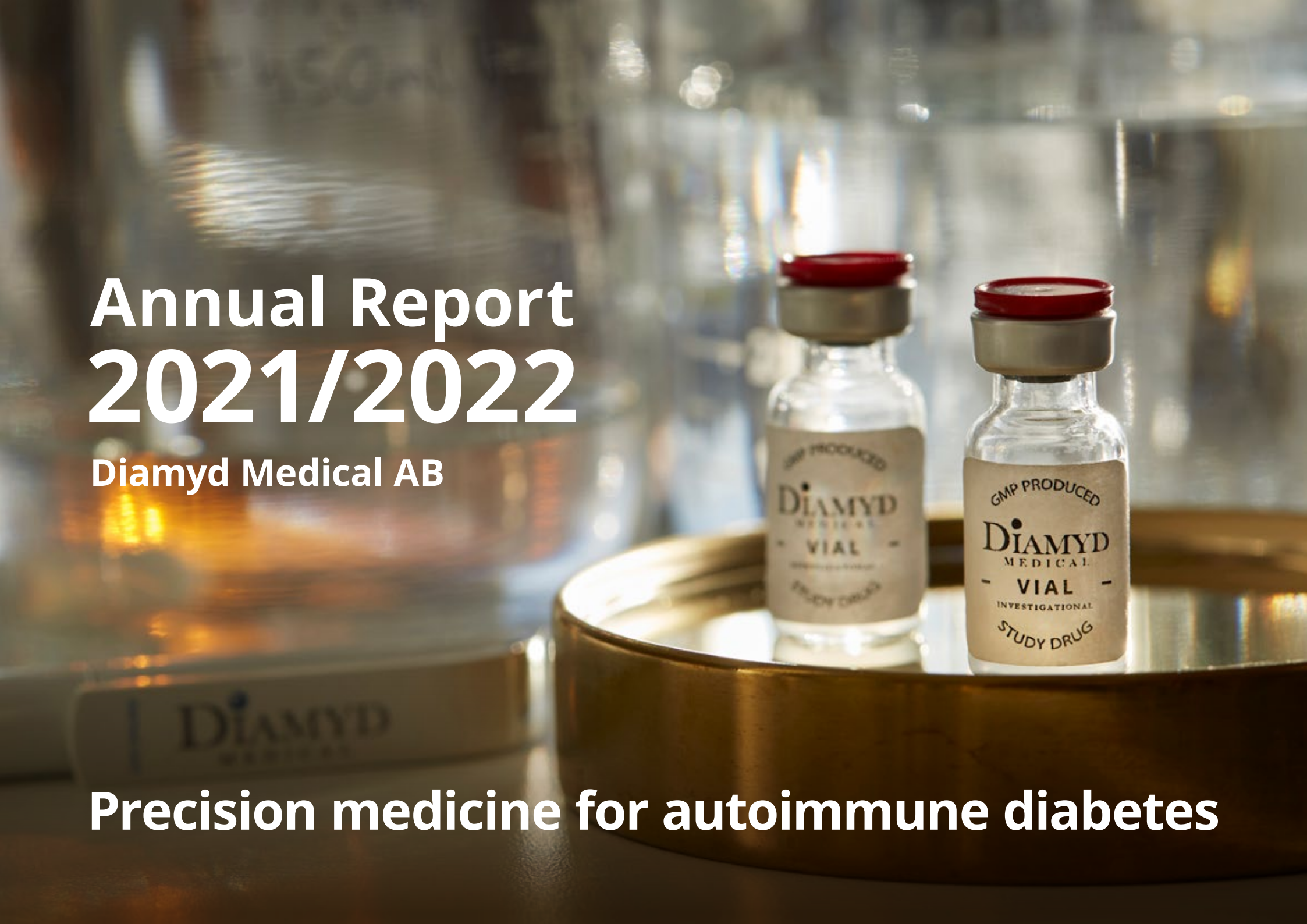
Annual Report 2021/2022

Diamyd Medical AB



Precision medicine for autoimmune diabetes

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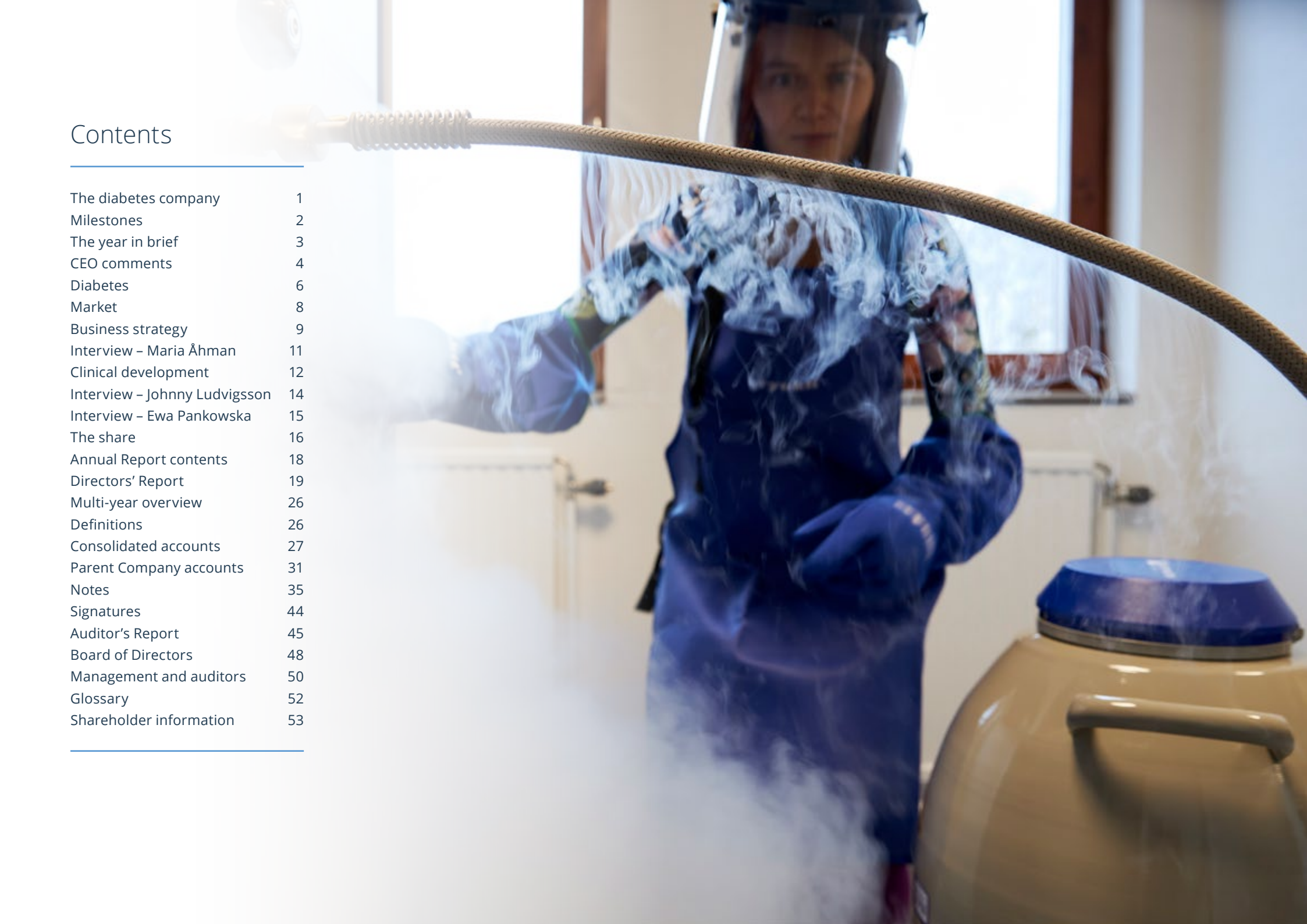


Diamyd Medical – an overview

Diamyd Medical is conducting a precision medicine and pivotal Phase III trial in autoimmune diabetes with antigen-specific therapy. The DIAGNODE-3 trial is being carried out at about 50 clinics in Europe.

Diamyd Medical is a growing diabetes company that develops disease-modifying treatments for autoimmune diabetes. The Company conducts operations at its head office in Stockholm and its own manufacturing facility in Umeå. The facility is used for manufacturing GAD65, the active compound in Diamyd®. Diamyd® is an antigen-specific immunotherapy to preserve endogenous insulin production in patients with type 1 diabetes and latent autoimmune diabetes in adults (LADA).

A large meta-analysis and previous clinical trials demonstrate the significant efficacy of Diamyd® in a genetically defined subpopulation of patients with newly diagnosed type 1 diabetes. About 40% of the total population with type 1 diabetes belongs to this genetic subgroup. The DIAGNODE-3 Phase III trial is taking place at about 50 clinics in Europe to confirm the findings, the first ever precision medicine Phase III trial in type 1 diabetes. The first patient was enrolled in the trial in May 2022. Preparations are under way for a clinical trial to evaluate Diamyd® for preventive purposes in people with a high risk of developing type 1 diabetes. The trial is part of the VINNOVA project ASSET, which is coordinated by Diamyd Medical. Read more on page 20.

Diamyd Medical also develops Remygen®, a regenerative and immunomodulation therapy in tablet form, for the treatment of autoimmune and type 2 diabetes. The trial is evaluating the potential to restore or stimulate the body's ability to produce insulin and to prevent hypoglycemia. A Phase I/II trial with Remygen® in patients who have lived with type 1 diabetes for at least five years is currently taking place at Uppsala University Hospital.

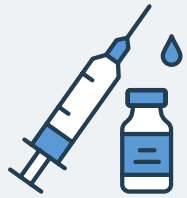
FACTS ABOUT DIABETES

Risk for complications reduced by 60-80%

Retaining the ability to produce insulin reduces the risk of complications by 60-80%.

The number of patients amounts to 537 million

Approximately 537 million people are living with diabetes today, and this figure is expected to reach 784 million by 2045. Of these, at least 10% have some form of autoimmune diabetes: type 1 diabetes or LADA.



Life expectancy ten years shorter

The life expectancy of a person with diabetes is ten years shorter compared with non-diabetic individuals.

Steps towards the goal

Milestones along the path to authorization and launch of a precision medicine treatment with Diamyd®

2020

MANUFACTURING
Establishment of own manufacturing of GAD65 in Umeå.

PUBLICATION
The peer-reviewed medical journal Diabetologica published a meta-analysis of the efficacy of Diamyd® in a genetically defined subpopulation.

ANALYSIS
Earlier prevention trials and one pilot study supported the shown efficacy of Diamyd® in a genetically defined subpopulation.

RESULTS
Topline results from the Phase IIb DIAGNODE-2 trial showed significant efficacy for Diamyd® in a genetically defined subpopulation.

