DIAMYD MEDICAL

Annual Report 2020/2021

Diamyd Medical AB

Contents

Events during the financial year

From Phase II to Phase III
In the Phase IIb DIAGNODE-2 trial, Diamyd® showed significant treatment effects in a genetically defined sub-population of newly diagnosed type 1 diabetes patients. Preparations for the follow-up Phase III DIAGNODE-3 trial commenced.

Divestment, new investment and financing
Diamyd Medical raised funds of MUSD 13.9 by divesting the company's holding in Companion Medical, Inc., and capital of MSEK 60 through a directed share issue. A new investment of MSEK 1.2 was made in MainlyAI AB, a company focused on the strategic application of artificial intelligence in areas such as the pharmaceutical sector.

Stronger international presence
Diamyd Medical presented at several international scientific conferences and participated in the publication of the DIAGNODE-2 trial results, which were published in the leading peer-reviewed medical journal Diabetes Care.

Events after the end of the financial year

Financing
A directed share issue raised gross proceeds of MSEK 150 for Diamyd Medical.

Phase III
While permission to commence the Phase III trial was granted by the Medical Products Agency in Sweden, and the European section of DIAGNODE-3 is expected to start before the end of the calendar year, the US Food and Drug Administration (FDA) has placed the trial on clinical hold pending a review of additional data that largely pertains to the investigational drug.

Financing
VINNOVA granted funding of MSEK 40 to Diamyd Medical for the prevention of autoimmune diseases.

Manufacturing/acquisitions
Diamyd Medical acquired the property in Umeå where the company is establishing GAD65 production, the active compound in the Diamyd® diabetes vaccine.

Diamyd Medical

Diamyd Medical develops precision medicine drugs for type 1 diabetes and other forms of autoimmune diabetes. The Diamyd® diabetes vaccine has reached its final stage of development – a Phase III clinical trial – the last step before filing a marketing authorization application. Based on already available data and alongside the Phase III trial, the possibility of being granted conditional marketing authorization is being evaluated.

Diamyd Medical is a growing diabetes company and had 19 employees at the end of the financial year, an increase of eight people during the year. The employees are divided between the head office in Stockholm and the company's own vaccine manufacturing facility, which is currently being established in Umeå. GAD65, the active compound in the Diamyd® precision medicine diabetes vaccine, will be manufactured there. The vaccine is an antigen-specific immunotherapy to preserve endogenous insulin production in patients with type 1 diabetes, and possibly patients with latent autoimmune diabetes in adults (LADA) as well.

The clinical trials and extensive meta-analysis conducted to date demonstrate the significant efficacy of Diamyd® in a large, genetically defined subpopulation of patients with newly diagnosed type 1 diabetes. About 40% of the total population of type 1 diabetes patients belong to this genetic cohort. Preparations for a Phase III trial with Diamyd® to confirm the results are ongoing.

The other investigational drug that Diamyd Medical is developing is the Remygen® tablet. The tablet is an oral regenerative and immunomodulatory therapy based on gamma-aminobutyric acid (GABA), an important neurotransmitter in the body. This therapy is being evaluated for its ability to restore or stimulate the body's ability to produce insulin, and to prevent hypoglycemia. An investigator-initiated 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.

Diamyd® is also being studied in a Phase I/II trial, GADinLADA, in LADA patients, and preparations are under way to evaluate Diamyd® for preventive purposes in people with a high risk of developing type 1 diabetes.

60-80%

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

463 million

Approximately 463 million people are living with diabetes today, and this figure is expected to reach 700 million by 2045. Of these, 10% have some form of autoimmune diabetes: type 1 diabetes or LADA.

Ten years shorter

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

Steps towards the goal

In recent years, Diamyd Medical has achieved several key milestones along the path to final authorization and launch of the therapeutic Diamyd® diabetes vaccine.

2019

ANALYSIS
Meta-analysis of earlier trials showed efficacy for Diamyd® in a genetically defined type 1 diabetes subpopulation.

2020

PATENTS
Patents granted in Europe and Japan for intralymphatic administration of Diamyd®.

PUBLICATION
The peer-reviewed medical journal Diabetologica published the meta-analysis that showed 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.

2021

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

ANALYSIS
Analyses of earlier prevention trials and one pilot study supported the results showing the efficacy of Diamyd® in a genetically defined subpopulation.

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.

PATENT
The company secured a European precision medicine patent for the prevention and treatment of autoimmune diabetes in a genetically defined subpopulation with GAD.

ANALYSIS
Additional analyses of data in the meta-analysis showed the clear efficacy of Diamyd® in a genetically defined subpopulation.

A chronic illness with serious complications

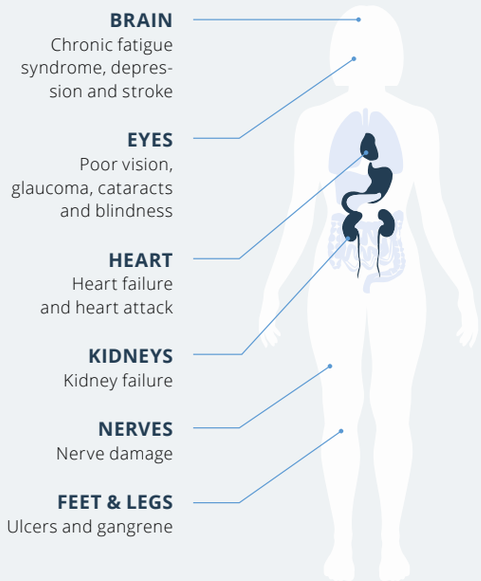
Diabetes is a group of metabolic diseases that are rising dramatically all over the world. The main symptom of these diseases is excessively high levels of glucose in the blood, due to the body's inability to produce or respond to the hormone insulin. Despite careful control and management of diabetes, these diseases often lead to long-term and serious complications.

