights on the same date was approximately 12.5%. Diamyd Medical owns 25% of the shares in the AI company MainlyAI AB. At August 31, 2023, the carrying amount was MSEK 1.3. Diamyd Medical did not receive any dividends from its holdings during the financial year.

ORGANIZATION

At August 31, 2023, the Company had 25 (21) employees equivalent to full-time employment, of whom 15 in Stockholm and 10 in Umeå. The average number of employees during the year was 22 (19). Personnel costs amounted to MSEK –25.7 (–20.3). For more information about salaries, other compensation and social security contributions, refer to Note 4.

Performance-based share program, LTI 2022

At the AGM on December 1, 2022, a resolution was adopted in accordance with the Board's proposal to introduce a new performance-based incentive scheme for employees at Diamyd Medical (LTI 2022). The program will run for about three years and participants in LTI 2022 are given an opportunity to be granted, free of charge, the right to acquire Class B shares in Diamyd Medical at a subscription price equivalent to the quotient value of the share within the framework of LTI 2022, or to receive a subscription warrant, free of charge, which provides entitlement to subscribe for one share in Diamyd Medical at a subscription price equivalent to the quotient value of the share, known as performance share rights. If the maximum number of performance share rights are exercised, 300,000 Class B shares may be allotted to participants under LTI 2022 and another 46,500 Class B shares used to cover possible social security contributions resulting from LTI 2022, which entails a dilutive effect of approximately 0.45% of the total number of shares in the Company.

At August 31, 2023, the Company had granted 27 participants performance share rights in accordance with LTI 2022. A total of 270,000 performance share rights have been granted. The LTI 2022 rights were valued on the allotment date at the fair value of the allotted equity instrument. At August 31, 2023, social security contributions for LTI 2022 amounted to MSEK 0.0 and personnel costs to approximately MSEK 0.41. The personnel costs were based on the allotment value, simulated using the Monte Carlo method.

RISK FACTORS

Drug development is usually a lengthy and capital-intensive process entrenched with a high degree of uncertainty due to the high degree of unpredictable and complex parameters of biological and medical processes. The following risks include both internal and external factors, with no order of precedence, that could have a material adverse impact on Diamyd Medical's operations, financial position and results.

Commercial risk and development risk

It cannot be guaranteed that the research and development projects and clinical trials the Company is involved in will result in products that can be approved and launched on the market, or that these products, once launched, will be commercially successful in any or all markets due to the inability to agree on pricing, due to a changed competitive situation or due to the Company alone or in collaboration with any partner does not succeed in marketing its products.

Clinical trials

The Company has concluded, and intends to conclude, agreements with various providers of clinical trial services conducted at clinics and hospitals. There is a risk that current and future suppliers will not deliver as contracted, which could lead to delays and increased costs. Should agreements with partners be terminated, there is no guarantee that these agreements can be replaced with other suppliers within a reasonable period of time, which could delay the clinical trials and, in turn lead to increased costs for the Company and delays in possible future revenues. A key component of clinical trials is the recruitment of trial participants.

Financial risk
Diamyd Medical has no products on the market and the Company has not yet generated any profits. Diamyd Medical has sufficient financial resources to fund the current scope of its operations for at least 12 months. However, the Company may seek additional financing from investors by issuing new shares, which may result in dilution for existing shareholders.

Liquidity risk
Liquidity risk is the risk that the Diamyd Medical will be unable to meet its short-term payment commitments. Liquidity risk is limited through liquidity planning and investments in financial instruments that can be redeemed at short notice. Investments may only be made in interest-bearing securities with low credit risk. In addition, there are limitations for how much may be invested in a single counterparty to avoid a concentration of credit risk. In accordance with the Company's financial policy, surplus liquidity is invested in bank deposits and in commercial papers with a rating of at least A- (S&P) and maturities of up to one year.

Currency risk
Diamyd Medical's accounting and functional currency is SEK. A relatively large share of the Company's development costs are paid in EUR and USD. As a result, the Company is exposed to foreign exchange risk in relation to cash flow within and outside Sweden and the eurozone, such as fluctuations in the exchange rate between the date on which an agreement was signed and the date on which payment is made under an agreement. In accordance with the Company's policy for financial risk, the Company exchanges 60-100% of the projected flows in USD and EUR.

Share-related risks
An investment in Diamyd Medical is associated with risk and the share price may rise as well as fall. As a result, an investor may lose all or some of their invested capital. Between September 1, 2022 and August 31, 2023, the lowest price paid for the Company's share was SEK 7.79 and the highest price paid was SEK 21.50. The share price may fluctuate due to the results of clinical trials, the general economic situation and changes in the stock market's interest in the Company and its share. The share price may therefore be affected by factors that are wholly or partially beyond the Company's control. An investment in shares in Diamyd Medical should therefore be preceded by a careful analysis of the Company, its competitors and business environment, general information about the industry, the general economic situation and other relevant information. There is a risk that shares in Diamyd Medical cannot be sold at a price that is acceptable to the shareholder.

Production risk
The production of an investigational drug for clinical trials requires production of the actual compound in adequate quantities and adequate quality. There is also a risk that Diamyd Medical will be unable to meet this need at a reasonable cost at any given time, which will affect the Company's ability to demonstrate the safety and efficacy of its investigational drugs in clinical trials, which could also delay clinical programs and commercialization and have a material adverse effect on the Company's operations, financial position and results. In 2020, Diamyd Medical started up a facility in Umeå to manufacture recombinant rhGAD65, the active ingredient in Diamyd®. The operation is under development and there is no guarantee it will be completed in time, or achieve the certification and authorization required for the manufacture of clinical trial materials and for market needs.

Intellectual property (IP) risk
There is no guarantee that the Company will develop products that can be patented or that the license rights to a patent can be maintained, renewed or provide sufficient protection for current or future discoveries. There is no guarantee that disputes over agreements or patents can be avoided or that any disputes arising can be settled in favor of the Company.

Key-person risk
Diamyd Medical is heavily reliant on key individuals. There is a risk that the Company's projects will be delayed or prematurely terminated if these individuals leave the Company or are unable to fulfill their duties for any other reason. There is also a risk that the Board, management or other key individuals may make bad decisions that could have an adverse effect on the Company.

Partnership, licensing and acquisition risk
Diamyd Medical's drug development strategy is based on licensing projects that have reached a certain stage of development to partners. The Company may also in-license or acquire projects, products or companies. There is no guarantee that Diamyd Medical will succeed in concluding partnerships and/or license agreements, and/or make acquisitions on commercial terms that are favorable for Diamyd Medical.

Regulatory approval risk
There is no guarantee that regulatory requirements with regard to the level of detail, amount of documentation or otherwise will remain unchanged. Such regulatory requirements may apply to the industry in general, or to Diamyd Medical specifically, and could result in higher costs and the delay or termination of projects.

Legal risk
Diamyd Medical's success is partly dependent on whether the Company's rights, such as patents and other contractual rights, can be safeguarded.

This means that the Company may sometimes be forced to pursue litigation. There is no guarantee that such disputes can be settled in favor of the Company.

CORPORATE GOVERNANCE

Diamyd Medical is a Swedish public company. Corporate governance is based on Swedish law, internal rules and instructions, Nasdaq First North Growth Market's Issuer Rules and other applicable rules. Since the Company's shares have been admitted to trading on Nasdaq First North Growth Market, Diamyd Medical is under no obligation to apply the Swedish Corporate Governance Code. Corporate governance is the framework of rules, practices and procedures by which Diamyd Medical is directed and controlled, attains the Company's objectives and creates value. The purpose of corporate governance is to assure shareholders and other stakeholders that the decisions made by the Company are characterized by trust, effective management and control, transparency, clarity and good business ethics.