2021

ANALYSIS
The follow-up analysis of data from DIAGNODE-2 provided further support for the efficacy of Diamyd®.

PATENT
A European patent was granted for the prevention and treatment of autoimmune diabetes in a genetically defined subpopulation with GAD65.

PUBLICATION
The peer-reviewed medical journal Diabetes Care published the results from the Phase IIb DIAGNODE-2 trial showing efficacy for Diamyd® in a genetically defined subpopulation.

ANALYSIS
Updated meta-analysis including the results from DIAGNODE-2 provided further support for the efficacy of Diamyd® in a genetically defined subpopulation.

2022

CLINICAL TRIAL
The European Phase III trial DIAGNODE-3 started, in which Diamyd® is given to type 1 diabetes patients who also carry the HLA DR3-DQ2 haplotype.

RESULTS
The primary goals for safety and tolerability were met in the Phase II GADinLADA clinical trial, in which Diamyd® was injected directly into the lymph nodes of LADA patients.

CLINICAL TRIAL
All patients received an additional injection ("booster") of Diamyd® in the DIAGNODE-B trial.

The year in brief

Significant events during the financial year

Promising results from Phase I/II trial with Diamyd® in LADA
The primary goals for safety and tolerability were met in the open-label investigator-initiated Phase II GAD-inLADA clinical trial. In the trial, Diamyd® was injected directly into lymph nodes of 14 patients with LADA in the 30-70 age group. Analyses showed a positive immune response to the treatment, and the clinical progression appears promising since all trial participants remained insulin independent 12 months after treatment.

Phase III trial with Diamyd® in type 1 diabetes
During the year, Diamyd Medical initiated the European Phase III trial DIAGNODE-3, and the first patient received their first intralymphatic injection of Diamyd® in May. The trial includes 330 patients aged 12-28 who are newly diagnosed with type 1 diabetes and carry the genetically defined haplotype HLA DR3-DQ2.

Phase I/II clinical trial regarding Remygen® for type 1 diabetes
The ReGenerate-1 investigator-initiated clinical trial for type 1 diabetes with Diamyd Medical's investigational drug Remygen® was fully recruited. Participants will be monitored for nine months, and the results are expected to be presented in the first quarter of 2023.

Wider patent for Diamyd®
Australia and China granted Diamyd Medical a wider patent for intralymphatic injections of antigens in autoimmune diabetes. The approval is an extension of the patent application that was previously granted in Australia for intralymphatic injections of GAD65, the active component in Diamyd® that Diamyd Medical is developing for type 1 diabetes and LADA.

DIAGNODE-3 placed on hold in the US
The start-up of the Phase III DIAGNODE-3 trial in the US was placed on clinical hold by the US Food and Drug Administration (FDA) pending a clarification of some remaining issues.

Financing
In September 2021, a directed issue of MSEK 150 was completed.

CEO comments

We are on the verge of radically changing how autoimmune diabetes should be treated. The antigen-specific immunotherapy Diamyd® targets individuals who carry a specific gene type found in up to 40 % of all people who suffer from or are at risk of autoimmune diabetes, a textbook example of precision medicine. This is a great discovery and a paradigm shift in the field.

We know that by treating patients suffering from autoimmune diabetes with Diamyd®, we have an opportunity to slow down the development of the disease by preserving the individual's own insulin production and thereby improving blood sugar control. Since the treatment is specifically aimed at the underlying disease, it has the potential to prevent future complications such as cardiovascular diseases, kidney diseases, blindness and amputations. This is a powerful message — the ability to prevent, decades in advance, serious and sometimes fatal complications by treating a very well-defined group of individuals based on their underlying disease and genetic profile — a textbook example of precision medicine.

The first-ever Phase 3 trial for precision medicine in type 1 diabetes is ongoing. DIAGNODE-3 is a groundbreaking trial where we only treat individuals who, through their genetics, have a high probability of responding to Diamyd®. In parallel with DIAGNODE-3, we are also conducting development of Diamyd® for the prevention of type 1 diabetes and for the treatment of individuals with the autoimmune form LADA (Latent Autoimmune Diabetes in Adults). We are also investigating the potential treatment benefits of Remygen, our second clinical asset in diabetes. We are building our own manufacturing facility for biological products in Umeå that will provide opportunities beyond what a traditional biotech company with contracted manufacturing has within reach. In addition, we have our strategic investments in artificial intelligence through MainlyAI and in cell therapies as part of NextCell Pharma.

Looking ahead, I can confidently say that the work we are doing is intended to solve a gigantic, unmet medical need. I would like to make a comparison here. The global prevalence of diabetes exceeded half a billion for the first time in history in 2021.

Those numbers are pretty much as high as the total number of people affected by COVID-19 so far, the largest pandemic in modern times that shut down much of the world and caused humanity to rally around a record-breaking investment in vaccine development. It took only 6 months to get the first covid vaccine approved while it has been 100 years since the discovery of insulin and the world's diabetics still do not have access to an approved drug that treats the underlying disease. This is despite the fact that diabetes can be attributed to about 6 million deaths in adults each year and 10% of the world's healthcare costs.

But with precision medicine, we will be able to change the treatment paradigm for diabetes and reverse what is today the largest silent epidemic in the world.

In addition to the fact that the field is gathered around precision medicine, it is also very gratifying that partnerships in type 1 diabetes are starting to happen, a clear measure that the larger players both have the resources to strengthen their own pipelines and an optimism that has not existed since several companies in type 1 diabetes more than a decade ago were in Phase 3 development. We also see that players who are not focused on diabetes have an interest in the area, which above all shows the investments that are being made in precision medicine and the prevention of complications such as cardiovascular diseases.

I am truly grateful to all our shareholders, partners and employees for your invaluable support. Without you, we would not have achieved the key discoveries that have made us one of the leading players in autoimmune diabetes and precision medicine.

Stockholm, November 9, 2022

ULF HANNELIUS
President & CEO Diamyd Medical AB

About diabetes

Diabetes is a group of metabolic diseases with symptoms that include excessively high levels of glucose in the blood due to the body's inability to produce or respond to insulin.

Different types of diabetes
The symptoms of diabetes include excessively high levels of glucose in the blood due to the body's inability to produce or respond to the hormone insulin. The are different types of diabetes:

- Autoimmune diabetes (10-20% of diabetes patients)
  - LADA
  - 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 immune system, for an unknown reason, destroys beta cells in the pancreas, the cells that produce insulin and thereby regulate blood sugar levels. Type 1 diabetes is often seen in children and adolescents while LADA develops in adults and has a slower disease progression.

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 weakened.

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.

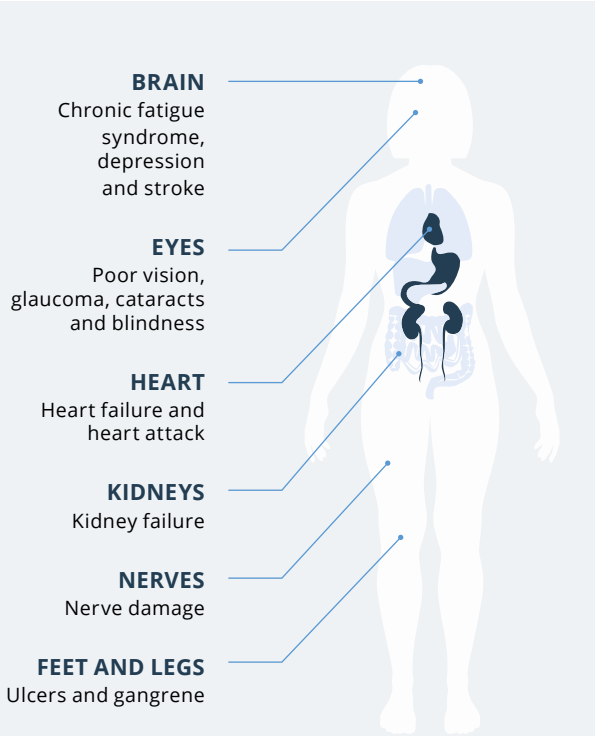
Diagnosis
Type 1 diabetes is often diagnosed when only a limited share of an individual's own ability to produce insulin remains. The patient must then immediately begin insulin therapy, otherwise the disease is life-threatening.

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 a antibody test.

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



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.

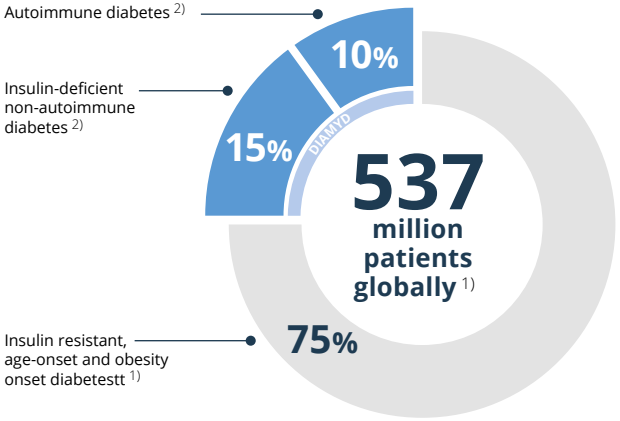
Consistently elevated blood sugar levels cause long-term diabetes complications:

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

Market

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 novel drugs that can reduce these consequences is great.

Approximately 537 million people between the ages of 20-79 are affected by diabetes. This figure is expected to reach 784 million people by 2045. In 2021, 6.7 million people died prematurely due to diabetes[1]. No cure for diabetes is currently available and the mainstay of treatment is either exogenous insulin or improved insulin sensitivity. In addition to human pain and suffering, the total cost of autoimmune diabetes on society is at least USD 966 billion annually, 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.



Cost-of-illness studies show that even a slightly positive effect on slowing the disease progression for individuals living with type 1 diabetes could be beneficial if translated into monetary values[3]. Research shows that even a small amount of preserved endogenous insulin production in these people could reduce long-term complications of diabetes, such as cardiovascular diseases, by up to 60-80%.

The market for Diamyd Medical

Diamyd® and Remygen® are in the clinical development stage and are drugs designed to preserve or restore the body's ability to produce insulin.

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, approximately 184,000 children and young people were diagnosed with type 1 diabetes and an estimated 40% belong to a genetically defined subpopulation who carry the HLA DR3-DQ2 genotype that studies have shown responds positively to treatment with Diamyd®.

The market for new-onset type 1 diabetes is estimated at more than USD 1 billion annually. 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. If the complications that could eventually be prevented – such as pain and suffering, and costs for loss of income – are also taken into account, Diamyd® becomes even more important. 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.

Remygen® is a treatment with tablets that works by stimulating the formation and function of insulin-producing beta cells and preventing hypoglycemia, a severe reduction in blood sugar levels. This investigational drug has potential for the treatment of type 1 diabetes, type 2 diabetes and LADA. The non-insulin anti-diabetic drugs market is currently dominated by drugs that need to be taken for extended periods and that only have a limited effect on the underlying disease mechanisms.