Glucose (blood sugar) levels are controlled by two pancreatic hormones, insulin and glucagon. Insulin is the hormone that helps transport glucose from food into the muscles and organs for metabolism. Glucagon is secreted when blood sugar levels fall too low and then raise the concentration of glucose in the blood. In diabetes, the body cannot produce or use its own insulin and additionally, glucagon release is usually inhibited.

If the body does not produce enough insulin or react to insulin, muscles and other organs will get too little glucose and blood sugar levels will rise too high. Despite correct treatment and management of the disease, diabetes nearly always leads to long-term complications. Sequelae, such as damage to the eyes, blood vessels and nervous system are common, and in addition to the personal pain and suffering, impose an economic burden on society.

The three most common forms of diabetes are type 2 diabetes, which is usually linked to lifestyle factors and age, type 1 diabetes which is caused by an autoimmune reaction and usually develops in children or young adults, and latent autoimmune diabetes in adults (LADA), which is similar to type 1 diabetes but usually develops later in life.

HOW THE BODY IS DAMAGED



Type 1 diabetes:
The body stops producing insulin
Type 1 diabetes is an autoimmune disease where the body's immune system, for an unknown reason, attacks and destroys beta cells, which are the cells in the pancreas that secrete insulin. When the body cannot produce enough insulin, glucose levels rise in the blood. To restore the glucose balance, the current standard of treatment is subcutaneous insulin administration. Blood sugar levels must be monitored 24 hours a day using blood tests, and insulin doses are adjusted thereafter.

There is no cure for type 1 diabetes, and the disease is associated with severe complications such as life-threatening low blood sugar, coma and serious sequelae. However, the risk of diabetic complications in patients with type 1 diabetes can be reduced by 60-80% when some form of endogenous insulin production is retained. Despite the major unmet need, there are still no disease-modifying drugs that can retain or increase the body's ability to produce insulin.

> *"When diabetes is uncontrolled, it has dire consequences for health and well-being. In addition, diabetes and its complications impact harshly on the finances of individuals and their families, and the economies of nations."*
>
> *Dr Margaret Chan, Director-General of the World Health Organization, 20062017 (Preface to Global report on diabetes, 2016)*

Type 2 diabetes:
The body does not produce enough insulin
In type 2 diabetes, the body gradually loses its ability to control blood sugar levels. The function of insulin-producing cells is destroyed by overload, and the body stops responding to the insulin. The disease is progressive, and even though dietary and lifestyle changes can prevent and control the condition to some extent, type 2 diabetes usually leads to permanent medication.

Available therapies work by either improving sensitivity to the insulin that the body is still producing, or by lowering blood sugar levels in some other way. Most often, the body is unable to produce enough insulin and daily insulin therapy is required.

LADA: latent autoimmune diabetes in adults (LADA) is a form of autoimmune diabetes. The body's immune system attacks the insulin-producing cells in the pancreas but with LADA, the progression of the disease is slower and the symptoms are not as easily recognized as for type 1 diabetes. The disease mainly affects adults and does not usually require immediate insulin treatment, which is why LADA is often misdiagnosed and treated as type 2 diabetes. About 10% of people diagnosed with type 2 diabetes actually have LADA.

After several years, LADA patients usually also require daily insulin injections to control their blood sugar levels. Like type 1 and type 2 diabetes, LADA is associated with serious diabetes complications.

Dear Shareholders and Readers,

In a changing world that at the time of writing is finding its way out of the largest pandemic in modern times, Diamyd Medical is standing strong. We have built an organization that is less dependent on external help to conduct the work around clinical trials, regulatory strategy, and analysis of data. We are establishing our proprietary manufacturing to ensure long-term access to the active component of our therapeutic diabetes vaccine Diamyd® when it is time for commercialization. Finally, we have convincing safety data and strong efficacy data that show that precision medicine is the way forward in diabetes and for our diabetes vaccine.

Diamyd Medical's greatest asset in addition to the expertise and experience built up in the company lies in our clinical data with the diabetes vaccine Diamyd® and the patents that protect the technology. Through extensive data analysis of previous trials with Diamyd®, we have identified on which individuals the vaccine is most likely to have a significant effect. We see that the vaccine has a clinically relevant and statistically significant effect on preserving endogenous insulin production and in improving blood glucose control in individuals with type 1 diabetes who carry a specific genetic type. This gene type, more specifically the HLA haplotype DR3-DQ2, is linked to a disease progression that is associated with autoimmunity against GAD, ie against the same endogenous antigen that constitutes the active component in Diamyd®. HLA is crucial for how the immune system recognizes and presents antigen, and this connection to a distinct scientific basis further increases the soundness and credibility of our analyses.

The precision medicine focus of the company is crucial for our journey forward and is in line with the changes that are being discussed both in the diabetes field and for healthcare in general. Through the progress of recent years, Diamyd Medical has received a great deal of attention where, in addition to scientific publications, we have had the opportunity to present findings from our trials and analyses at several of the largest international scientific conferences in the diabetes field.