Annual General Meeting

Under the Swedish Companies Act, the AGM is the Company's highest decision-making body. At the AGM, the shareholders exercise their right to vote on matters submitted to the Meeting, such as the adoption of income statements and balance sheets, appropriation of the Company's profit, discharge from liability for members of the Board and the Chief Executive Officer, the election of Board members and auditors, and remuneration of the Board and auditors. In addition to the AGM, Extraordinary General Meetings (EGMs) may also be held.

Board of Directors

Under the Swedish Companies Act, the Board of Directors is responsible for the Company's organization and for directing the Company's affairs. The Board is responsible for continuously assessing the Company's operations and financial situation. The key role of the Board is to act on behalf of the Company's shareholders to ensure that the owners' expectations of long-term, satisfactory returns are met. Diamyd Medical's Board should consist of between three and eight members.

In March 2023, Dr Karin Rosen joined the Board of Directors as an adjunct member. Karin Rosén will be proposed for election to the Board at the Company's next AGM on November 30, 2023. After the end of the financial year, in October 2023, the Board of Directors appointed Anders Essen-Möller as Chairman, and former Chairman Erik Nerpin was appointed Vice Chairman.

The Board held 16 minuted meetings during the 2022/2023 financial year. The matters addressed included production and other investment-related issues, financing, regulatory issues and the Phase III program, annual and interim reports, information and communication. In addition to the minuted meetings, the Chairman of the Board and other Board members maintained regular contact with the Company's CEO. The Board received regular reports on the Company's financial position, in accordance with specific reporting instructions.

Chief Executive Officer

The Chief Executive Officer (CEO) is responsible for overseeing the day-to-day administrative and operational functions of the business, and leading the Company in accordance with the Board's guidelines and decisions. In addition to the delegation of responsibilities that is generally applicable under the Swedish Companies Act, the CEO's instructions regulate the duty and obligation to provide the Board with information and the necessary support for decision-making, the role of Secretary at Board meetings, the duty and obligation to ensure compliance with the Board's decisions regarding objectives, mission, strategic plans, and other guidelines, and the proposal of reviews thereof to the Board.

Internal control

The Board is responsible for the Company's internal control. The internal control system includes control of Diamyd Medical's organization, procedures and activities. The purpose is to ensure reliable and accurate financial reporting, that the Company's financial statements are prepared in accordance with the law and applicable accounting standards, and that other requirements are followed. The internal control system also aims to monitor compliance with Diamyd Medical's policies and instructions. In addition, the protection of the Company's assets is monitored, and it is ensured that the Company's resources are used in a cost-efficient and otherwise appropriate manner.

Risk management

Risk management is part of the Board and the CEO's internal governance and control of the operations. It involves identification of the most important risks associated with implementation of the Company's strategy and overall objectives, as well as other risks. Refer to the section on "Risk factors" above. Strategic risks are managed directly by the CEO as part of the day-to-day operations. The Board monitors exposure to these risks to ensure an ability to achieve strategies and objectives. The CEO is responsible for the ongoing management of all operational risks, and for ensuring that action plans are implemented when necessary to eliminate or minimize the impact of the risks identified.

THE SHARE

At August 31, 2023, the number of shares in Diamyd Medical was 85,782,314, comprising 83,226,091 Class B shares (one-tenth of a vote per share) and

2,556,223 Class A shares (one vote per share). The rounded quotient value of both Class A and Class B shares was SEK 0.1014. The shares are denominated in Swedish kronor (SEK). At the end of the financial year (August 31, 2023), the share capital amounted to SEK 8,700,150.

NEW SHARE ISSUE

A rights issue was completed during the financial year based on the authorization granted by the AGM on December 1, 2022. The new issue increased the number of shares in the Company by 8,855,375 to 85,782,314, and the share capital by SEK 898,123 to SEK 8,700,150. The issue was fully registered with the Swedish Companies Registration Office on July 6, 2023.

OWNERSHIP STRUCTURE

At August 31, 2023, the number of shareholders was 16,001 (16,519). The ten largest owners of Diamyd Medical held shares corresponding to 35.8% of the capital and 49.4% of the votes. Both Class A and Class B shares are freely transferable.

THE COMPANY'S FUTURE DEVELOPMENT

At the end of the financial year, Diamyd Medical's cash and cash equivalents and short-term investments amounted to MSEK 127.5.

A rights issue was completed after the end of the financial year that raised proceeds of approximately MSEK 78 for the Company before issue expenses.

The Board and CEO deem that the Company has sufficient funds to cover its capital requirements over the next 12 months.

PROPOSED ALLOCATION OF NON-RESTRICTED EQUITY

According to the balance sheet, the Parent Company's non-restricted equity amounts to the following:

SEK	
Share premium reserve	460,285,769
Retained earnings	–169,062,493
Result for the year	–121,906,141
Non-restricted equity	**169,317,135**

The Board proposes that the Company's retained earnings of SEK 169,317,135 be carried forward. The Company's earnings for the financial year and financial position at August 31, 2023 are presented in the following income statement and balance sheet, cash flow statement and summary of changes in equity, with the accompanying notes.

DIVIDEND

The Board proposes that no dividend be paid for the 2022/2023 financial year.

Multi-year overview

GROUP, KSEK	2022/23	2021/22	2020/21	2019/20	2018/19	2017/18	2016/17	2015/16	2014/15	2013/14
Net income	546	454	253	341	1,568	726	922	757	513	443
R&D costs	–69,909	–75,567	–56,860	–13,810	–22,359	–29,118	–12,871	–6,220	–9,686	–5,465
Personnel costs	–25,658	–20,259	–16,174	–9,195	–7,891	–7,831	–7,031	–7,671	–7,366	–6,716
Result for the year	–116,073	–103,517	60,046	9,709	–36,610	–43,953	–25,555	–32,008	–21,397	–16,034
Cash flow from operating activities	–110,962	–93,219	–109,468	16,154	–39,185	–41,564	–25,808	–17,752	–18,311	–16,690
Cash and cash equivalents and short-term investments at the balance-sheet date	127,533	159,668	139,376	68,362	56,714	44,112	85,726	31,396	29,727	35,675
Equity ratio, %	82	91	94	81	85	78	88	77	85	87
Profit/loss per share, before and after dilution, SEK	–1.5	–1.4	0.9	0.1	–0.5	–0.8	–0.7	–1.3	–1.0	–0.8

2021/22 and 2022/23 pertain to the Group, previous years pertain to the Parent Company.

PARENT COMPANY, KSEK	2022/23	2021/22	2020/21	2019/20	2018/19	2017/18	2016/17	2015/16	2014/15	2013/14
Net income	690	506	253	341	1,568	726	922	757	513	443
R&D costs	–69,909	–75,567	–56,860	–13,810	–22,359	–29,118	–12,871	–6,220	–9,686	–5,465
Personnel costs	–25,658	–20,259	–16,174	–9,195	–7,891	–7,831	–7,031	–7,671	–7,366	–6,716
Result for the year	–121,906	–102,381	60,046	9,709	–36,610	–43,953	–25,555	–32,008	–21,397	–16,034
Cash flow from operating activities	–111,819	–93,255	–109,468	16,154	–39,185	–41,564	–25,808	–17,752	–18,311	–16,690
Cash and cash equivalents and short-term investments at the balance-sheet date	124,918	159,145	139,376	68,362	56,714	44,112	85,726	31,396	29,727	35,675
Equity ratio, %	84	92	94	81	85	78	88	77	85	87
Profit/loss per share, before and after dilution, SEK	–1.6	–1.3	0.9	0.1	–0.5	–0.8	–0.7	–1.3	–1.0	–0.8

Definitions

Share price The closing price on August 31.
Equity per share Equity divided by number of shares at the end of the financial year.
Average number of shares The weighted average number of shares during the year.
Result per share Profit/loss for the year divided by average number of shares.
Equity ratio Equity divided by total assets at the balance-sheet date, expressed as a percentage.