1) *IDF Diabetes Atlas 2021 – 10th edition*

2) *Ahlqvist et al. Novel subgroups of adult-onset diabetes and their association with outcomes: a data-driven cluster analysis of six variables. Lancet, 2018*

3) *Modeling the total economic value of novel T1D therapeutic concepts, January 2020, Health Advances.*

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. In a future commercialization of the Diamyd® and Remygen® drugs, Diamyd Medical intends to produce and sell products through licensing agreements with one or more major players and through in-house production and sales in selected markets.

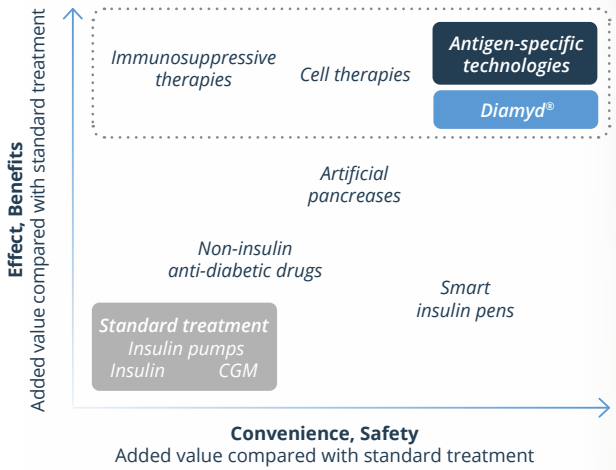
Drug development

The current mainstay 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, Diamyd® has demonstrated excellent safety and shown significantly positive efficacy in a genetically defined subpopulation, corresponding to about 40% of all individuals with type 1 diabetes, making it the first potential precision medicine treatment ever for type 1 diabetes.

Diamyd Medical is also developing the non-insulin drug Remygen®, which aims to stimulate the body's ability to recreate insulin-producing beta cells as well as preventing hypoglycemia, a severe reduction in blood sugar levels. Remygen® has potential to treat patients with type 1 diabetes, type 2 diabetes and LADA. Remygen® is based on a known compound and will most likely follow a registration process in the US that enables a faster route-to-market, since a large proportion of clinical trials that are otherwise necessary are not needed.

Market position of Diamyd®



Existing patents

The Company has obtained patents for intralymphatic administration of Diamyd® in Europe, Japan, Russia, Israel, Australia and China, and patent applications have been filed in 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 part of an exclusive license from the University of California, Los Angeles (UCLA), the Company has already been granted a US patent until 2032 for the use of GAD65 to treat diabetes, a substance patent. Additionally, the Company has been granted a patent in Europe for the prevention and treatment of autoimmune diabetes in people carrying the genetically defined HLA DR3-DQ2 genotype. The patent is valid until 2035, and patent applications have been filed in other countries. As a biologic drug, Diamyd® also receives 12 and 10 years of market exclusivity in the US and Europe, respectively, independent of patent protection. The US FDA has also granted orphan drug designation for Diamyd®, which provides marketing exclusivity for seven years from the date on which marketing authorization is issued.

In-house manufacturing

Diamyd Medical is establishing a manufacturing facility in Umeå, which is part of the Company's ambition to be an integrated pharmaceutical company in selected markets. The COVID-19 pandemic showed that supply chains, pharmaceutical production and some healthcare may suffer when enormous resources are required by a pandemic.

The facility will manufacture GAD65, the active component in Diamyd® and one of the most important antigens in type 1 diabetes. GAD65 manufacturing has been refined over many years of development together with the previous contract manufacturer. Investing in in-house production has given the Company full control over the supply of this key asset and may offer additional opportunities in biologics manufacturing in the future. The facility in Umeå comprises 1,000 m² with clean rooms, laboratories and office premises. Pending marketing authorization of the drug, the facility is ready for large-scale production in accordance with current guidelines. During the year, Diamyd Medical acquired the property that houses its production.

STRATEGIC HOLDING

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

Alongside clinical trials, NextCell Pharma also runs Sweden's first family cord blood bank – Cellaviva. Since February 2021, Diamyd Medical has owned 20% of the research and technology company MainlyAI AB, which is active in AI development.

Quality and safety

Building up in-house production of recombinant GAD65, the active ingredient in the antigen-specific immunotherapy Diamyd®, and thereby gaining direct control of the technology is a strategic, long-term decision by Diamyd Medical.

Maria Åhman is Quality Assurance Manager at Diamyd Medical's manufacturing unit for active compounds in Umeå. She is responsible for ensuring product quality and safety and for creating the quality systems needed to support the processes. Operations must comply with the stringent requirements on pharmaceutical production imposed by authorities.

"I usually say that it should be easy to do the right thing and see it as my task to implement processes that are easy to follow," says Maria Åhman. *"Governing documents, requirements and boundaries must be clear. There should be no room for misunderstanding the information."*

One central aspect of quality management is to assess and manage risks in the operations. Everything that happens must be easy to document and monitor, and procedures are also needed to manage any deviations. The process must be reproduceable. Given that it contains many stages and parameters, it is crucial to retain control at every step of the way.

"We must have control over the procurement of ingredients and ensure that all machinery is validated and complies with the maintenance program," says Maria and continues, "The staff is naturally an important part of operations, and require appropriate training. Everyone involved must carefully document who is doing what and when."

Pharmaceutical production must comply with the international Good Manufacturing Practice (GMP) regulations, which describe standards for manufacturing and control. The regulations are regularly updated to ensure quality, sustainability and safety for, inter alia, new production methods.

Diamyd Medical is establishing the production process required to fulfill GMP requirements in Europe, and the operation is designed to also fulfil the requirements in other markets.

"Globally, you can see the value of making the same demands on pharmaceutical production, and we are currently moving towards more harmonized requirements. The purpose is to create a process that guarantees that every patient receives a drug that is appropriate for the intended use, that produces the intended effect, is safe and is always of the same high quality."

Maria Åhman
Quality Assurance Manager
Umeå

Clinical development

Diamyd® and Remygen® are drugs in the clinical development stage. These drugs can reduce the risk of diabetes complications, simplify treatment and reduce the cost of diabetes on society. Diamyd® is in Phase III clinical trials for type 1 diabetes and clinical Phase I/II for LADA. Remygen® is in Phase I/II clinical trials for type 1 diabetes.

CLINICAL TRIALS

Trial	Indication	Product	Participants	Sponsor	Phase I	Phase IIa	Phase IIb	Phase III	Status
DIAGNODE-3	Newly diagnosed type 1 diabetes, carrying the HLA DR2-DQ3 genotype	Diamyd®	330	Diamyd Medical					The first patient received their first intralymphatic injection of Diamyd® in May 2022.
DIAGNODE-B	Type 1 diabetes, carrying the HLA DR3-DQ2 genotype and previously treated with Diamyd®	Diamyd®	6	Linköping University					All patients have now received a booster of Diamyd®. Participants will be monitored for 12 months.
GADinLADA	Newly diagnosed LADA	Diamyd®	15	NTU Trondheim					The trial was completed with positive results. Trial participants remained insulin independent 12 months after treatment.
ReGenerate-1	Type 1 diabetes	Remygen®	36	Uppsala University					During the year, the main study was fully recruited, and participants will be monitored for nine months. The results are expected in the first quarter of 2023.

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 trials with more than 900 subjects who received active treatment provide evidence of good safety and a significant treatment effect in a genetically defined subpopulation. The investigational drug is based on the active compound GAD65 (glutamic acid decarboxylase), a protein produced by insulin-producing beta cells. The effect is achieved by reprogramming antigen-specific immune cells by injecting Diamyd® under the skin, or in low doses into superficial lymph nodes. In 2022, a Phase III trial (DIAGNODE-3) commenced with Diamyd® for type 1 diabetes in a genetically defined subpopulation. Diamyd® was also tested for patients and recently underwent GADinLADA, a Phase I/II clinical trial, with 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), 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. Remygen® is currently being tested in a Phase I/II clinical trial (ReGenerate-1).

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 DIAGNODE-2 clinical trial, where Diamyd® showed a significant treatment effect 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 a placebo. The Phase III trial began in 2022, and the first patient received their first intralymphatic injection of Diamyd® in May. The trial will include about 330 people aged 12-29 who have recently been diagnosed with type 1 diabetes and belong to the genetically

defined subpopulation with HLA haplotype DR3-DQ2 (about 40% of the total population). Approximately 30 clinics in Europe, out of the total of 50 clinics that are expected to take part in the trial, have already initiated the trial. A primary analysis will take place 24 months after the trial commences.

DIAGNODE-B – Diamyd®
An open-label, investigator-initiated clinical trial, in which Diamyd® is injected directly into the lymph nodes in type 1 diabetes patients who also carry the HLA DR3-DQ2 haplotype and who were previously treated with intralymphatic injections of Diamyd® in the DIAGNODE-1 or DIAGNODE-2 trials. The aim of the trial is to evaluate the safety of a booster (fourth/fifth) injection with Diamyd® and the impact on the immune system and the body's endogenous capacity to produce insulin. All patients have now received an additional injection of Diamyd®. Participants will be monitored for 12 months.

ReGenerate-1 – Remygen®
The Phase I/II ReGenerate-1 trial comprises two studies – an initial safety and dose-escalation study with fewer patients, and a main study comprising a total of 36 patients, who will be followed for up to nine months depending on their dose expansion cohort. The initial study demonstrated good safety and a potentially positive effect on resistance to hypoglycemia. During the year, the main study was fully recruited. Participants will be monitored for nine months, and the results are expected to be presented in the first quarter of 2023. The trial will study the drug's safety and its ability to recreate the body's endogenous insulin secretion and prevent hypoglycemia in people with lifelong type 1 diabetes.

SELECTION OF PUBLICATIONS

Publication	Studies included	Main findings
Hannelius et al. Diabetologia. 2020 Oct;63(10):2177-2181.	Meta-analysis of three previous clinical trials with Diamyd®	Identification of responder populations of patients with type 1 diabetes who carry the HLA DR3-DQ2 genotype marker, among whom a significant dose-dependent effect of Diamyd® in preserving endogenous insulin production was demonstrated.
Ludvigsson et al. Diabetes Care. 2021 Jul;44(7):1604-1612.	DIAGNODE-2	Significant effect on the preservation of endogenous insulin production (mixed-meal stimulated C-peptide response) in type 1 diabetes patients with HLA DR3-DQ2 was confirmed in a pre-specified subgroup analysis.
Nowak et al. Diabetes Obes Metab. 2022 Aug;24(8):1647-1655.	Updated meta-analysis of DIAGNODE-2 and three previous clinical trials with Diamyd®	An updated meta-analysis of more than 600 patients indicates a connection between the positive treatment effect on the preservation of endogenous insulin production and improved blood glucose (measured as HbA1c).
Nowak et al. J Clin Endocrinol Metab. 2022 Aug 18;107(9):2644-2651.	DIAGNODE-2	The follow-up analysis demonstrates significant and clinically relevant effects on continuous glucose monitoring (CGM) in patients with HLA DR3-DQ2.