We are also very proud that within the framework of precision health, grants have been awarded from the Swedish governmental innovation agency VINNOVA. Here, we coordinate the five-year innovation environment ASSET (AI for Sustainable Prevention of Autoimmunity in the Population) which aims to identify opportunities for national screening and preventive precision medical treatment of individuals who are at high risk of being diagnosed with type 1 diabetes.

"We have convincing safety data and strong efficacy data that show that precision medicine is the way forward in diabetes and for our diabetes vaccine."

This project will give Diamyd Medical the opportunity to work directly with artificial intelligence together with the company Mainly AI, which we also have invested in, and thereby expand our commitment and competence in data-driven development.

With this in mind, we are moving forward with great confidence but also great respect for what is required to take the diabetes vaccine Diamyd® all the way to market. The importance of manufacturing has been emphasised in our interactions with regulatory authorities where they want to ensure there are no ambiguities about the pharmaceutical product itself when a pivotal trial is launched, in our case the Phase 3 trial DIAGNODE-3. The resources we invest in manufacturing and our regulatory work will pay off handsomely, and here we do a thorough job to ensure not to risk stumbling on the finish line.

One hundred years after the discovery of insulin, we are now on the threshold of being able to change the treatment paradigm for autoimmune diabetes. We and other players in the field can state with great certainty that type 1 diabetes will within a few years have its first disease-modifying treatments approved. This should be considered a minor revolution given the possibilities these treatments will open up for. I am extremely proud that Diamyd Medical is at the forefront of this development. We have the potential to go all the way and establish the company as a leading commercial player in the fields of diabetes, autoimmune diseases, and precision medicine.

Stockholm, November 10, 2021

ULF HANNELIUS
CEO Diamyd Medical AB

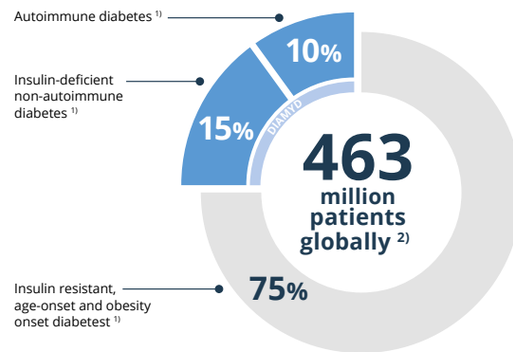
Global need for diabetes drugs

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

Approximately 463 million people between the ages of 20-79 are affected by diabetes. This figure is likely to exceed 700 million people by 2045. 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 approximately USD 760 billion annually, or about 10% of global health expenditure. Most of these costs are attributable to long-term diabetes complications, such as cardiovascular problems, kidney damage and nerve damage.

About 10% of all those affected have type 1 diabetes. The market potential for a drug that can suppress the autoimmune process in people with this type of diabetes, which is associated with serious complications, is estimated to be several billion dollars per year.

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.



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

2) *IDF Diabetes Atlas Ninth edition 2019*

Research shows that even small amounts of preserved endogenous insulin production in these people could reduce up to 60-80% of the long-term complications of diabetes.

The market for Diamyd Medical

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

The therapeutic Diamyd® diabetes vaccine is being developed to preserve the body's ability to produce insulin in patients newly diagnosed with type 1 diabetes. Every year, approximately 133,000 children and young people are diagnosed with type 1 diabetes and an estimated 40% belong to the specific genetically defined subpopulation (positive for the HLA DR3-DQ2 genotype) that studies have shown responds positively to intralymphatic treatment with Diamyd®.

The market value of 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 size of the market would be even greater. If the complications that could eventually be prevented – such as pain and suffering, and costs for loss of work – are also taken into account, treatment with 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 an oral treatment that works by stimulating the formation and function of insulin-producing beta cells. This investigational drug has potential for the treatment of both type 1 and

type 2 diabetes, as well as 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.

The estimated size of the non-insulin anti-diabetic drugs market is USD 22 billion and this figure is expected to grow substantially if Remygen® and other similar regenerative therapies receive market authorization.

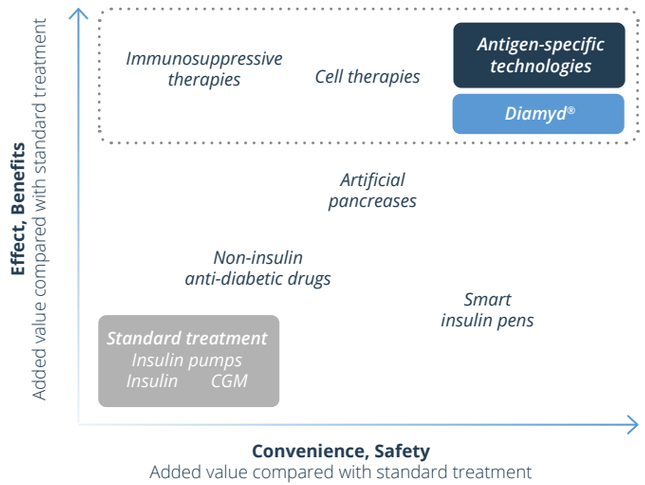
Drug development

The current mainstay treatment for type 1 diabetes is life-sustaining, subcutaneous deliveries of insulin by injection or pump therapy, combined with continuous glucose monitoring (CGM). However, drug development is under way on multiple fronts. Non-insulin drugs are one direction, of which Remygen® is one example. Aids such as artificial pancreases and smart insulin pens to help patients manage their condition, are another. In addition, therapies targeting the underlying causes of the disease are also under development.