Consolidated income statement

KSEK	Note	Sep 1, 2022 – Aug 31, 2023	Sep 1, 2021 – Aug 31, 2022
OPERATING INCOME			
Net income	3	546	454
Other operating income	3	3,201	2,131
TOTAL OPERATING INCOME		**3,747**	**2,584**
OPERATING EXPENSES			
External research and development costs		–69,909	–75,567
External patent and license costs		–3,634	–4,403
Personnel costs	4	–25,658	–20,259
Other external expenses	5, 6, 7	–14,037	–11,669
Other operating expenses		–1,486	–1,240
Amortization/depreciation and impairment of assets	8, 11.13	–4,869	–4,383
Participations in earnings from associates	15	–4,960	–3,239
TOTAL OPERATING EXPENSES		**–124,553**	**–120,760**
OPERATING RESULT		**–120,806**	**–118,176**
Gain on sale of financial asset	9	-	6,653
Interest income and similar profit items	9	4,735	8,259
Interest expense and similar loss items		–3	–253
TOTAL FINANCIAL ITEMS		**4,732**	**14,659**
RESULT AFTER NET FINANCIAL ITEMS		**–116,073**	**–103,517**
Income tax	10	-	-
RESULT FOR THE PERIOD		**–116,073**	**–103,517**

Consolidated balance sheet

KSEK	Note	Aug 31, 2023	Aug 31, 2022
ASSETS			
Fixed assets			
Intangible assets	8		
Patents		-	-
Tangible assets			
Land and buildings	11	28,959	22,609
Construction in progress	12	825	-
Machinery and inventory	13	22,538	23,139
Financial assets			
Deferred tax		1,536	1,676
Participations in associates	15	10,567	15,463
Other long-term receivables	17	573	626
Total fixed assets		**64,999**	**63,513**
Current assets			
Accounts receivable		59	251
Other receivables		3,996	2,194
Prepaid expenses and accrued income	18	9,221	10,897
Short-term investments		-	39,907
Cash and cash equivalents		127,533	119,761
Total current assets		**140,809**	**173,011**
TOTAL ASSETS		**205,808**	**236,524**

KSEK	Note	Aug 31, 2023	Aug 31, 2022
EQUITY AND LIABILITIES			
Equity			
Share capital	19	8,700	7,802
Statutory reserve		200	200
Share premium reserve		460,286	390,507
Retained earnings		–183,716	–80,613
Result for the period		-116,073	–103,517
Total equity		**169,397**	**214,379**
Provisions			
Pensions and other commitments	20	692	777
Total provisions		**692**	**777**
Long-term liabilities			
Other long-term liabilities	21	15,865	-
Total long-term liabilities		**15,865**	**-**
Current short-term liabilities			
Trade payables		4,886	9,778
Other current liabilities		9,431	6,559
Accrued expenses and deferred income	22	5,537	5,030
Total short-term liabilities		**19,854**	**21,367**
TOTAL EQUITY AND LIABILITIES		**205,808**	**236,524**

Consolidated cash flow statement

KSEK	Note	Sep 2022 – Aug 2023	Sep 2021 – Aug 2022
OPERATING ACTIVITIES			
Operating result		–120,806	–118,176
Interest received		1,051	67
Interest paid		–3	–253
Non-cash flow items			
Amortization/depreciation	11, 13	4,869	4,383
Other non-cash flow items	15	5,374	3,239
CASH FLOW BEFORE CHANGES IN WORKING CAPITAL		**–109,515**	**–110,741**
Increase (-) decrease (+) receivables		66	10,095
Increase (+) decrease (-) liabilities		–1,513	7,426
TOTAL CASH FLOW FROM OPERATING ACTIVITIES		**–110,962**	**–93,219**
INVESTING ACTIVITIES			
Investments in tangible and intangible assets		–11,442	–34,652
Investments in financial assets		–64	-
Gain on divestment of financial assets	9	-	6,653
Loan payment		-	–8,815
Matured short-term investments		39,907	89,984
Investment in short-term investments		-	–129,891
CASH FLOW FROM INVESTING ACTIVITIES		**28,401**	**–76,722**
FINANCING ACTIVITIES			
New share issue		75,271	150,000
Issue expenses		–4,594	–7,845
Long-term liabilities		15,865	-
CASH FLOW FROM FINANCING ACTIVITIES		**86,542**	**142,155**
CASH FLOW FOR THE PERIOD		3,981	–27,786
Total cash and cash equivalents at the beginning of the period		119,761	139,376
Effects of currency translation on cash and cash equivalents		3,791	8,171
TOTAL CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD		**127,533**	**119,761**

Consolidated change in equity

KSEK	Share capital	Statutory reserve	Share premium reserve	Other non-restricted equity	Total equity
OPENING BALANCE OCTOBER 31, 2021	**7,259**	**200**	**248,895**	**–80,613**	**175,741**
Result for the period	-	-	-	–103,517	–103,517
New share issue	543	-	149,457	-	150,000
Issue expenses	-	-	–7,845	-	–7,845
CLOSING BALANCE AUGUST 31, 2022	**7,802**	**200**	**390,507**	**–184,130**	**214,379**
OPENING BALANCE SEPTEMBER 1, 2022	**7,802**	**200**	**390,507**	**–184,130**	**214,379**
Result for the period	-	-	-	–116,073	–116,073
New share issue	898	-	74,373	-	75,271
Issue expenses	-	-	–4,594	-	–4,594
Incentive scheme, LTI 2022	-	-	-	414	414
CLOSING BALANCE AUGUST 31, 2023	**8,700**	**200**	**460,286**	**–299,789**	**169,397**

Parent Company income statement

KSEK	Note	Sep 1, 2022 – Aug 31, 2023	Sep 1, 2021 – Aug 31, 2022
OPERATING INCOME			
Net income	3	690	506
Other operating income	3	3,094	1,593
TOTAL OPERATING INCOME		**3,784**	**2,099**
OPERATING EXPENSES			
External research and development costs		–69,909	–75,567
External patent and license costs		–3,634	–4,403
Personnel costs	4	–25,658	–20,259
Other external expenses	5, 6, 7	–15,089	–11,587
Other operating expenses		–1,486	–1,240
Amortization/depreciation and impairment of assets	8, 13	–3,466	–2,503
TOTAL OPERATING EXPENSES		**–119,242**	**–115,559**
OPERATING RESULT		**–115,458**	**–113,460**
Impairment of participations in associates	15	–11,781	–3,818
Gain on sale of financial asset	9	-	6,653
Interest income and similar profit items	9	5,335	8,497
Interest expense and similar loss items		–3	–253
RESULT AFTER NET FINANCIAL ITEMS		**–121,906**	**–102,381**
Income tax	10	-	-
RESULT FOR THE PERIOD		**–121,906**	**–102,381**