Clinical trials completed during the year

GADinLADA – Diamyd®
GADinLADA was an open-label investigator-initiated clinical trial in which Diamyd® was injected directly into the lymph nodes together vitamin D. The trial included 14 patients aged 30-70 years who had been diagnosed with LADA but had not yet been treated with insulin. The objective was to study the safety of intralymphatic treatment with Diamyd® in LADA patients, and to continuously assess the immunological and clinical response over a 12-month period. The trial met the primary goals for safety and tolerability. Analyses also showed a positive immune response to the treatment, and the clinical progression appears promising since all trial participants remained insulin independent 12 months after treatment.

Collaboration in international research

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 it presence at scientific conferences on key areas such as human genetics and diabetes.

"Finally a way to treat the disease after 100 years of life-sustaining insulin"

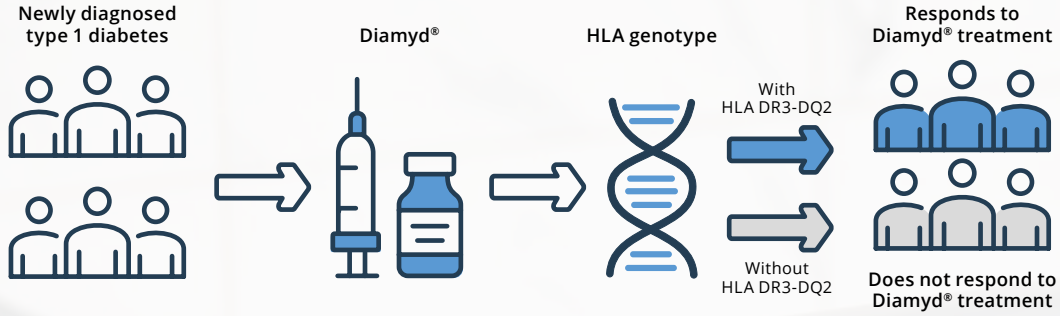
The results of the Phase II DIAGNODE-2 trial, in which intralymphatic treatment of GAD-alum (Diamyd®) was tested in patients with type 1 diabetes, demonstrated significant treatment effect in patients belonging to the HLA genotype DR3-DQ2.

The precision medicine treatment with Diamyd® is now being evaluated in Diamyd Medical's DIAGNODE-3 Phase III trial, which will include a total of 330 patients from about 50 clinics.

This is a large patient cohort to be able to provide a sufficiently large basis for a statistically valid result. Professor Johnny Ludvigsson, the coordinating investigator for DIAGNODE-3, is optimistic:

"If the trial is successful, intralymphatic Diamyd would provide an easier treatment, fewer complications, longer lives and better quality of life," says Professor Johnny Ludvigsson. The disease is a source of substantial and unnecessary suffering for patients and their loved ones, and a significant cost for society.

"Diamyd has real potential to make a big difference! Some endogenous insulin production can help the patient in the short term by reducing the risk of hypoglycemia, and in the long term by reducing the risk of sequelae that arise from type 1 diabetes," says Professor Johnny Ludvigsson.



Johnny Ludvigsson
Professor at Linköping University

Topline results from the Phase IIb DIAGNODE-2 trial showed significant treatment efficacy for Diamyd® in a genetically defined subgroup of individuals with type 1 diabetes, corresponding to approximately 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 a Phase III DIAGNODE-3 trial.

"If we successfully develop the right treatment, we will improve the quality of patients' lives"

Type 1 diabetes is an autoimmune disease where the body's immune system mistakenly attacks the insulin-producing cells in the pancreas. Type 1 diabetes has become increasingly common in developed countries. Looking at Poland over the past 30 years, the number of type 1 diabetes patients has increased by 250%.

Dr Ewa Pankowska is the principal investigator for DIAGNODE-3 at the Warsaw Institute of Diabetology in Poland. She is responsible for managing the study, enrollment of patients and coordination of the medical team involved in the study.

"It is important to remember that we do not yet have a cure for diabetes, we can currently only treat the disease through continuous injections of insulin," says Dr Ewa Pankowska.

Dr. Pankowska sees the increasing research efforts tackling the treatment of type 1 diabetes. Current development is looking into how to help restore the body's ability to produce insulin on its own and specifically stimulate the growth and function of beta cells which produce insulin through so called immunomodulators.

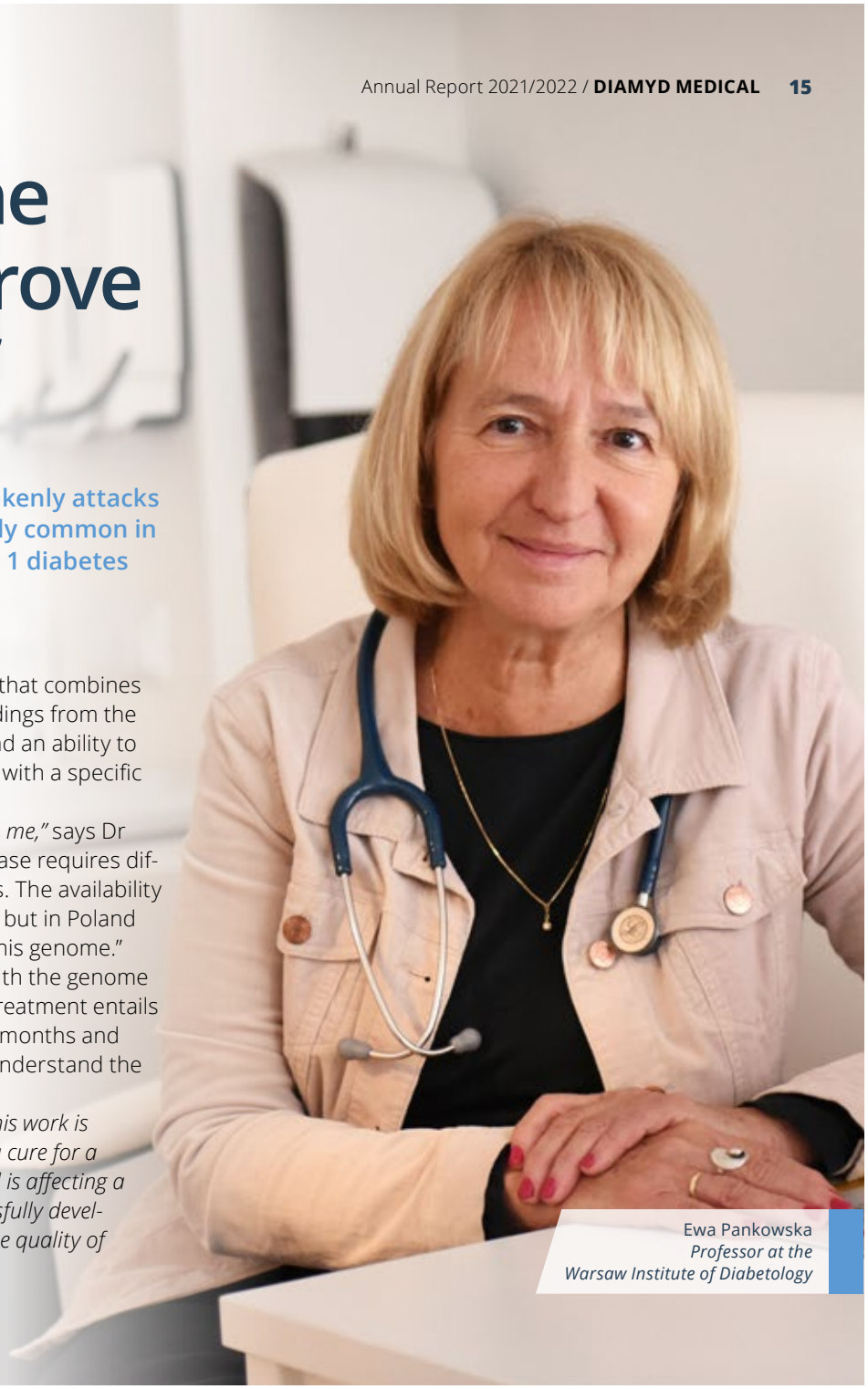
"I have been following the progress of this product, Diamyd®, during the past 10 years," says Dr Ewa Pankowska. *"What is especially interesting in the case of Diamyd® is that a meta analysis was required in order to understand the positive effects of the product, and these benefits could not be seen in individual studies."*

A meta analysis is a statistical analysis that combines the results of multiple studies. The findings from the meta analysis showed that Diamyd® had an ability to restore insulin production for patients with a specific genome type – HLA DR3-DQ2.

"These finding were very interesting to me," says Dr Pankowska. "It suggested that the disease requires different treatments for different patients. The availability of this genome varies across countries but in Poland 10-15% of the entire population have this genome."

In the DIAGNODE-3 trial patients with the genome type HLA DR3-DQ2 are enrolled. The treatment entails a total of three injections during three months and an observation period of one year to understand the treatment's effects.

Dr Ewa Pankowska is optimistic. *"This work is important because we are trying to find a cure for a disease that does not yet have a cure and is affecting a growing number of patients. If we successfully develop the right treatment, we will improve the quality of patients' lives."*



Ewa Pankowska
Professor at the Warsaw Institute of Diabetology

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, 2022, the number of shares in Diamyd Medical was 76,926,939, comprising 74,370,716 Class B shares (one-tenth of a vote per share held) and 2,556,223 Class A shares (one vote per share held), with a quotient value of approximately SEK 0.1014. The shares are denominated in Swedish kronor (SEK). At the end of the financial year (August 31, 2022), the share capital amounted to SEK 7,802,027.

Share performance

The last price paid at August 31, 2022 was SEK 14.58 (33.70), generating a market cap of MSEK 1,084 (2,326) for Diamyd Medical calculated on the number of Class B shares. The highest price paid during the financial year was SEK 39.84 (74.70). The lowest price paid was SEK 10.40 (24.60). The average share price was SEK 19.49 (39.08). During the financial year, a total of 73,686,834 (117,743,208) Class B shares were traded on Nasdaq First North Growth Market for a total value of MSEK 1,436 (4,713).

New share issue

A directed share issue of 5,357,143 new Class B shares at a subscription price of SEK 28 was completed during the year. The offering raised gross proceeds of MSEK 150 for the Company. The offering was subscribed by both Swedish institutional and qualified retail investors.

Ownership structure

At August 31, 2022, the number of shareholders was 16,519 (16,247). The ten largest owners of Diamyd Medical held shares corresponding to 37.5% of the capital and 51.9% of the votes.