The goal of the antigen-specific immunotherapy with the therapeutic Diamyd® diabetes vaccine is to fundamentally change the disease by reprogramming the body's immune system so that it no longer attacks the insulin-producing cells. This treatment has the potential for long-term efficacy. In contrast to other technologies under development, Diamyd® has demonstrated excellent safety and the treatment is fast and easy – no hospital admission is required.

The treatment has shown significantly positive efficacy in a genetically defined subpopulation, those carrying the HLA DR3-DQ2 genotype, which is about 40% of all people with type 1 diabetes.

Diamyd'®s market position



Patents at the core of the strategy

The mainstay of Diamyd Medical's business strategy is the patents that protect the commercial use of the company's products. The out-licensing strategy, which is aimed at partnerships with one or more large pharmaceutical company, also offers the possibility of retaining some market share in order to develop a fully integrated pharmaceutical company.

The business strategy is based on several key components: the clinical and immunological results, the ongoing execution of activities, and the company's intellectual property rights – which provide commercial protection for Diamyd Medical's products. In addition to the potential for own sales, future revenue streams are expected to comprise upfront and milestone payments from licensing agreements, and royalties on commercialization and sales.

In-house manufacturing
Establishment of the manufacturing facility in Umeå is a step towards more integrated operations. During the year, small-scale experimental production of GAD65 – the active ingredient in the Diamyd® precision medicine diabetes vaccine, was established and, pending marketing authorization of the drug, the facility is ready for large-scale production in accordance with current guidelines.

The main factors underlying the current value of projects – and thereby the size of partnership agreements – are the size of the market, the pricing of the products, future market share and the likelihood of reaching the market.

The COVID-19 pandemic has reshaped the future of the pharmaceutical industry and highlighted the importance of manufacturing control. Investing in in-house production of GAD65 has given the company full control over the supply of this key asset.

Route to market
Combined with a major unmet medical need, the positive results from completed clinical trials and their good safety profiles – are positioning Diamyd® to become a mainstay of genetically defined, precision medicine for the treatment of autoimmune diabetes. 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 the preclinical studies and clinical trials required for new compounds will not be needed.

Existing patents
Diamyd Medical's intellectual property rights are mainly protected by the company's own patent applications and exclusive licenses. The company has been granted patents for intralymphatic administration of Diamyd® in Europe, Japan, Russia, Israel and Australia, and patents are pending in other countries. 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 GAD to treat diabetes. Diamyd Medical has also been granted a precision medicine 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.

As a biologic drug, Diamyd® also receives 12 and 10 years of market exclusivity in the US and Europe, respectively, independent of patent protection, from the date on which marketing authorization is issued. The US Food and Drug Administration (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.

Contributions to 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 with GAD. The company is also strengthening it presence at scientific conferences on key areas such as human genetics and diabetes.

STRATEGIC HOLDING

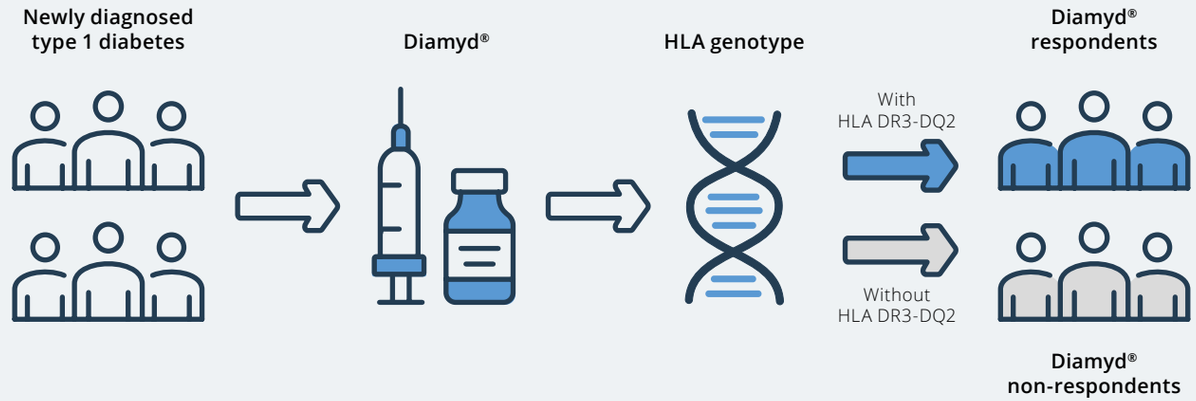
Diamyd Medical is the largest shareholder of NextCell Pharma AB, which is developing stem cell therapies with the investigational drug ProTrans, which showed a significant effect in treatment of type 1 diabetes in a Phase II trial. Alongside of clinical trials, NextCell Pharma also runs Sweden's first family cord blood bank in the company's secondary name of Cellaviva. Since February 2021, Diamyd Medical has owned 20% of the research and technology company MainlyAI AB, which is focused on helping businesses become more sustainable using artificial intelligence (AI) applications, also within drug manufacturing. Diamyd Medical collaborates with MainlyAI in regard to the production facility in Umeå, and within the context of type 1 diabetes treatment.