Parent Company balance sheet

KSEK	Note	Aug 31, 2023	Aug 31, 2022
ASSETS			
Fixed assets			
Intangible assets			
Patents	8	-	-
Tangible assets			
Machinery and inventory	13	22,296	22,868
Financial assets			
Shares in subsidiaries	14	15,900	14,900
Long-term receivables from subsidiaries	16	18,000	9,325
Participations in associates	15	16,686	28,403
Other long-term receivables	17	573	626
Total fixed assets		**73,455**	**76,120**
Current assets			
Accounts receivable		-	251
Receivables from Group companies		727	-
Other receivables		3,771	2,351
Prepaid expenses and accrued income	18	9,200	11,203
Short-term investments		-	39,907
Cash and cash equivalents		124,918	119,238
Total current assets		**138,616**	**172,950**
TOTAL ASSETS		**212,071**	**249,070**

KSEK	Note	Aug 31, 2023	Aug 31, 2022
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	19	8,700	7,802
Statutory reserve		200	200
Non-restricted equity			
Share premium reserve		460,286	390,507
Retained earnings		–169,062	–67,095
Result for the period		–121,906	–102,381
TOTAL EQUITY		**178,217**	**229,033**
Provisions			
Pensions and other commitments	20	692	777
Total provisions		**692**	**777**
Long-term liabilities			
Other long-term liabilities	21	15,865	-
Total long-term liabilities		**15,865**	**-**
Short-term liabilities			
Trade payables		3,839	9,584
Other current liabilities		7,820	4,722
Liabilities to Group companies		100	-
Accrued expenses and deferred income	22	5,537	4,953
Total short-term liabilities		**17,296**	**19,260**
TOTAL EQUITY AND LIABILITIES		**212,071**	**249,070**

Parent Company cash flow statement

KSEK	Note	Sep 2022 – Aug 2023	Sep 2021 – Aug 2022
OPERATING ACTIVITIES			
Operating result		–115,458	–113,460
Interest received		1,650	304
Interest paid		–3	–253
Non-cash flow items			
Amortization/depreciation		3,466	2,503
Other non-cash flow items		381	-
CASH FLOW BEFORE CHANGES IN WORKING CAPITAL		**–109,963**	**–110,906**
Increase (-) decrease (+) receivables		107	9,794
Increase (+) decrease (-) liabilities		–1,963	7,858
TOTAL CASH FLOW FROM OPERATING ACTIVITIES		**–111,819**	**–93,255**
INVESTING ACTIVITIES			
Investments in tangible and intangible assets	13	–2,894	–19,752
Investments in financial assets	14, 15	–1,064	–14,900
Loans to subsidiaries		–8,675	–9,325
Gain on divestment of financial assets	9	-	6,653
Matured short-term investments		39,907	89,984
Investment in short-term investments		-	–129,891
CASH FLOW FROM INVESTING ACTIVITIES		**27,273**	**–77,231**
FINANCING ACTIVITIES			
New share issue		75,271	150,000
Issue expenses		–4,594	–7,845
Long-term liabilities		15,865	-
CASH FLOW FROM FINANCING ACTIVITIES		**86,542**	**142,155**
CASH FLOW FOR THE PERIOD		1,996	–28,331
Total cash and cash equivalents at the beginning of the period		119,238	139,376
Effects of currency translation on cash and cash equivalents		3,684	8,193
TOTAL CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD		**124,918**	**119,238**

Parent Company change in equity

KSEK	Share capital	Statutory reserve	Share premium reserve	Other non-restricted equity	Total equity
OPENING BALANCE SEPTEMBER 1, 2021	**7,259**	**200**	**248,895**	**–67,095**	**189,258**
Result for the period	-	-	-	–102,381	–102,381
New share issue	543	-	149,457	-	150,000
Issue expenses	-	-	–7,845	-	–7,845
CLOSING BALANCE AUGUST 31, 2022	**7,802**	**200**	**390,507**	**–169,476**	**229,033**
OPENING BALANCE SEPTEMBER 1, 2022	**7,802**	**200**	**390,507**	**–169,476**	**229,033**
Result for the period	-	-	-	–121,906	–121,906
New share issue	898	-	74,373	-	75,271
Issue expenses	-	-	–4,594	-	–4,594
Incentive scheme, LTI 2022	-	-	-	414	414
CLOSING BALANCE AUGUST 31, 2023	**8,700**	**200**	**460,286**	**–290,969**	**178,217**

Notes

The financial statements have been prepared in accordance with the Swedish Annual Accounts Act and the Swedish Accounting Standards Board's BFNAR 2012:10 Annual report and consolidated financial statements (K3).

NOTE 1 RECOGNITION AND MEASUREMENT PRINCIPLES

CONSOLIDATED FINANCIAL STATEMENTS
The Group was formed on October 31, 2021. The consolidated financial statements encompass the Parent Company Diamyd Medical AB and the companies over which the Parent Company has a direct or indirect controlling influence (subsidiary). Controlling influence entails a right to formulate another corporate financial and operating strategy to obtain economic benefits. When assessing whether a controlling influence exists, account should be taken of financial instruments that may carry voting rights that can be utilized without delay or converted into equity instruments that carry voting rights. Consideration should also be taken of whether the Company has the ability to govern operations through an agent. Controlling influence normally exists when the Parent Company directly or indirectly holds shares that represent more than 50% of the votes. A subsidiary's revenues and expenses are included in the consolidated financial statements from the date of the acquisition until the date when the Parent Company no longer has a controlling influence over the subsidiary. All intra-Group transactions, dealings and unrealized gains or losses relating to intra-Group transactions were eliminated when preparing the consolidated financial statements.

Revenue recognition
Sales of goods or services are recognized when the risks and rewards of ownership have been transferred from the seller to the buyer in accordance with the terms of sale. The sale is recognized less sales tax and discounts.

Public funding
Public funding is recognized at fair value when there is reasonable certainty that the funding will be received and that the Group will meet the conditions tied to the funding. Before the conditions for recognition as revenues are met, funding received is recognized as a liability.

Associates
Associates are consolidated in the consolidated financial statements by applying the equity method, which means shares in the associate are initially measured at cost in the consolidated financial statements, and are then adjusted to reflect the Company's share of the associate's results with a delay of one quarter. The Parent Company recognizes associates at cost less any impairment losses. Any dividends are recognized as financial income. Impairment tests are carried out on an annual basis.

Intangible assets
Intangible assets refer to license rights, acquired directly or through business combinations. Patent license fees are recognized as an asset if the licenses pertain to a controllable asset deemed commercially viable. This also applies if the license rights are deemed transferable at their fair value. The licenses are amortized on a straight-line basis over their estimated useful life from the date they become usable. Proprietary patent rights, technology rights, trademarks and other similar assets are not assigned any value. No development costs meet the criteria for capitalization, which means that all research and development costs are expensed as incurred.

Financial instruments
A financial asset or liability is recognized on the balance sheet in accordance with the contractual terms of the instrument. A financial asset is derecognized when the contractual rights to the cash flows from the asset have expired or are forfeited. A financial liability (or part of the liability) is derecognized when the obligation specified in the contract is discharged, canceled or expires. Current assets and current liabilities are initially measured at cost. Long-term receivables are initially measured at amortized cost. Current assets are subsequently measured using the lowest value principle, which means the lower of cost or net realizable value at the balance-sheet date. Current liabilities are measured at their nominal amounts. The Company assesses the fair values of financial assets on an annual basis to determine whether there is any indication that an asset may be impaired. The assessment is made on a case-by-case basis.

Leases
All leases, both finance and operating leases, are recognized as operating leases. Operating leases are recognized as an expense over the lease term on a straight-line basis.