Dividend

The Board proposes that no dividend be paid for the 2021/2022 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, 2021/2022

Data per share	2021/22	2020/21
Share price, August 31, SEK	14.6	33.7
Share performance, %	–56	–6
Equity per share, SEK	2.8	2.6
Result per share, SEK	–1.4	0.9
Average no. of shares	76,530,657	69,794,454
No. of shares at August 31	76,926,939	71,569,796

Ownership structure by size of holding at August 31, 2022

Holding	No. of shareholders	Class A shares	Class B shares	Holding (%)	Votes (%)	Market cap (KSEK)
1 – 500	9,398		1,424,129	1.85	1.43	20,764
501 – 1,000	2,072		1,621,943	2.11	1.62	23,648
1,001 – 5,000	3,386		8,148,868	10.59	8.15	118,810
5,001 – 10,000	768		5,703,133	7.41	5.71	83,152
10,001 – 15,000	304		3,787,448	4.92	3.79	55,221
15,001 – 20,000	168		3,022,296	3.93	3.02	44,065
20,001 –	423	2,556,223	50,662,899	69.18	76.28	738,665
Total	**16,519**	**2,556,223**	**74,370,716**	**100**	**100**	**1,084,325**

Ten largest shareholders at August 31, 2022

Name	Class A shares	Class B shares	Holding (%)	Votes (%)
Försäkringsaktiebolaget, Avanza Pension		9,947,205	12.93	9.95
Lindkvist, Bertil		6,240,000	8.11	6.24
Essen-Möller, Anders	556,223	2,813,040	4.38	8.38
Essen-Möller, Maria-Teresa	400,000	963,998	1.77	4.97
Nordnet Pensionsförsäkring AB		3,247,596	4.22	3.25
Essen-Möller, Jon	400,000	963,998	1.77	4.97
Essenshaw, My	400,000	561,226	1.25	4.56
Hillborg, Erika	400,000	490,000	1.16	4.49
Essen-Möller, Martin	400,000	355,120	0.98	4.36
Konstruktions och Försäljningsaktiebolag		725,000	0.94	0.73
Total, ten largest owners	**2,556,223**	**26,307,183**	**37.52**	**51.90**
Other shareholders		48,063,533	62.48	41.76
Total	**2,556,223**	**74,370,716**	**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
Total		**7,802,027**	**2,556,223**	**74,370,716**	**7,802,027**

[1)] *Offset issues.*

[2)] *Warrant redemption scheme.*

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, 2021–August 31, 2022.

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 Properties 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. Comparative figures for the previous financial year pertain exclusively to the Parent Company. Diamyd Medical's Class B shares have been traded on Nasdaq First North Growth Market under the DMYD ticker since May 20, 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. A Phase III trial is under way and is currently enrolling patients in a number of countries in Europe. Statistically significant results have been shown in a large genetically defined subpopulation in a large-scale meta-analysis as well as in the Company's European Phase IIb trial DIAGNODE-2, in which Diamyd® was administered directly into the lymph nodes in children and young adults with recently diagnosed type 1 diabetes. A vaccine manufacturing facility is under development in Umeå for the production of recombinant GAD65, the active ingredient in 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. An investigator-initiated Remygen® trial in individuals living with type 1 diabetes for more than five years is ongoing at Uppsala University Hospital.

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. Remygen® is currently being tested in a Phase I/II clinical trial (ReGenerate-1), in which clinical efficacy is being studied in order to optimize the treatment in preparation for pivotal trials.

Clinical trials

Intralymphatic immunotherapy with Diamyd®

DIAGNODE-3 is a Phase III trial that will include about 330 people aged 12-29 who have recently been 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 will be 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 will be carried out at about 50 clinics. After an initial month in which all trial participants receive vitamin D, the individuals will be randomized 2:1, i.e. two out of three trial participants will receive three intralymphatic injections of Diamyd® and one in three will 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 Coordinating Investigator of the trial is Professor Johnny Ludvigsson from Linköping University. The sponsor is Diamyd Medical.

DIAGNODE-B is an open-label, investigator-initiated clinical trial in type 1 diabetes patients who also carry the HLA DR3-DQ2 haplotype and who were previously treated with intralymphatic injections of Diamyd®. The trial has accepted six patients who have either been treated with four injections in DIAGNODE-1, who have now received a fifth intralymphatic injection of Diamyd®, or patients who took part in DIAGNODE-2, who have now received a fourth intralymphatic injection of Diamyd® approximately four years after the most recent injection. The aim of the trial is to evaluate the safety of a booster (fourth/fifth) injection with Diamyd® and the impact on the immune system and the body's endogenous capacity to produce insulin. The patients will be monitored for 12 months after the injection. The trial is taking place at the clinical trials unit (Kliniska Forskningsenheten) at Linköping University Hospital. The sponsor is Linköping University with Professor Johnny Ludvigsson as the sponsor's representative. Diamyd Medical is contributing the investigational drug, expertise and some financial support.

Investigator-initiated clinical trial with Remygen®

ReGenerate-1 is an open-label investigator-initiated clinical trial with Remygen®. The trial includes approximately 36 patients in the 18–50 age group who have had type 1 diabetes for more than five years and have low to non-existing insulin production. Safety and initial effect results from the initial dose escalation portion of the trial have paved the way to begin the main study and also demonstrated a potential effect of Remygen® to improve the hormonal response to hypoglycemia. The main study evaluates whether the insulin-producing cells can regenerate and whether the hormonal response to hypoglycemia can be improved with Remygen® and the combination of Remygen® and Alprazolam. Professor Per-Ola Carlsson is leading the trial at Uppsala University, which is the sponsor of the study. The results are expected to be presented in the first quarter of 2023.

In-house manufacturing of GAD65

Diamyd Medical is developing a new vaccine manufacturing facility in Umeå for the production of recombinant GAD65, the active pharmaceutical ingredient in the antigen-specific immunotherapy Diamyd®. The facility comprises clean rooms, laboratories and office premises, enabling control, predictability and scalability in the manufacturing technology for the active ingredient in Diamyd®. Small-scale experimental production of GAD65 was established during the year. Large-scale production will primarily be installed with equipment from Cytiva. In September 2021, Diamyd Medical acquired the property with the manufacturing facility. The acquisition aimed to further strengthen control over the manufacturing process and enable expansion. A consideration of MSEK 24.5 was paid for the property, which comprises approximately 2,000 m² including the 1,000 m² that Diamyd Medical uses to manufacture GAD65, and the total land area of 9,000 m².

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, 2022, Diamyd Medical's share of capital and voting rights in the company was approximately 12.5%, recognized as about MSEK 27.2 in the Parent Company. Diamyd Medical also owns 20% of the shares in the AI company MainlyAI AB. At August 31, the carrying amount was MSEK 1.2.

SIGNIFICANT EVENTS DURING THE FINANCIAL YEAR

- A directed share issue of 5,357,143 new Class B shares at a subscription price of SEK 28 was completed in September 2021. The price corresponded to a discount of approximately 17% based on the volume-weighted average price on Nasdaq First North Growth Market for the 30 days of trading preceding the issue. The offering raised gross proceeds of MSEK 150 for the Company.
- Diamyd Medical acquired the property in Umeå where the Company is establishing production of the recombinant GAD65 protein, the active ingredient in Diamyd®. A consideration of MSEK 24.5 was paid for the property, which comprises approximately 2,000 m², and the total site area of 9,000 m².
- The start-up of the Phase III DIAGNODE-3 trial in the US was placed on clinical hold by the US FDA pending a clarification of some remaining issues related to the investigational drug.
- The Swedish Medical Products Agency approved the start-up of the Phase III DIAGNODE-3 trial.
- VINNOVA granted funding of MSEK 40 to Diamyd Medical and partners for an innovation milieu in sustainable precision health for the prevention of autoimmune diseases. The project will be led by Diamyd Medical and the objective 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. Diamyd Medical's share of the five-year grant is approximately MSEK 18.
- Diamyd Medical decided on November 30, 2021 to pause the start-up of the precision medicine Phase III DIAGNODE-3 trial and the initiation of other clinical trials with the Diamyd® diabetes vaccine (GAD/alum) pending further evaluation of the manufacturing process. A new analysis, which was not linked to the manufacturing facility in Umeå, demonstrated a potential occurrence of a contamination early in the manufacturing process of the existing investigational drug and Diamyd Medical was to evaluate its elimination before further clinical work is carried out. In early February 2022, the Company announced that the initiation of DIAGNODE-3 was continuing in Europe. The results of detailed analyses of the manufacturing process showed there was no risk associated with an earlier suspected contamination.
- Diamyd Medical announced in May 2022 that its principal owner Anders Essen-Möller had reported to the Swedish Financial Supervisory Authority the divestment of 4,500,000 Diamyd Medical shares in the form of gift. Essen-Möller's five children each received 400,000 Class A shares and 500,000 Class B shares.
- In July 2022, the Company announced promising topline results for intralymphatic Diamyd® in patients with LADA. The primary goals for safety and tolerability were met in the open-label investigator-initiated Phase II GADinLADA trial, in which Diamyd® was injected directly into lymph nodes of 14 patients with LADA in the 30-70 age group. Analyses also showed a positive immune response to the treatment, and the clinical progression appears promising since all trial participants remained insulin independent 12 months after treatment.

SIGNIFICANT EVENTS AFTER THE END OF THE FINANCIAL YEAR

No significant events occurred after the end of the financial year.

FINANCIAL INFORMATION, GROUP

Revenues

Revenues amounted to MSEK 2.6 (0.4). The increase was mainly attributable to grants from VINNOVA for the innovation environment ASSET (AI for Sustainable Prevention of Autoimmunity in the Society). See also Note 3.

Earnings

Net result for the year amounted to MSEK –103.5 (60.0). The year-on-change was mainly attributable to the non-recurring effect in the preceding year from a gain on divestment of the holding in Companion Medical (MSEK 144.4) as well as higher research and development costs (–18.7) due to the expansion of the Phase III DIAGNODE-3 trial and the establishment of GAD65 manufacturing at the facility in Umeå.

Financial position

At August 31,2022, cash and cash equivalents and short-term investments amounted to MSEK 159.7 (139.4). Equity amounted to MSEK 214.4.

Result from shares and participations

At August 31, 2022, 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 27.2 after impairment of approximately MSEK 3.8, based on the difference between cost and market value at August 31, 2022. The share of capital and voting rights on the same date was approximately 12.5%. Diamyd Medical owns 20% of the shares in the AI company MainlyAI AB. At August 31, 2022, the carrying amount was MSEK 1.2. Diamyd Medical did not receive any dividends from its holdings during the financial year.