Ready for the next step

Diamyd® and Remygen® are both drugs in the clinical development stage that can dramatically reduce the risk of diabetic complications. The upcoming Phase III trial will study the promising potential to develop the therapeutic Diamyd® diabetes vaccine as a personalized treatment for many patients with type 1 diabetes.

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.



About Diamyd®

Diamyd® is an antigen-specific immunotherapy, a therapeutic diabetes vaccine, 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 self-antigen expressed 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. Diamyd® does not weaken the body's immune system, in contrast to immunosuppressive therapies that can increase the risk of viral infections with possible post-viral complications.

In 2021, preparations commenced for a Phase III trial (DIAGNODE-3) with Diamyd® for type 1 diabetes in the genetically defined subpopulation that showed a significant treatment effect in the Phase IIb trial (DIAGNODE-2). Diamyd® is also being tested in patients with LADA in a Phase I/II clinical trial (GADinLADA) at the Norwegian University of Science and Technology in Trondheim in Norway, and the Karolinska Institute in Stockholm in Sweden.

About Remygen®

Remygen® is an oral regenerative and immunomodulation therapy for both forms of autoimmune diabetes (type 1 and LADA) and type 2 diabetes. This investigational drug is Diamyd Medical's own formulation of GABA (gamma-aminobutyric acid), best known for its role as a neurotransmitter in the central nervous system.

In clinical trials, GABA has been shown to stimulate the release of the glucose-regulating hormones insulin and glucagon, and the hormonal response to hypoglycemia (low blood sugar levels). Preclinical studies have presented strong evidence that GABA stimulates the formation and function of the insulin and glucagon-producing cells in the pancreas, and that GABA modulators such as Alprazolam can increase the positive effects of GABA on insulin-producing cells.

Remygen® is currently being tested in a Phase I/II clinical trial (ReGenerate-1) at Uppsala University Hospital, where the clinical efficacy is being studied in order to optimize the treatment prior to pivotal trials.

Ongoing clinical trials

Clinical trials of the investigational drugs Diamyd® and Remygen® are being carried out to develop therapies that stop the autoimmune attack on insulin-producing cells in diabetes, and that preserve or restore the body's ability to produce insulin.

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, and from a previously completed and published meta-analysis. The Phase III trial is planned to commence at end of 2021, with the objective to verify the efficacy shown in the DIAGNODE-2 clinical trial in a large number of patients belonging to the specific subpopulation.

The trial will include about 330 people aged 12-28 who have recently been diagnosed with type 1 diabetes and belong to the genetically defined subpopulation that responded positively to treatment with Diamyd® in DIAGNODE-2. It is planned to take place at around 50 clinics, where an estimated 40% of all people with type 1 diabetes belong to this subpopulation.

After the first month, when all trial participants will receive vitamin D, two of three trial participants will be randomly selected for three intralymphatic injections of Diamyd® at monthly intervals. One of three will receive a placebo. A primary analysis will then take place 24 months after the trial commences.

Ongoing clinical trials

Product	Indication	Trial	Partci -pants	Sponsor	Phase I	Phase IIa	Phase IIb	Phase III	Status
Diamyd® intralymphatic	Type 1 diabetes, newly diagnosed, HLA DR3-DQ2 carrier	DIAGNODE-3	330	Diamyd Medical					Planned start at the end of 2021.
Diamyd® intralymphatic	LADA, newly diagnosed	GADinLADA	15	NTU Trondheim					Fully recruited. First results expected in early 2022.
Remygen®	Type 1 diabetes	ReGenerate-1	36	Uppsala University					Results from initial study published. Main study is ongoing

GADinLADA – Diamyd®

This trial is an open-label investigator-initiated clinical trial where Diamyd® is injected directly into the lymph node, combined with supplements of vitamin D. The trial includes 14 patients aged 30-70 years who have been diagnosed with LADA but not yet treated with insulin. The objective is 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 is taking place in Norway and Sweden and is fully recruited, and the initial results are planned to be announced in early 2022.

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.

The main study is assessing the safety of Remygen®, both alone and in combination with the GABA receptor modulator Alprazolam, on the ability to restore endogenous insulin production, and the investigational drug's preventive effects on hypoglycemia in people with lifelong type 1 diabetes.

Diamyd® as precision medicine treatment

The completed Phase IIb DIAGNODE-2 trial showed a good treatment outcome with the therapeutic Diamyd® diabetes vaccine for the participating type 1 diabetes patients belonging to a genetically defined subpopulation. This demonstrates significant potential for Diamyd® as a precision medicine for a large subpopulation.

There are strong arguments emerging in current research to support a precision medicine approach to type 1 diabetes, with the aim of focusing on the actual disease mechanism and tailoring treatments to individual patients who are most likely to respond to the treatment. Precision medicine is simply the right drug for the right patient at the right time. This approach has already been highly successful in cancer therapy, where specific immunotherapies target tumors that express specific biomarkers. Much seems to indicate that the treatment of type 1 diabetes is moving in the same direction.