Income tax
Current tax is income tax for the current financial year, pertaining to taxable profit for the year. Deferred tax assets

Note 1, cont.

related to loss carryforwards or other future tax losses are only recognized to the extent it is probable that the tax loss can be recovered against future taxable profit.

Provisions
Provisions are recognized when there is a present obligation (legal or constructive) resulting from a past event where it is probable that an outflow of resources will be required to settle the obligation. Provisions are reviewed annually.

Employee benefits
Employee benefits in the form of salaries, paid vacation and sick leave, and pensions are recognized as they are earned. Pensions and other post-employment benefits are classified as either defined-contribution or defined-benefit pension schemes. The Company has defined-contribution pension schemes for which it pays fixed fees to an insurance company and has no obligation to pay additional fees. All of these pension costs are charged to operating profit. The Company also has one defined-benefit pension scheme related to a former employee. The premium payments ceased when employment was terminated, and there is no obligation to make any further payments. Therefore, no actuarial assumptions are required to calculate pension obligations or costs, nor is it possible to recognize actuarial gains or losses.

Receivables and liabilities in foreign currency
Receivables and liabilities in foreign currency are translated using the applicable exchange rates at the balance-sheet date. Currency gains and losses arising from the payment of such transactions, and from the translation of monetary assets and liabilities in foreign currency using the closing rate, are recognized in profit or loss. All exchange-rate differences are recognized in profit or loss.

Depreciation/amortization of fixed assets
Fixed assets are depreciated/amortized using the straight-line method over their estimated useful life. Depreciation/amortization according to plan has been calculated using the original cost and depreciation/amortization rates based on the estimated useful life of the assets. The useful life of the fixed assets is tested annually. Patents are amortized over five years. Machinery and equipment are depreciated over three to ten years and buildings up to 50 years.

Cash flow statement
The cash flow statement has been prepared using the indirect method. The cash flow reported only includes inflows and outflows of cash transactions. In addition to cash and bank balances, the classification of cash and cash equivalents also includes short-term investments, such as commercial papers with a maturity date of three months or less from their date of issue, that can easily be converted into a known amount and are only exposed to a negligible risk of value fluctuation.

ACCOUNTING POLICIES FOR THE PARENT COMPANY
Subsidiaries
Shares in subsidiaries are recognized at cost. Dividends from subsidiaries are recognized as income when the right to receive a dividend is deemed certain and can be reliably calculated.

NOTE 2 ESTIMATES AND JUDGMENTS

The financial statements have been prepared in accordance with BFNAR 2012:10 (K3), which requires management to make estimates and assumptions that affect the application of the Company's accounting policies and the amounts recognized in the financial statements. The actual results may differ from these estimates and judgments, which is why they are continuously evaluated. The effect of a change in an accounting estimate is recognized in the period in which the change took place if the change affects that period only, or in the period in which the change took place and future periods if the change affects both. The judgments made by management with the most significant effects on the amounts recognized in the financial statements and that could have a material effect on future periods are set out below.

Intangible assets
Patent license fees are recognized as an asset if these could be regarded as a controllable asset deemed commercially viable.

Tangible assets
In conjunction with the acquisition of the Formen 12 property in Umeå, which is owned by the subsidiary Diamyd Biomanufacturing AB, its building was divided into components for accounting purposes. The division was based on the building's condition and use, and an assessment was conducted to decide on the useful life for each component, which was used as a basis for the depreciation periods.

Financial assets
At August 31, 2023, participations in associates amounted to KSEK 16,686 in the Parent Company, and consisted of shares in NextCell Pharma AB and MainlyAI AB. Following impairment tests of the holdings, an impairment of the holding in NextCell Pharma AB was undertaken in an amount of KSEK 11,781. The ownership interest in NextCell Pharma amounts to approximately 12.5% and is classified as an associate since Anders Essen-Möller, Board member and major owner in Diamyd Medical, is Chairman of NextCell Pharma.

NOTE 3 OPERATING INCOME

	2022/23	2021/22
Sales of GAD for research purposes	375	386
Rental income and other lease-related income	278	597
Operating exchange gains	170	381
Accrued funding received	2,924	1,213
Other income	-	8
Total	**3,747**	**2,584**

Parent Company, **KSEK**	2022/23	2021/22
Sales of GAD for research purposes	375	386
Operating exchange gains	170	381
Accrued funding received	2,924	1,213
Intra-Group invoicing	315	120
Total	**3,784**	**2,099**

Group, KSEK
Accrued funding received related to eligible costs for VINNOVA-financed projects. There are no contingent assets or contingent liabilities in connection with this funding.

NOTE 4 PERSONNEL COSTS

Parent Company and Group

Average no. of employees	2022/23	2021/22
Of whom women	14	11
Of whom men	8	8
Total	**22**	**19**

Gender representation on Board and Management Team	Aug 31, 2023		Aug 31, 2022	
	Women	Men	Women	Men
Board	3	4	2	4
Management Team	4	3	4	2
Total	**7**	**7**	**6**	**6**

Salaries, other compensation and social security contributions 2022/2023 KSEK	Salary/fees and other compensation	Pension costs	Social security contributions	Incentive scheme, LTI 2022	Total
Erik Nerpin, Chairman	175	-	55	-	230
Anders Essen-Möller, Board member [1]	1,051	-	13	-	1,064
Maria-Teresa Essen-Möller, Board member	125	-	39	-	164
Torbjörn Bäckström, Board member	125	-	13	-	138
Mark Atkinson, Board member [2]	175	-	-	-	175
Karin Hehenberger, Board member	125	-	-	-	125
Karin Rosén, Adjunct Board member	28	-	-	-	28
Ulf Hannelius, President and CEO [3]	2,131	463	412	-	3,006
Other employees	15,134	2,151	2,358	-	19,642
Incentive scheme, LTI 2022 [4]	-	-	-	414	414
Total	**19,069**	**2,614**	**2,889**	**414**	**24,986**

[1] *Of the amount, 125 refers to Board fees and 926 to consulting fees. See also Note 5.*
[2] *Of the amount, 125 refers to Board fees and 50 to consulting fees. See also Note 5.*
[3] *There is a mutual notice period of three months between the Company and CEO Ulf Hannelius. There is no separate severance agreement.*
[4] *At August 31, 2023, the Company had granted 27 participants performance share rights in accordance with LTI 2022.*
A total of 270,000 performance share rights have been granted. The LTI 2022 rights were valued on the allotment date at the fair value of the allotted equity instrument.
The personnel costs were based on the allotment value, simulated using the Monte Carlo method.

Salaries, other compensation and social security contributions 2021/2022 KSEK	Salary/fees and other compensation	Pension costs	Social security contributions	Total
Erik Nerpin, Chairman	169	-	53	222
Anders Essen-Möller, Board member	1,045	-	12	1,057
Maria-Teresa Essen-Möller, Board member	119	-	37	156
Torbjörn Bäckström, Board member	119	-	12	131
Mark Atkinson, Board member	169	-	-	169
Karin Hehenberger, Board member	94	-	-	94
Ulf Hannelius, President and CEO	1,967	427	413	2,808
Other employees	12,067	1,638	1882	15,588
Total	**15,748**	**2,065**	**2,410**	**20,223**

NOTE 5 RELATED-PARTY TRANSACTIONS

During the year, companies represented by a related party to the principal owner and Board member Anders Essen-Möller were engaged on a consultancy basis. Total consulting fees and salaries paid to related parties amounted to KSEK 1,548 (1,302), of which Anders Essen-Möller, as a working Board member, was paid an amount of KSEK 926 (926) through a company owned by Essen-Möller. Board member Mark Atkinson received compensation of KSEK 50 (50) for consulting services. The Arm's Length principle was applied to pricing.