ORGANIZATION

At August 31, 2022, the Company had 21 (19) employees, of whom 13 in Stockholm and 8 in Umeå. The average number of employees during the year was 19 (14). Personnel costs amounted to MSEK –20.3 (–16.2). For more information about salaries, other compensation and social security contributions, refer to Note 4.

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. It cannot be ruled out that the ongoing the COVID-19 pandemic will complicate and/or delay the recruitment of patients, which could lead to significant delays in the trials and therefore increase the Company's costs.

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.

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, 2021 and August 31, 2022, the lowest price paid for the Company's share was SEK 10.40 and the highest price paid was SEK 39.84. 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 partnership and/or licensing agreements, and/or make acquisitions on terms that are commercially advantageous 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 Annual General Meeting (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.

At the AGM on December 2, 2021, Dr Karin Hehenberger was elected to the Board.

The Board held 15 minuted meetings during the 2021/2022 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, 2022, the number of shares in Diamyd Medical was 76,926,939, comprising 74,370,716 Class B shares (one-tenth of a vote per share held) and 2,556,223 Class A shares (one vote per share held). 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, 2022), the share capital amounted to SEK 7,802,027.

NEW SHARE ISSUE

A directed share issue was completed during the financial year with deviation from the preferential right of existing shareholders, following a decision by the Board based on the authorization granted by the AGM on November 26, 2020. The share issue increased the number of shares in the Company by 5,357,143 to 76,926,939 and the share capital by SEK 543,215 to SEK 7,802,027. The issue was fully registered with the Swedish Companies Registration Office on September 27, 2021.

OWNERSHIP STRUCTURE

At August 31, 2022, the number of shareholders was 16,519 (16,247). The ten largest owners of Diamyd Medical held shares corresponding to 37.5% of the capital and 51.9% 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 159.7.

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	390,507,306
Retained earnings	–67,095,483
Result for the year	–102,381,009
Non-restricted equity	**221,030,814**

The Board proposes that the Company's retained earnings of SEK 221,030,814 be carried forward. The Company's earnings for the financial year and financial position at August 31, 2022 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 2021/2022 financial year.

Multi-year overview

GROUP, KSEK	2021/22	2020/21	2019/20	2018/19	2017/18	2016/17	2015/16	2014/15	2013/14
Net income	454	253	341	1,568	726	922	757	513	443
R&D costs	–75,567	–56,860	–13,810	–22,359	–29,118	–12,871	–6,220	–9,686	–5,465
Personnel costs	–20,259	–16,174	–9,195	–7,891	–7,831	–7,031	–7,671	–7,366	–6,716
Result for the year	–103,517	60,046	9,709	–36,610	–43,953	–25,555	–32,008	–21,397	–16,034
Cash flow from operating activities	–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	159,668	139,376	68,362	56,714	44,112	85,726	31,396	29,727	35,675
Equity ratio, %	91	94	81	85	78	88	77	85	87
Profit/loss per share, before and after dilution, SEK	–1.4	0.9	0.1	–0.5	–0.8	–0.7	–1.3	–1.0	–0.8

2021/22 pertains to the Group, previous years pertain to the Parent Company.

PARENT COMPANY, KSEK	2021/22	2020/21	2019/20	2018/19	2017/18	2016/17	2015/16	2014/15	2013/14
Net income	506	253	341	1,568	726	922	757	513	443
R&D costs	–75,567	–56,860	–13,810	–22,359	–29,118	–12,871	–6,220	–9,686	–5,465
Personnel costs	–20,259	–16,174	–9,195	–7,891	–7,831	–7,031	–7,671	–7,366	–6,716
Result for the year	–102,381	60,046	9,709	–36,610	–43,953	–25,555	–32,008	–21,397	–16,034
Cash flow from operating activities	–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	159,145	139,376	68,362	56,714	44,112	85,726	31,396	29,727	35,675
Equity ratio, %	92	94	81	85	78	88	77	85	87
Profit/loss per share, before and after dilution, SEK	–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	Aug 31, 2022	Aug 31, 2021
OPERATING INCOME			
Net income	3	454	253
Other operating income	3	2,131	191
TOTAL OPERATING INCOME		**2,584**	**444**
OPERATING EXPENSES			
External research and development costs		–75,567	–56,860
External patent and license costs		–4,403	–2,501
Personnel costs	4	–20,259	–16,174
Other external expenses	5, 6, 7	–11,669	–9,457
Other operating expenses		–1,240	–551
Result from participations in associates	13	–3,239	-
Amortization/depreciation and impairment of assets	8, 11	–4,383	–782
TOTAL OPERATING EXPENSES		**–120,760**	**–86,324**
OPERATING RESULT		**–118,176**	**–85,880**
Gain on sale of financial asset	9	6,653	144,414
Interest income and similar profit items	9	8,259	1,965
Interest expense and similar loss items		–253	–453
TOTAL FINANCIAL ITEMS		**14,659**	**145,926**
RESULT AFTER NET FINANCIAL ITEMS		**–103,517**	**60,046**
Income tax	10	-	-
RESULT FOR THE PERIOD		**–103,517**	**60,046**

The Group was formed on October 31, 2021 when Diamyd Medical AB acquired Diamyd Properties AB. Accordingly, the first months of the financial year include amounts pertaining only to the Parent Company. The comparative period pertains to the Parent Company

Consolidated balance sheet

KSEK	Note	Aug 31, 2022	Aug 31, 2021
ASSETS			
Fixed assets			
Intangible assets	8		
Patents		-	65
Tangible assets			
Land and buildings	11	22,609	-
Machinery and inventory	11	23,139	5,553
Financial assets			
Deferred tax		1,676	-
Participations in associates	13	15,463	32,220
Other long-term receivables	15	626	626
Total fixed assets		**63,513**	**38,464**
Current assets			
Accounts receivable		251	51
Other receivables		2,194	1,594
Prepaid expenses and accrued income	16	10,897	21,953
Short-term investments		39,907	-
Cash and cash equivalents		119,761	139,376
Total current assets		**173,011**	**162,974**
TOTAL ASSETS		**236,524**	**201,438**

KSEK	Note	Aug 31, 2022	Aug 31, 2021
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	17	7,802	7,259
Statutory reserve		200	200
Non-restricted equity			
Share premium reserve		390,507	248,895
Retained earnings		–80,613	–127,141
Result for the period		–103,517	60,046
Total equity		**214,379**	**189,258**
Provisions			
Pensions and other commitments	18	777	777
Total long-term liabilities		**777**	**777**
Current liabilities			
Trade payables		9,778	5,572
Other current liabilities		6,559	1,039
Accrued expenses and deferred income	19	5,030	4,792
Total current liabilities		**21,367**	**11,402**
TOTAL EQUITY AND LIABILITIES		**236,524**	**201,438**

The Group was formed on October 31, 2021 when Diamyd Medical AB acquired Diamyd Properties AB. Accordingly, the first months of the financial year include amounts pertaining only to the Parent Company. The comparative period pertains to the Parent Company

Consolidated cash flow statement

KSEK	Note	Sep 2021 – Aug 2022	Sep 2020 – Aug 2021
OPERATING ACTIVITIES			
Operating result		–118,176	–85,880
Interest received		67	0
Interest paid		–253	–71
Non-cash flow items			
Amortization/depreciation		4,383	782
Other non-cash flow items	13	3,239	362
CASH FLOW BEFORE CHANGES IN WORKING CAPITAL		**–110,741**	**–84,806**
Increase (-) decrease (+) receivables		10,095	–19,566
Increase (+) decrease (-) liabilities		7,426	–5,095
TOTAL CASH FLOW FROM OPERATING ACTIVITIES		**–93,219**	**–109,468**
INVESTING ACTIVITIES			
Investments in tangible and intangible assets		–34,652	–4,225
Investments in financial assets		-	–20,477
Divestment of financial assets		-	2,827
Gain on divestment of financial assets	9	6,653	144,414
Loan payment		–8,815	-
Matured short-term investments		89,984	9,995
Investment in short-term investments		–129,891	-
CASH FLOW FROM INVESTING ACTIVITIES		**–76,722**	**132,533**
FINANCING ACTIVITIES			
New share issue		150,000	60,000
Issue expenses		–7,845	–3,276
CASH FLOW FROM FINANCING ACTIVITIES		**142,155**	**56,724**
CASH FLOW FOR THE PERIOD		–27,786	79,789
Total cash and cash equivalents at the beginning of the period		139,376	58,367
Effects of currency translation on cash and cash equivalents		8,171	1,221
TOTAL CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD		**119,761**	**139,376**

The Group was formed on October 31, 2021 when Diamyd Medical AB acquired Diamyd Properties AB. Accordingly, the first months of the financial year include amounts pertaining only to the Parent Company. The comparative period pertains to the Parent Company

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**

The Group was formed on October 31, 2021.

Parent Company income statement

KSEK	Note	Aug 31, 2022	Aug 31, 2021
OPERATING INCOME			
Net income	3	506	253
Other operating income	3	1,593	191
TOTAL OPERATING INCOME		**2,099**	**444**
OPERATING EXPENSES			
External research and development costs		–75,567	–56,860
External patent and license costs		–4,403	–2,501
Personnel costs	4	–20,259	–16,174
Other external expenses	5, 6, 7	–11,587	–9,457
Other operating expenses		–1,240	–551
Amortization/depreciation and impairment of assets	8, 11	–2,503	–782
TOTAL OPERATING EXPENSES		**–115,559**	**–86,324**
OPERATING RESULT		**–113,460**	**–85,880**
Impairment of participations in associates	13	–3,818	–
Gain on sale of financial asset	9	6,653	144,414
Interest income and similar profit items	9	8,497	1,965
Interest expense and similar loss items		–253	–453
TOTAL FINANCIAL ITEMS		**11,079**	**145,926**
RESULT AFTER NET FINANCIAL ITEMS		**–102,381**	**60,046**
Income tax	10	-	-
RESULT FOR THE PERIOD		**–102,381**	**60,046**

Parent Company balance sheet

KSEK	Note	Aug 31, 2022	Aug 31, 2021
ASSETS			
Fixed assets			
Intangible assets			
Patents	8	-	65
Tangible assets			
Machinery and inventory	11	22,868	5,553
Financial assets			
Shares in subsidiaries	12	14,900	-
Long-term receivables from subsidiaries		9,325	-
Participations in associates	13	28,403	32,220
Other long-term receivables	15	626	626
Total fixed assets		**76,120**	**38,464**
Current assets			
Accounts receivable		251	51
Other receivables		2,351	1,594
Prepaid expenses and accrued income	16	11,203	21,953
Short-term investments		39,907	-
Cash and cash equivalents		119,238	139,376
Total current assets		**172,950**	**162,974**
TOTAL ASSETS		**249,070**	**201,438**