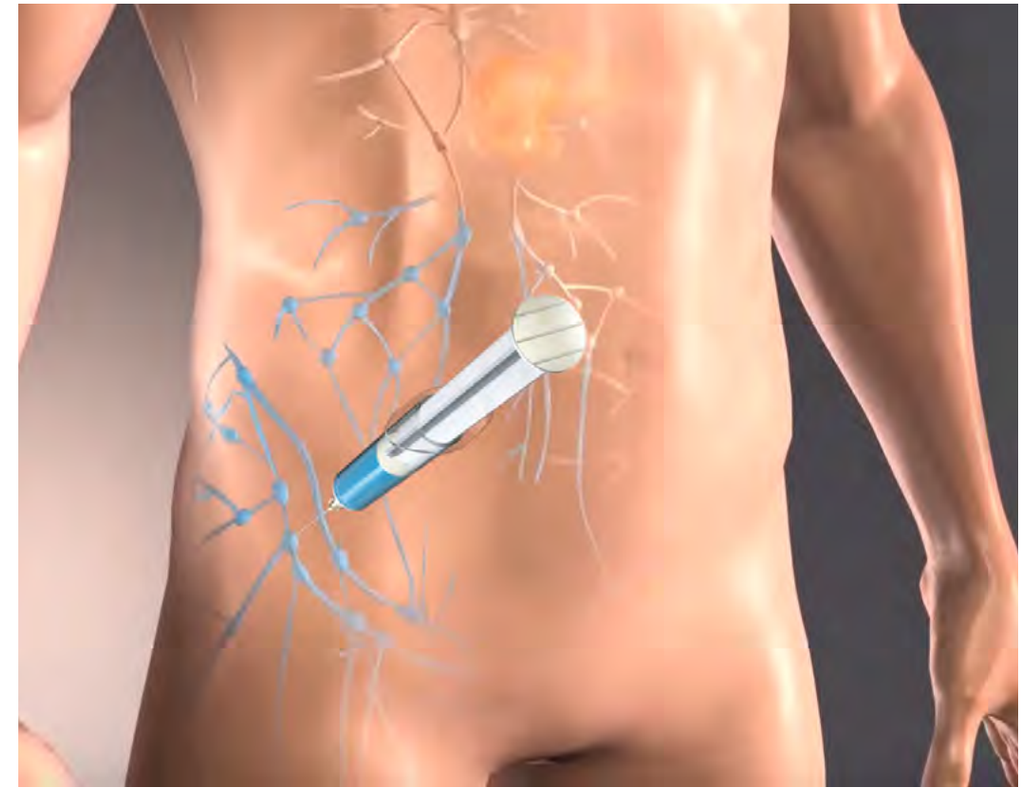
Breakthrough for Diamyd®

The results from the Phase IIb DIAGNODE-2 trial were published in the peer-reviewed medical journal Diabetes Care in May 2021. They confirm that a genetically defined subpopulation of patients with type 1 diabetes responds clinically to Diamyd® injected directly into the lymph node on three occasions at monthly intervals. The trial participants were also given oral supplements of vitamin D/placebo for four months.

A total of 109 patients aged 12-24 years took part in the trial. The participants, all with new-onset type 1 diabetes, came from 18 clinics across Sweden, Spain, the Czech Republic and the Netherlands. In the genetically defined subpopulation of patients carrying the HLA (Human Leukocyte Antigen) DR3-DQ2 genotype, those who received active treatment preserved more than 50% of their endogenous insulin production compared with a placebo. No serious vaccine-related adverse events were reported in the trial.

In line with meta-analysis

The results from DIAGNODE-2 are in line with the meta-analysis published in the peer-reviewed medical journal Diabetologia comprising data from more than 500 patients treated with subcutaneous injections of Diamyd® in three earlier randomized placebo-controlled trials. An updated meta-analysis that also includes DIAGNODE-2 data provides further support for the effects of Diamyd® in people with type 1 diabetes who also carry the HLA DR3-DQ2 genotype. The analysis, which is based on data from more than 600 participants in four placebo-controlled clinical trials, shows a positive and significant treatment effect for both preservation of endogenous insulin production and improved control over average blood glucose. The analysis also supports the fact that the treatment has a particularly positive effect on individuals positive for the HLA DR3-DQ2 genotype, but negative for the HLA DR4-DQ8 genotype.



The findings support the view that it is possible to identify patients who are far more likely to respond to a GAD treatment, based on a recognized and scientifically sound DNA profile.

Routes of administration

Trials have also studied various routes of administration to identify ways to further increase the effectiveness of the Diamyd® precision medicine diabetes vaccine. In addition to subcutaneous injection (under the skin), from where it is transported to the lymph nodes, intralymphatic injection, where Diamyd® is injected directly into the lymph nodes, has been studied.

In both cases, antigen-reactive cells in the lymph node acquire an anti-inflammatory profile that spreads throughout the body. When the cells then encounter self-antigens in the pancreas, the autoimmune attack on the insulin-producing beta cells is limited. The fact that intralymphatic administration results in stronger immunological and clinical efficacy has also been demonstrated previously in relation to allergic diseases. This is the method used in the DIAGNODE-1, 2 and 3 clinical trials with Diamyd®.