Group, KSEK	2022/23	2021/22
Consulting fees and salaries to related parties	1,548	1,302
Consulting fees to Board members	976	976

Parent Company, KSEK	2022/23	2021/22
Consulting fees and salaries to related parties	1,548	1,302
Consulting fees to Board members	976	976

NOTE 6 AUDITOR'S FEES

Group, KSEK	2022/23	2021/22
BDO Mälardalen AB		
Audit assignments	524	350
Other accountancy services	8	13
Baker Tilly Umeå AB		
Audit assignments	-	32
Total	**532**	**395**

Parent Company, KSEK	2022/23	2021/22
BDO Mälardalen AB		
Audit assignments	524	350
Other accountancy services	8	13
Total	**532**	**363**

NOTE 7 LEASES

Group, KSEK	2022/23	2021/22
Lease payments, incl. rent during the year	831	749
Future lease payments incl. rent are due for payment as follows:		
Within 1 year	837	742
Within 2-5 years	793	1,422
Total	**1,630**	**2,165**

Parent Company, KSEK	2022/23	2021/22
Lease payments, incl. rent during he year	2,319	1,581
Future lease payments incl. rent are due for payment as follows:		
Within 1 year	3,118	1,900
Within 2-5 years	9,164	3,737
Within 6-10 years	11,400	-
Total	**23,682**	**5,637**

At August 31, 2023, the Parent Company had one rental agreement for office premises in Stockholm with a remaining term of one year and one month, and one rental agreement with Diamyd Biomanufacturing AB for office and lab premises in Umeå with a remaining term of 11 years and nine months.

NOTE 8 PATENTS

Group, KSEK	Aug 31, 2023	Aug 31, 2022
Opening cost	11,076	11,076
Purchases	-	-
Sales/disposals	-	-
Closing accumulated costs	**11,076**	**11,076**
Amortization for the year	-	–65
Closing accumulated amortization	**–11,076**	**–11,076**
Closing carrying amount	**0**	**0**

Parent Company, KSEK	Aug 31, 2023	Aug 31, 2022
Opening cost	11,076	11,076
Purchases	-	-
Sales/disposals	-	-
Closing accumulated costs	**11,076**	**11,076**
Amortization for the year	-	–65
Closing accumulated amortization	**–11,076**	**–11,076**
Closing carrying amount	**0**	**0**

NOTE 9 FINANCIAL INCOME

Group, KSEK	2022/23	2021/22
Gain on sale of shares in Companion Medical, Inc.	-	6,653
Interest income	1,051	67
Exchange gains	3,684	8,193
Total	**4,735**	**14,912**

Parent Company, KSEK	2022/23	2021/22
Gain on sale of shares in Companion Medical, Inc.	-	6,653
Interest income	1,650	304
Exchange gains	3,684	8,193
Total	**5,335**	**15,150**

NOTE 10 INCOME TAX

Group, KSEK	2022/23	2021/22
Current tax		
Reconciliation of effective tax		
Profit/loss before tax	–116,073	–103,517
Tax expense 20.6% (20.6%)	–23,911	–21,324
Tax effect of:		
Non-deductible expenses	135	43
Non-taxable income	–1	–1,370
Other unrecognized expenses	–946	–1,616
Loss carryforwards incurred during the year	–24,723	–24,267
Loss carryforwards utilized during the year	-	-
Tax expense	**-**	**-**

Parent Company, KSEK	2022/23	2021/22
Current tax		
Reconciliation of effective tax		
Profit/loss before tax	–121,906	–102,381
Tax expense 20.6% (20.6%)	–25,113	–21,090
Tax effect of:		
Non-deductible expenses	2,562	830
Non-taxable income	–1	–1,370
Other unrecognized expenses	–946	–1,616
Loss carryforwards incurred during the year	–23,498	–23,246
Loss carryforwards utilized during the year	-	-
Tax expense	**-**	**-**

NOTE 11 LAND AND BUILDINGS

Group, KSEK	Aug 31, 2023	Aug 31, 2022
Land and buildings		
Opening cost	24,476	-
Property purchases	-	24,476
Investments in existing properties	7,723	-
Closing cost	**32,199**	**24,476**
Opening depreciation land and buildings	–1,866	-
Depreciation for the year land and buildings	–1,374	–1,866
Closing accumulated depreciation	**–3,240**	**–1,866**
Closing carrying amount land and buildings	**28,959**	**22,610**

NOTE 12 CONSTRUCTION IN PROGRESS

Group, KSEK	Aug 31, 2023	Aug 31, 2022
Construction in progress		
Opening cost	-	-
Construction in progress purchases	825	-
Closing carrying amount construction in progress	**825**	**0**

NOTE 13 MACHINERY AND EQUIPMENT

Group, KSEK	Aug 31, 2023	Aug 31, 2022
Machinery and equipment		
Opening cost	27,381	7,343
Purchases	2,894	20,038
Reclassification	–1,403	–
Closing cost	**28,872**	**27,381**
Opening depreciation machinery and equipment	–4,242	–1,790
Depreciation for the year machinery and equipment	–3,495	–2,452
Reclassification	1,403	-
Closing accumulated depreciation	**–6,334**	**–4,242**
Closing carrying amount machinery and equipment	**22,538**	**23,139**

Parent Company, KSEK	Aug 31, 2023	Aug 31, 2022
Machinery and equipment		
Opening cost	27,095	7,343
Purchases	2,894	19,752
Closing cost	**29,989**	**27,095**
Opening depreciation machinery and equipment	–4,227	–1,790
Depreciation for the year machinery and equipment	–3,466	–2,437
Closing accumulated depreciation	**–7,693**	**–4,227**
Closing carrying amount machinery and equipment	**22,296**	**22,868**

NOTE 14 PARTICIPATIONS IN SUBSIDIARIES

Parent Company, KSEK						Aug 31, 2023	Aug 31, 2022
Company	**Corp. Reg. No.**	**Registered office**	**Votes, %**	**Share of capital, %**	**No. of shares**	**Carrying amount**	**Carrying amount**
Diamyd Biomanufacturing AB	559041-0931	Stockholm, Region Stockholm	100.0	100.0	500	15,900	14,900
Closing accumulated costs					**500**	**15,900**	**14,900**
Closing carrying amount					**500**	**15,900**	**14,900**

The year-on-change pertains to shareholders' contributions paid of MSEK 1.