KSEK	Note	Aug 31, 2022	Aug 31, 2021
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	17	7,802	7,259
Statutory reserve		200	200
Non-restricted equity			
Share premium reserve		390,507	248,895
Retained earnings		–67,095	–127,141
Result for the period		–102,381	60,046
TOTAL EQUITY		**229,033**	**189,258**
Provisions			
Pensions and other commitments	18	777	777
Total long-term liabilities		**777**	**777**
Current liabilities			
Trade payables		9,584	5,572
Other current liabilities		4,722	1,039
Accrued expenses and deferred income	19	4,953	4,792
Total current liabilities		**19,260**	**11,402**
TOTAL EQUITY AND LIABILITIES		**249,070**	**201,438**

Parent Company cash flow statement

KSEK	Note	Sep 2021 – Aug 2022	Sep 2020 – Aug 2021
OPERATING ACTIVITIES			
Operating result		–113,460	–85,880
Interest received		304	0
Interest paid		–253	–71
Non-cash flow items			
Amortization/depreciation		2,503	782
Other non-cash flow items		-	362
CASH FLOW BEFORE CHANGES IN WORKING CAPITAL		**–110,906**	**–84,806**
Increase (-) decrease (+) receivables		9,794	–19,566
Increase (+) decrease (-) liabilities		7,858	–5,095
TOTAL CASH FLOW FROM OPERATING ACTIVITIES		**–93,255**	**–109,468**
INVESTING ACTIVITIES			
Investments in tangible and intangible assets	11	–19,752	–4,225
Investments in financial assets	12	–14,900	–20,477
Loans to subsidiaries		–9,325	-
Divestment of financial assets		-	2,827
Gain on divestment of financial assets	9	6,653	144,414
Matured short-term investments		89,984	9,995
Investment in short-term investments		–129,891	-
CASH FLOW FROM INVESTING ACTIVITIES		**–77,231**	**132,533**
FINANCING ACTIVITIES			
New share issue		150,000	60,000
Issue expenses		–7,845	–3,276
CASH FLOW FROM FINANCING ACTIVITIES		**142,155**	**56,724**
CASH FLOW FOR THE PERIOD		–28,331	79,789
Total cash and cash equivalents at the beginning of the period		139,376	58,367
Effects of currency translation on cash and cash equivalents		8,193	1,221
TOTAL CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD		**119,238**	**139,376**

Parent Company change in equity

KSEK	Share capital	Statutory reserve	Share premium reserve	Other non-restricted equity	Total equity
OPENING BALANCE SEPTEMBER 1, 2020	**7,015**	**200**	**192,414**	**–127,140**	**72,489**
Result for the period	-	-	-	60,046	60,046
New share issue	243	-	59,757	-	60,000
Issue expenses	-	-	–3,276	-	–3,276
CLOSING BALANCE AUGUST 31, 2021	**7,259**	**200**	**248,895**	**–67,095**	**189,258**
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**

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. Comparative figures pertain to the Parent Company. 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. During the financial year, the subsidiary Diamyd Properties AB was recognized in accordance with K2. 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 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. Tangible assets are depreciated over three to ten 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
The differences between the Parent Company's and Group's accounting policies are described below:

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, its building has for accounting purposes been divided into components. 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, 2022, participations in associates amounted to KSEK 28,402 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 3,818. 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.

Accrued expenses
Other accrued expenses mainly consist of costs to contract research organizations for providing clinical trial services. The amount is based on an assessment of agreements and completed parts of assignments.

NOTE 3 OPERATING INCOME

Group, KSEK	2021/22	2020/21
Sales of GAD for research purposes	386	253
Rental income and other lease-related income	597	-
Operating exchange gains	381	191
Accrued funding received	1,213 [1)]	-
Other income	8	-
Total	**2,584**	**444**

Parent Company, KSEK	2021/22	2020/21
Sales of GAD for research purposes	386	253
Operating exchange gains	381	191
Accrued funding received	1,213 [1)]	-
Intra-Group invoicing	120	-
Total	**2,099**	**444**

[1)] Accrued income has been recognized equivalent to the share of the cost that is eligible for the VINNOVA-financed ASSET project. See also page 21. There are no contingent assets or contingent liabilities in connection with this funding.

NOTE 4 PERSONNEL COSTS

Parent Company

Average no. of employees	2021/22	2020/21
Of whom women	11	9
Of whom men	8	5
Total	**19**	**14**

Gender representation on Board and Management Team	Aug 31, 2022		Aug 31, 2021	
	Women	Men	Women	Men
Board	2	4	2	4
Management Team	4	2	4	2
Total	**6**	**6**	**6**	**6**

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)]	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 [2)]	169	-	-	169
Karin Hehenberger	94	-	-	94
Ulf Hannelius, President and CEO [3)]	1,967	427	413	2,808
Other employees	12,067	1,638	1882	15,588
Total	**15,748**	**2,065**	**2,410**	**20,223**

[1)] Of the amount, 119 refers to Board fees and 926 to consulting fees. See also Note 5.
[2)] Of the amount, 100 refers to Board fees and 105 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.

Salaries, other compensation and social security contributions 2020/2021 KSEK	Salary/fees and other compensation	Pension costs	Social security contributions	Total
Erik Nerpin, Chairman	150	-	47	197
Anders Essen-Möller, Board member	1,026	-	10	1,036
Maria-Teresa Essen-Möller, Board member	100	-	31	131
Torbjörn Bäckström, Board member	100	-	10	110
Mark Atkinson, Board member	205	-	-	205
Karin Hehenberger, Board member	100	-	-	100
Ulf Hannelius, President and CEO	1,845	369	522	2,736
Other employees	9,295	1,282	1,643	12,220
Total	**12,821**	**1,651**	**2,264**	**16,736**

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 1,302 (1,040). As a working Board member, Anders Essen-Möller was paid an amount of KSEK 926 (926) through a company owned by Essen-Möller. Board member Mark Atkinson received compensation of KSEK 50 (105) for consulting services. The Arm's Length principle was applied to pricing.

***Group,* KSEK**	2021/22	2020/21
Consulting fees and salaries to related parties	1,302	1,040
Consulting fees to Board members	976	1,131

***Parent Company,* KSEK**	2021/22	2020/21
Consulting fees and salaries to related parties	1,302	1,040
Consulting fees to Board members	976	1,131

NOTE 6 AUDITOR'S FEES

***Group,* KSEK**	**2021/22**	**2020/21**
BDO Mälardalen AB		
Audit assignments	350	300
Other accountancy services	13	-
Baker Tilly Umeå AB		
Audit assignments	32	-
Total	**395**	**300**

***Parent Company,* KSEK**	**2021/22**	**2020/21**
BDO Mälardalen AB		
Audit assignments	350	300
Other accountancy services	13	-
Total	**363**	**300**

NOTE 7 LEASES

***Group,* KSEK**	**2021/22**	**2020/21**
Lease payments, incl. rent during the year	749	815
Future lease payments incl. rent are due for payment as follows:		
Within 1 year	742	1,158
Within 2-5 years	1,422	1,191
Total	**2,165**	**2,349**

***Parent Company,* KSEK**	**2021/22**	**2020/21**
Lease payments, incl. rent during the year	1,581	815
Future lease payments incl. rent are due for payment as follows:		
Within 1 year	1,900	1,158
Within 2-5 years	3,737	1,191
Total	**5,637**	**2,349**

At August 31, 2022, the Parent Company had one rental agreement for office premises in Stockholm with a remaining term of two years and one month, and one rental agreement with Diamyd Properties AB for office and lab premises in Umeå with a remaining term of 12 years and nine months.

NOTE 8 PATENTS

***Group,* KSEK**	**Aug 31, 2022**	**Aug 31, 2021**
Opening cost	11,076	11,076
Purchases	-	-
Sales/disposals	-	-
Closing accumulated costs	**11,076**	**11,076**
Amortization for the year	–65	–139
Closing accumulated amortization	**–11,076**	**–11,012**
Closing carrying amount	**0**	**65**

***Parent Company,* KSEK**	**Aug 31, 2022**	**Aug 31, 2021**
Opening cost	11,076	11,076
Purchases	-	-
Sales/disposals	-	-
Closing accumulated costs	**11,076**	**11,076**
Amortization for the year	–65	–139
Closing accumulated amortization	**–11,076**	**–11,012**
Closing carrying amount	**0**	**65**

NOTE 9 FINANCIAL INCOME

Group, KSEK	2021/22	2020/21
Gain on sale of shares in Companion Medical, Inc.	6,653	144,414
Interest income	67	3
Exchange gains	8,193	1,961
Total	**14,912**	**146,378**

Parent Company, KSEK	2021/22	2020/21
Gain on sale of shares in Companion Medical, Inc.	6,653	144,414
Interest income	304	3
Exchange gains	8,193	1,961
Total	**15,150**	**146,378**

NOTE 10 INCOME TAX

Group, KSEK	2021/22	2020/21
Current tax		
Reconciliation of effective tax		
Profit/loss before tax	–103,517	60,046
Tax expense 20.6% (21.4%)	21,324	–12,850
Tax effect of:		
Non-deductible expenses	43	–8
Non-taxable income	–1,370	30,905
Other unrecognized expenses	–1,616	–701
Loss carryforwards incurred during the year	–18,381	–17,346
Loss carryforwards utilized during the year		
Tax expense	**-**	**-**

Parent Company, KSEK	2021/22	2020/21
Current tax		
Reconciliation of effective tax		
Profit/loss before tax	–102,381	60,046
Tax expense 20.6% (21.4%)	21,090	–12,850
Tax effect of:		
Non-deductible expenses	830	–8
Non-taxable income	–1,370	30,905
Other unrecognized expenses	–1,616	–701
Loss carryforwards incurred during the year	–18,934	–17,346
Loss carryforwards utilized during the year		
Tax expense	**-**	**-**

NOTE 11 TANGIBLE ASSETS

Group, KSEK	Aug 31, 2022	Aug 31, 2021
Machinery and equipment		
Opening cost	7,343	3,118
Purchases	20,038	4,225
Closing cost	**27,381**	**7,343**
Depreciation for the year		
Machinery and equipment	–2,452	–632
Closing accumulated depreciation	**–4,242**	**–1,790**
Closing carrying amount machinery and equipment	**23,139**	**5,553**

Group, KSEK	Aug 31, 2022	Aug 31, 2021
Land and buildings		
Opening cost	-	-
Property purchases	24,476	-
Closing cost	**24,476**	**-**
Depreciation for the year		
Land and buildings	–1,866	-
Closing accumulated depreciation	**–1,866**	**-**
Closing carrying amount land and buildings	**22,610**	**-**

Parent Company, KSEK	Aug 31, 2022	Aug 31, 2021
Machinery and equipment		
Opening cost	7,343	3,118
Purchases	19,752	4,225
Closing cost	**27,095**	**7,343**
Depreciation for the year		
Machinery and equipment	–2,437	–632
Closing accumulated depreciation	**–4,227**	**–1,790**
Closing carrying amount machinery and equipment	**22,868**	**5,553**

During the year, Diamyd Medical AB acquired the Formen 12 property, the property where Diamyd Medical AB is establishing GAD65 manufacturing. The property was purchased through the acquisition of all of the shares in Mark & Schakt Fastigheter i Umeå AB. The company subsequently changed its name to Diamyd Properties AB. The acquisition was recognized as an asset acquisition. The property was acquired through the purchase of shares for MSEK 14.9 and the payment of loans.