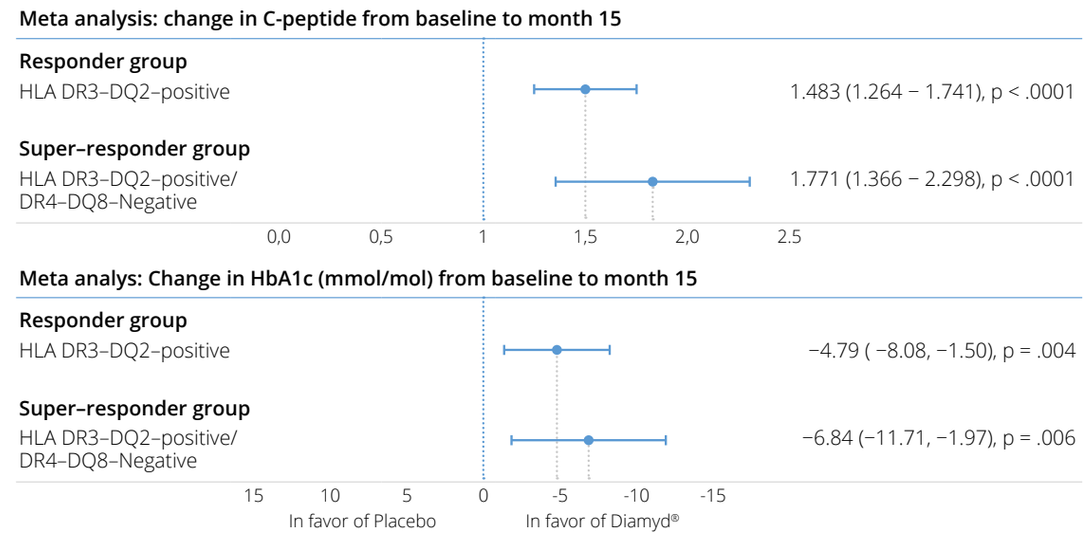
Patented treatment

Diamyd Medical has been granted patents for intralymphatic administration of Diamyd® in Europe, Japan, Russia, Israel and Australia. As part of an exclusive license from the University of California, Los Angeles (UCLA), Diamyd Medical has also been granted a US patent for the treatment of diabetes with GAD, a major autoantigen in diabetes.

In August 2021, the European Patent Office also announced that Diamyd Medical's precision medicine patent application would be granted for the prevention and treatment of autoimmune diabetes in people carrying the HLA DR3-DQ2 genotype. It provides uniform protection in Europe for the treatment or prevention of genetically defined autoimmune diabetes with GAD, which is the active ingredient in Diamyd®.

A safe and convenient treatment

In trials with over 1,500 participants in total, the thereapeutic diabetes vaccine Diamyd® has shown an excellent safety profile. No serious adverse events have been reported and data shows no difference in the adverse events profile between the approximately 900 people treated with the active compound and the over 500 people treated with a placebo. The most commonly reported type of adverse event is irritation around the injection site, while the good safety profile and convenience of the treatment are further supported by the fact that 99% of all trial participants completed their treatment and monitoring.



The diagram above shows the estimated effect of 34 injections (three injections will be given in the planned Phase III DIAGNODE-3 trial) of Diamyd® compared with a placebo on preservation of endogenous insulin production (measured as C-peptide) and control of 500 blood glucose (measured as HbA1c level) in people with DR3DQ2 (responder group) and individuals who are DR3DQ2 positive, but DR4DQ8 negative (superresponder group). A C-peptide effect of 1,483, for example, can be interpreted to show that C-peptide levels dropped by 48.3% less, on average, over the 15month period in people treated with Diamyd, compared with people given a placebo. An HbA1c effect of 4.79 mmol/mol, for example, can be interpreted as that the change in blood glucose level during the trial period was 4.79 mmol/mol lower in placebo-treated patients than in Diamyd-treated patients. The analysis is based on data from over 600 participants in four placebo-controlled clinical trials. The results show a statistically significant treatment effect on preserved endogenous insulin production and improved blood glucose control, where the best effect is seen in members of the superresponder group who received three or four injections of Diamyd®.

Phase III in the starting block

The global, placebo-controlled Phase III DIAGNODE-3 trial is scheduled to commence at the end of 2021. The precision medicine trial of Diamyd® for type 1 diabetes will take place at around 50 clinics across the world. Extensive preparations have taken place prior to the trial.

"It is highly significant that Diamyd® has now reached Phase III – its the final stage before applying for marketing authorization, which is very exciting but also time-consuming," says Martina Widman, Director of Clinical Development at Diamyd Medical.

All 330 patients in the Phase III trial belong to the genetically defined subpopulation of type 1 diabetes patients that seem to respond best to treatment with Diamyd® (those who carry the HLA DR3-DQ2 genotype).

"This cohort represents about 40% of all type 1 diabetes patients. The clinical results to date show that Diamyd® slows down beta-cell destruction, which improves the patient's own ability to preserve insulin production. At the same time, no serious adverse events have been identified," she says.

Extensive preparation

A huge amount of documentation is required before a Phase III trial can start, including contracts with partners and clinics, manuals for every stage of the trial for the clinics, and applications for approval from the relevant authorities and ethics review boards.

"Since we are a small organization ourselves, we've engaged ICON, a clinical research provider, to help us conduct DIAGNODE3. Every element of every stage must be carefully planned before the trial commences. The preparations are therefore very important. You have to allow enough time to think though the entire process before the trial starts. Any changes after that can be expensive, time-consuming and difficult," she says.