Information about equity and earnings for Diamyd Biomanufacturing AB		
Equity according to most recently adopted financial statements	45	124
Result according to most recently adopted financial statements	-79	-24

NOTE 15 PARTICIPATIONS IN ASSOCIATES

Group, KSEK	Aug 31, 2023	Aug 31, 2022
Opening cost	15,463	32,220
Participations acquired in associates during the year	64	-
Adjustment of share in profits using the equity method	–4,960	–16,757
Carrying amount at year end	**10,567**	**15,463**

Parent Company, KSEK	Aug 31, 2023	Aug 31, 2022
Opening cost	28,402	32,220
Participations acquired in associates during the year	64	-
Impairment of participations in associates during the year	–11,781	–3,818
Carrying amount at year end	**16,686**	**28,402**

Group, KSEK						Aug 31, 2023	Aug 31, 2022
Company	**Corp. Reg. No.**	**Registered office**	**Votes, %**	**Share of capital, %**	**No. of shares**	**Carrying amount**	**Carrying amount**
NextCell Pharma AB	556965-8361	Huddinge, Region Stockholm	12.5	12.5	4,283,861	9,303	14,263
MainlyAI AB	559258-7538	Stockholm, Region Stockholm	25.0	25.0	5,625	1,264	1,200

Parent Company, KSEK						Aug 31, 2023	Aug 31, 2022
Company	**Corp. Reg. No.**	**Registered office**	**Votes, %**	**Share of capital, %**	**No. of shares**	**Carrying amount**	**Carrying amount**
NextCell Pharma AB	556965-8361	Huddinge, Region Stockholm	12.5	12.5	4,283,861	15,422	27,203
MainlyAI AB	559258-7538	Stockholm, Region Stockholm	25.0	25.0	5,625	1,264	1,200

Information about equity and earnings for NextCell Pharma AB		
Equity according to most recently adopted financial statements	115,539	150,093
Result according to most recently adopted financial statements	–34,554	–24,557

Information about equity and earnings for MainlyAI AB		
Equity according to most recently adopted financial statements	2,208	2,210
Result according to most recently adopted financial statements	–3	–15

NOTE 16 LONG-TERM RECEIVABLES FROM SUBSIDIARIES

Parent Company, KSEK	Aug 31, 2023	Aug 31, 2022
Opening cost	9,325	-
Loans to Diamyd Biomanufacturing AB	8,675	9,325
Closing accumulated costs	**18,000**	**9,325**
Closing carrying amount	**18,000**	**9,325**

NOTE 17 OTHER LONG-TERM RECEIVABLES

Group, KSEK	Aug 31, 2023	Aug 31, 2022
Opening cost	626	626
Impairment	–52	-
Closing accumulated costs	**573**	**626**
Closing carrying amount	**573**	**626**

Parent Company, KSEK	Aug 31, 2023	Aug 31, 2022
Opening cost	626	626
Impairment	–52	-
Closing accumulated costs	**573**	**626**
Closing carrying amount	**573**	**626**

The amount consists of a pension provision in an endowment policy.

NOTE 18 PREPAID EXPENSES AND ACCRUED INCOME

Group, KSEK	2022/23	2021/22
Prepaid rent	14	11
Prepaid insurance premiums	503	579
Prepaid research and development costs	7,690	10,133
Other prepaid expenses	399	142
Other accrued income	614	33
Total	**9,221**	**10,897**

Parent Company, KSEK	2022/23	2021/22
Prepaid rent	14	11
Prepaid insurance premiums	490	567
Prepaid research and development costs	7,690	10,133
Other prepaid expenses	399	221
Other accrued income	606	271
Total	**9,200**	**11,203**

NOTE 19 SHARE CAPITAL

For a specification of the Parent Company's changes in equity, refer to *"Change in equity"* on page 42. At August 31, 2023, the number of shares in Diamyd Medical AB comprised 83,226,091 Class B shares (one-tenth of a vote per share held) and 2,556,223 Class A shares (one vote per share held). At the end of the financial year, Diamyd Medical AB's share capital amounted to SEK 8,700,150 (7,802,027). The (rounded) quotient value was 0.1014 (0.1014). All shares issued are fully paid.

NOTE 20 PROVISIONS

Group, KSEK	Aug 31, 2023	Aug 31, 2022
Opening cost	777	777
Impairment	–85	-
Closing accumulated costs	**692**	**777**
Closing carrying amount	**692**	**777**

Parent Company, KSEK	Aug 31, 2023	Aug 31, 2022
Opening cost	777	777
Impairment	–85	-
Closing accumulated costs	**692**	**777**
Closing carrying amount	**692**	**777**

The amount consists of a pension provision in an endowment policy including payroll tax.

NOTE 21 LONG-TERM LIABILITIES

Group, KSEK	Aug 31, 2023	Aug 31, 2022
Opening cost	-	-
Other long-term liabilities, JDRF	15,865	-
Closing carrying amount	**15,865**	**-**

Parent Company, KSEK	Aug 31, 2023	Aug 31, 2022
Opening cost	-	-
Other long-term liabilities, JDRF	15,865	-
Closing carrying amount	**15,865**	**-**
Of which due later than 5 years	**15,865**	**-**

Diamyd Medical will receive financing, within the framework of its partnership with JDRF (www.jdrf.org), when certain milestones have been reached in the DIAGNODE-3 trial. During the 2022-2023 financial year, Diamyd Medical passed two such milestones and received a total of MSEK 15.9 from JDRF. Further milestones with accompanying payments are expected to be achieved in 2023-2024.

If Diamyd Medical obtains commercial approval for Diamyd® in the future and sales of the drug are commercially successful, JDRF will receive limited royalties from income within the framework of the partnership. In such a case, this is expected to occur at the earliest two years after the start of commercial sales. As a result of Diamyd Medical's commitments pertaining to future royalties, payments from JDRF are recognized as long-term liabilities.

NOTE 22 ACCRUED EXPENSES AND DEFERRED INCOME

Group, KSEK	2022/23	2021/22
Accrued vacation pay	2,434	2,067
Accrued social security contributions	765	650
Accrued salaries	534	-
Prepaid rental income	-	57
Accrued research costs	672	1,139
Other accrued expenses	1,131	1,117
Total	**5,537**	**5,030**

Parent Company, KSEK	2022/23	2021/22
Accrued vacation pay	2,434	2,067
Accrued social security contributions	765	650
Accrued salaries	534	-
Accrued research costs	672	1,139
Other accrued expenses	1,131	1,097
Total	**5,537**	**4,953**

NOTE 23 PLEDGED ASSETS AND CONTINGENT LIABILITIES

Group and Parent Company, KSEK	2022/23	2021/22
Pledged assets	-	239
Total	**-**	**239**

The previous year's pledged assets consist of a bank guarantee for rental payments for office premises.

NOTE 24 SIGNIFICANT EVENTS AFTER THE END OF THE FINANCIAL YEAR

- The Board of Directors resolved, subject to approval from an Extraordinary General Meeting, on a rights issue of approximately MSEK 243.
- An Extraordinary General Meeting on October 10, 2023 approved the rights issue.
- Preliminary results from DIAGNODE-B provided additional support for the safety and feasibility of intralymphatic booster injections of Diamyd® and showed only a small decline in stimulated endogenous insulin production one year following the additional injection and up to eight years from type 1 diabetes diagnosis.
- Follow-up study suggests Diamyd® may offer advantages in delaying type 1 diabetes onset.
- Diamyd Medical announced that the proceeds from the rights issue amounted to approximately MSEK 78 before the deduction of issue expenses.

NOTE 25 APPROPRIATION OF PROFIT

Parent Company

The following profits are at the disposal of the AGM

	SEK
Share premium reserve	460,285,769
Retained earnings	–169,062,493
Result for the year	–121,906,141
	169,317,135
The Board and CEO propose that the following profits be carried forward SEK	**169,317,135**

Signatures of the Board of Directors and Chief Executive Officer

The Group's income statements and balance sheets will be submitted to the AGM on November 30, 2023 for adoption. The Board of Directors and the Chief Executive Officer provide their assurance that the Annual Report has been prepared in accordance with generally accepted accounting policies and presents a true and fair view of the operations, financial position and earnings, and that the Directors' Report presents a true and fair view of the Group's and Parent Company's operations, financial position and earnings and describes the material risks and uncertainties faced by the Group and Parent Company.