NOTE 12 PARTICIPATIONS IN SUBSIDIARIES

Parent Company, KSEK

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

NOTE 13 PARTICIPATIONS IN ASSOCIATES

Group, KSEK	Aug 31, 2022	Aug 31, 2021
Opening cost	32,220	11,743
Participations acquired in associates during the year	-	20,477
Impairment of participations in associates during the year	-	-
Adjustment of share in profits using the equity method	–16,757	-
Carrying amount at year end	**15,463**	**32,220**

Parent Company, KSEK	Aug 31, 2022	Aug 31, 2021
Opening cost	32,220	11,743
Participations acquired in associates during the year	-	20,477
Impairment of participations in associates during the year	–3,818	-
Adjustment of share in profits using the equity method	-	-
Carrying amount at year end	**28,402**	**32,220**

Group, KSEK Company	Corp. Reg. No.	Registered office	Votes, %	Share of capital, %	No. of shares	Aug 31, 2022 Carrying amount	Aug 31, 2021 Carrying amount
NextCell Pharma AB	556965-8361	Huddinge, Region Stockholm	12.5	12.5	4,283,861	14,263	31,020
MainlyAI AB	559258-7538	Stockholm, Region Stockholm	20.0	20.0	125	1,200	1,200

Parent Company, KSEK Company	Corp. Reg. No.	Registered office	Votes, %	Share of capital, %	No. of shares	Aug 31, 2022 Carrying amount	Aug 31, 2021 Carrying amount
NextCell Pharma AB	556965-8361	Huddinge, Region Stockholm	12.5	12.5	4,283,861	27,202	31,020
MainlyAI AB	559258-7538	Stockholm, Region Stockholm	20.0	20.0	125	1,200	1,200

Information about equity and earnings for NextCell Pharma AB		
Equity according to most recently adopted financial statements	150,093	26,218
Result according to most recently adopted financial statements	–24,557	–17,681
Information about equity and earnings for MainlyAI AB		
Equity according to most recently adopted financial statements	2,210	2,225
Result according to most recently adopted financial statements	-15	0

NOTE 14 LONG-TERM RECEIVABLES FROM SUBSIDIARIES

Parent Company, KSEK	Aug 31, 2022	Aug 31, 2021
Opening cost	-	-
Loans to Diamyd Properties AB	9,325	-
Closing accumulated costs	**9,325**	**-**
Closing carrying amount	**9,325**	**-**

NOTE 15 OTHER LONG-TERM RECEIVABLES

Group, KSEK	Aug 31, 2022	Aug 31, 2021
Opening cost	626	626
Purchases	-	-
Closing accumulated costs	**626**	**626**
Closing carrying amount	**626**	**626**

Parent Company, KSEK	Aug 31, 2022	Aug 31, 2021
Opening cost	626	626
Purchases	-	-
Closing accumulated costs	**626**	**626**
Closing carrying amount	**626**	**626**

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

NOTE 16 PREPAID EXPENSES AND ACCRUED INCOME

Group, KSEK	2021/22	2020/21
Prepaid rent	11	14
Prepaid insurance premiums	579	557
Prepaid production costs	10,133	21,139
Other prepaid expenses	142	243
Other accrued income	33	-
Total	**10,897**	**21,953**

Parent Company, KSEK	2021/22	2020/21
Prepaid rent	11	14
Prepaid insurance premiums	567	557
Prepaid production costs	10,133	21,139
Other prepaid expenses	221	243
Other accrued income	271	-
Total	**11,203**	**21,953**

NOTE 17 SHARE CAPITAL

For a specification of the Parent Company's changes in equity, refer to *"Change in equity"* on page 34. At August 31, 2022, the number of shares in Diamyd Medical AB comprised 74,370,716 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 7,802,027 (7,258,812). The (rounded) quotient value was 0.1014 (0.1014). All shares issued are fully paid.

NOTE 18 PROVISIONS

Group, KSEK	Aug 31, 2022	Aug 31, 2021
Opening cost	777	777
Impairment	-	-
Closing accumulated costs	**777**	**777**
Closing carrying amount	**777**	**777**

Parent Company, KSEK	Aug 31, 2022	Aug 31, 2021
Opening cost	777	777
Impairment	-	-
Closing accumulated costs	**777**	**777**
Closing carrying amount	**777**	**777**

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

NOTE 19 ACCRUED EXPENSES AND DEFERRED INCOME

Group, KSEK	2021/22	2020/21
Accrued vacation pay	2,067	1,612
Accrued social security contributions	650	506
Accrued interest expense	0	1
Prepaid rental income	57	-
Accrued research costs	1,139	1,696
Other accrued expenses	1,117	977
Total	**5,030**	**4,792**

Parent Company, KSEK	2021/22	2020/21
Accrued vacation pay	2,067	1,612
Accrued social security contributions	650	506
Accrued interest expense	0	1
Accrued research costs	1,139	1,696
Other accrued expenses	1,097	977
Total	**4,953**	**4,792**

NOTE 20 PLEDGED ASSETS AND CONTINGENT LIABILITIES

Group and Parent Company, KSEK	2021/22	2020/21
Pledged assets	239	239
Total	**239**	**239**

Pledged assets consist of a bank guarantee for rental payments for office premises.

NOTE 21 SIGNIFICANT EVENTS AFTER THE END OF THE FINANCIAL YEAR

No significant events occurred after the balance-sheet date.

NOTE 22 APPROPRIATION OF PROFIT

Parent Company

The following profits are at the disposal of the AGM

	SEK
Share premium reserve	390,507,306
Retained earnings	–67,095,483
Result for the year	–102,381,010
	221,030,814

The Board and CEO propose that the following profits be carried forward SEK **221,030,814**

Signatures of the Board of Directors and Chief Executive Officer

The Group's income statements and balance sheets will be submitted to the Annual General Meeting on December 1, 2022 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 9, 2022

Erik Nerpin
Chairman

Anders Essen-Möller
Board member

Maria-Teresa Essen-Möller
Board member

Torbjörn Bäckström
Board member

Mark A. Atkinson
Board member

Karin Hehenberger
Board member

Ulf Hannelius
Chief Executive Officer

Our Auditor's Report was submitted on November 9, 2022.

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 2021-09-01 -- 2022-08-31. The annual accounts and consolidated accounts of the company are included on pages 18-44 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 Augusti 2022 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 1-17. 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 2021-09-01 -- 2022-08-31 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 9 November 2022
BDO Mälardalen AB

Johan Pharmanson
Authorized Public Accountant

Board

Erik Nerpin

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 since 2012. Chair of Kancera AB and Blasieholmen Investment Group AB. Board member of various companies, including Effnetplattformen AB.

Holding in Diamyd Medical
at August 31, 2022: 41,065 Class B shares.

Anders Essen-Möller

Board member
Born in 1941

M.Sc. Founder of Diamyd Medical and CEO 1996–2007. Independent of the Company, is a major owner. 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, 2022: 556,223 Class A shares and 2,813,040 Class B shares. Holding in endowment policy: 1,187,000 Class B shares.

Maria-Teresa Essen-Möller

Board member
Born in 1970

M.Sc. in Business Administration. Chief Commercial Officer at ScientificMed AB. Independent of the Company, but not independent of its principal owner. Previous experience includes CEO of Health Solutions AB and Digital Marketing Manager at Sanofi. Board member since 2009.

Holding in Diamyd Medical
at August 31, 2022:
400,000 Class A shares and 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, 2022: 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, 2022: 16,750 Class B shares.

Karin Hehenberger

Board member
Born in 1972

M.D., PhD, Karolinska Institutet, post-doc at Joslin Diabetes Center, Harvard Medical School. Founder and CEO of Lyfebulb, Board member of 3B Future Health Ventures Advisory Board, Deputy Board member of AADI pharmaceuticals, Board member of Rolf Luft Foundation for Diabetes Research, Board member of the American Diabetes Association NY/NJ Community Board. Previous senior positions in the life science industry. Independent of the Company and its principal owner. Board member since 2021.

Holding in Diamyd Medical
at August 31, 2022: 10,000 Class B shares.

Management

Ulf Hannelius

CEO
Born in 1975

PhD in Molecular Biology from Karolinska Institutet 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. Chairman of Diamyd Properties AB, Board member of MainlyAI AB. Joined Diamyd Medical in 2015, CEO since 2016.

Holding in Diamyd Medical at August 31, 2022: 167,500 Class B shares.

Anna Styrud

Chief Financial Officer
Born in 1961

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

Holding in Diamyd Medical at August 31, 2022: 110,000 Class B shares.

Martina Widman

Chief Operating Officer
Born in 1981

M.Sc. 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, 2022: 10,000 Class B shares.

Anton Lindqvist

Chief Scientific Officer
Born in 1980

M.Sc. 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, 2022: –

Maja Johansson

Site Manager, Umeå
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 Properties AB. Maja Johansson joined Diamyd Medical in 2020.

Holding in Diamyd Medical at August 31, 2022: –

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, 2022: –

Christoph Nowak

Chief Medical 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, 2022: 4,678 Class B shares.

Auditors

The Company's auditors are BDO Mälardalen AB, domiciled at Box 24193, SE-104 51 Stockholm, Sweden. Johan Pharmanson (born 1964) is the principal auditor.

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 Annual General Meeting will be held on December 1, 2022 at 3:00 p.m. at Hotell Kung Carl, Birger Jarlsgatan 21 in Stockholm, Sweden.

PARTICIPATION

Shareholders who wish to participate in the meeting must be included in the shareholders' register maintained by Euroclear Sweden AB on November 23, 2022, and are requested to notify Diamyd Medical of their intention to attend the meeting by November 25, 2022. To be entitled to participate in the AGM, those shareholders who have registered their shares in the name of a nominee must temporarily register their shares in their own name with Euroclear Sweden AB. Such requests for registration should be made to the bank or fund manager that manages the shares in good time before November 25, 2022. The shareholder's request must have been executed by November 25, 2022. The manager should therefore be contacted well in advance of this date.

FINANCIAL CALENDAR

AGM	December 1, 2022
Quarterly Report (Sep-Nov)	January 25, 2023
Quarterly Report (Sep-Feb)	April 5, 2023
Quarterly Report (Sep-May)	June 28, 2023
Year-end Report (Sep-Aug)	October 11, 2023

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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