Stockholm, November 8, 2023

Anders Essen-Möller
Chairman

Erik Nerpin
Vice Chairman

Maria-Teresa Essen-Möller
Board member

Torbjörn Bäckström
Board member

Mark A. Atkinson
Board member

Karin Hehenberger
Board member

Ulf Hannelius
Chief Executive Officer

Karin Rosén
Adjunct Board member

Our Auditor's Report was submitted on November 8, 2023.

BDO Mälardalen AB

Johan Pharmanson
Authorized Public Accountant

Auditor's Report

To the general meeting of the shareholders of Diamyd Medical Aktiebolag
Corporate identity number 556242-3797

REPORT ON THE ANNUAL ACCOUNTS AND CONSOLIDATED ACCOUNTS

Opinions

We have audited the annual accounts and consolidated accounts of Diamyd Medical Aktiebolag for the financial year 2022-09-01 -- 2023-08-31. The annual accounts and consolidated accounts of the company are included on pages 27-52 in this document.

In our opinion, the annual accounts and consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of parent company and the group as of 31 August 2023 and their financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the group.

Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the "Auditor's Responsibilities" section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Other Information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 1-26. The Board of Directors and the Managing Director are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the Board of Directors and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act. The board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts, the Board of Directors and the Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intends to liquidate the company, to cease operations, or has no realistic alternative but to do so.

Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not

a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.
- Conclude on the appropriateness of the Board of Directors' and the Managing Director's use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

REPORT ON OTHER LEGAL AND REGULATORY REQUIREMENTS

Opinions

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Director of Diamyd Medical Aktiebolag for the financial year 2022-09-01 -- 2023-08-31 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

Basis for Opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the "Auditor's Responsibilities" section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Responsibilities of the Board of Directors and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional scepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality.

This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

Stockholm, November 8, 2023
BDO Mälardalen AB

Johan Pharmanson
Authorized Public Accountant

Glossary

Alpha cells – Cells in the pancreas that secrete the glucagon hormone.

Antigen – A protein or a part of a protein that can stimulate an immune response.

Antigen-specific immunotherapy – A treatment method based on reprogramming the immune system's reactivity to a specific antigen, such as an allergy therapy or Diamyd Medical's Diamyd®.

Autoimmune disease – A disease that occurs when the body's immune system attacks the body's own antigens, which sets off the disease.

Autoimmune attack – A process in which the body's immune system attacks and destroys its own body tissue.

Beta cells – The cells in the islets of Langerhans in the pancreas that secrete the hormone insulin.

Blood sugar level – The concentration of sugar (glucose) in the blood.

Blood sugar regulation – The process by which the body maintains levels of blood sugar within a narrow range. This is accomplished
by the secretion of pancreatic hormones including insulin and glucagon.

Pancreas – One of the organs that make up the body's gastrointestinal system with the function of secreting digestive enzymes in the gastrointestinal tract after a meal, and regulating blood sugar levels through the release of alpha and beta cells by the islets of Langerhans in pancreatic tissue.

C peptide – A byproduct of endogenous insulin production that is secreted by beta cells in an amount that is proportional to the body's own insulin.

Diabetes – A group of chronic diseases characterized by too much glucose (blood sugar) in the blood resulting from the body's inability to produce, or properly use, its own insulin.

Diamyd® – An antigen-specific immunotherapy that can reprogram the immune system's response to GAD65.

DR3-DQ2 – The name of an HLA genotype associated with a higher risk for type 1 diabetes and good evidence of treatment effect with Diamyd®.

GAD65 (Glutamic acid decarboxylase) – The active ingredient in Diamyd®, a protein with a molecular weight of 65 kDa which catalyzes the formation of GABA and is expressed in beta cells. Patients with type 1 diabetes often develop an immune response to GAD65.

GABA (Gamma-aminobutyric acid) – A neurotransmitter, or a molecule that is used by cells to send signals to other cells, which triggers a response in nerve cells and beta cells, for example. GABA works by hampering immune cell activation and stimulating beta-cell proliferation in the islets of Langerhans.

Glucagon – A hormone secreted by alpha cells in the pancreas when blood sugar levels are too low. This stimulates the liver to release glucose into the bloodstream.

Glucose – A simple sugar, and the most important molecule for the body's energy metabolism.

cGMP (Current Good Manufacturing Practice) – A system for ensuring that pharmaceutical products are consistently produced and controlled according to quality standards.

HbA1c (Glycosylated hemoglobin) – A measure of the average concentration of sugar in the blood over the past three months. Also referred to as average blood glucose.

HLA type (Human Leukocyte Antigen) – A person's set of genes responsible for regulating the immune system. Different variants affect the occurrence of certain diseases.

Hyperglycemia – A condition in which the body's blood sugar levels are too high.

Hypoglycemia – A condition in which the body's blood sugar levels fall too low.

Insulin – A hormone secreted by beta cells in the pancreas when blood sugar levels in the body rise. Insulin affects the cells in muscles and other body tissue that absorb glucose from the blood.

Intralymphatic injection – Direct injection into a lymph node.

Clinical trials – Studies carried out on humans to test future drugs.

Islets of Langerhans – Clusters of cells in the pancreas containing mainly alpha and beta cells.

LADA (Latent Autoimmune Diabetes in Adults) – A form of diabetes that is clinically similar to type 2 diabetes, but where patients quickly progress to insulin-dependency and have normal or lower body mass index. Also known as type 1.5 diabetes.

Lymph node – A component of the lymphatic system, where immune cells congregate and interreact with each other and antigens. The lymphatic system drains immune cells and waste products from tissues.

Long-term complications – The diabetes-related health problems that manifest after several years of having the disease, such as cardiovascular diseases, kidney damage or nerve damage.

Preclinical studies – Studies carried out on animals and various cell systems.

Precision medicine – Treatment of a medical condition with the aim that it should only be given to those patients who respond to that particular treatment, and that therapies are tailored to specific medical conditions to avoid unnecessary adverse events.

Investigational drug – A drug that is under investigation in clinical trials or preclinical studies.

Remygen® – An investigational drug with the active ingredient GABA, which is used to induce beta-cell regeneration.

Sponsor – The individual or entity responsible for starting, organizing and/or financing a clinical trial.

Subcutaneous injection – An injection into the tissue layer under the skin.

Type 1 diabetes – A type of diabetes that is thought to be caused or triggered by an autoimmune attack – when the body's immune system attacks the beta cells in the pancreas – and the disease progression leads directly to the need for insulin therapy.

Type 2 diabetes – A type of diabetes characterized by insulin resistance in the body's cells, which over time usually results in the destruction of beta cells and the need for insulin therapy.

Shareholder information

ANNUAL GENERAL MEETING

Diamyd Medical AB's AGM will be held on November 30, 2023 at 3:00 p.m. at Hotell Kung Carl, Birger Jarls-gatan 21 in Stockholm, Sweden.

FINANCIAL CALENDAR

AGM	November 30, 2023
Quarterly Report (Sep-Nov)	January 24, 2024
Quarterly Report (Sep-Feb)	March 27, 2024
Quarterly Report (Sep-May)	June 26, 2024
Year-end report (Sep-Aug)	October 9, 2024

DISTRIBUTION POLICY

The Annual Report is available in PDF format from www.diamyd.com. Requests for printed copies of the Annual Report should be e-mailed to info@diamyd.com or sent by mail to Diamyd Medical AB, Box 7349, 103 90 Stockholm, Sweden.

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Production: Diamyd Medical in partnership with Wildeco
Photo: Johan Olsson, Mattias Bardå, Jim Halling, Staffan Gustavsson, Diamyd Medical's archive.

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