The right team

The right team and the right partners are crucial to a clinical trial, according to Martina. Especially when it comes to selecting the clinics, they have to be dedicated as well as having the right patient base. In DIAGNODE-3, patients must have been diagnosed with type 1 diabetes within the past six months, have the appropriate genetic profile and meet a raft of other criteria.

"Maintaining a focus on the patient perspective and how patients perceive the trial is essential because without them, we wouldn't have a trial. Being diagnosed with diabetes is already overwhelming, so we do our utmost to ensure that the patients don't find it too difficult to participate in our trial."

Via clinics, physicians, social media and a recruitment website, information will be spread to patients recently diagnosed with type 1 diabetes. Patient recruitment will start at the end of 2021 and then continue for about two years. All stages are monitored to ensure they are carried out correctly. When the trial is completed, the database is closed and the results are analyzed using a pre-planned statistical analysis.

"I see a lot of similarities between the start-up of a Phase III trial and how an athlete prepares for a major event. Planning and preparation are the key to a successful outcome. And in our case, a well-conducted clinical trial," says Martina Widman.

Efficiency and control with in-house manufacturing

Alongside of clinical trials, Diamyd Medical has taken several important steps in its focus to become an integrated pharmaceutical company, not least by establishing its own vaccine facility in Umeå. During the year, the manufacturing facility commenced small-scale production of GAD, the active compound in Diamyd®.

In-house production unit

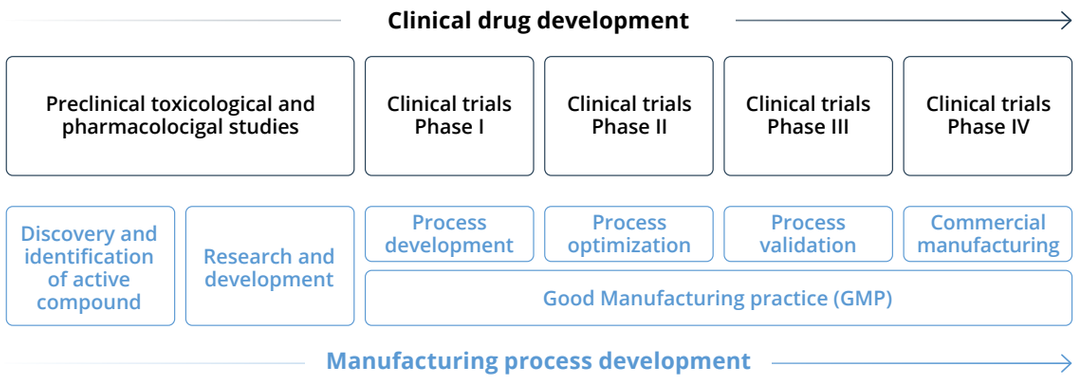
At a time when the COVID-19 pandemic has highlighted the significance of having control over manufacturing processes and supply chains, Diamyd Medical's establishment of an in-house production unit in Umeå is a critical strategic investment. The facility enables full control over supplies of the key asset GAD, the recombinant human protein comprising the active ingredient in the therapeutic Diamyd® precision medicine diabetes vaccine. GAD is one of the most important antigens in type 1 diabetes and the antigen that defines autoimmunity in patients with LADA (the latent form of autoimmune diabetes).

Manufacturing process strategy

GAD manufacturing has been refined over the many years of development conducted jointly with previous contract manufacturers. The accumulation of manufacturing knowledge is a key asset for Diamyd Medical.

By taking over and further developing the process technology from the previous contract manufacturer, the company is taking direct control over the manufacturing process prior to possible future in-house commercial manufacturing and/or a transfer of the technology to a pharmaceutical partner or several contract manufacturers.

The establishment in Umeå is a major step in Diamyd Medical's focus to become a fully integrated pharmaceutical company with the capacity for a commercial launch of Diamyd®.



Drugs undergo a long development process before they are introduced into clinical practice. Prior to submisson for approval and registration, the drug candidate must procees through several development stages. Alongside of the preclinical and clinical development, extensive manufacturing process development is taking place to ensure that a commercially viable manufacturing process is in place when marketing authorization is recieved.

Focus on market and sustainability

In order to achieve efficient and sustainable manufacturing, the facility has been designed to implement artificial intelligence (AI) solutions in the manufacturing process. This is taking place in a VINNOVA-funded project conducted jointly with the sustainability-focused research and technology company MainlyAI and the Royal Institute of Technology (KTH).

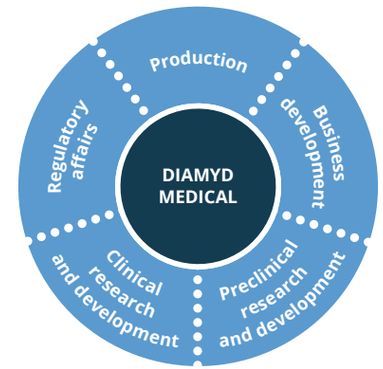
Drug manufacturing is heavily regulated and must be compliant with Current Good Manufacturing Practice (cGMP) regulations. Biologics manufacturing is complex and an important piece of the puzzle in novel drug development. The future cGMP-certified manufacturing process in the facility at Umeå is a key element of Diamyd Medical's regulatory strategy for possible future conditional and fast-tracked marketing authorizations.

The facility's first priority is to produce GAD for commercial use. Small-scale production has already been established and preparations for a commercial scale-up are ongoing. The processes are mainly carried out using equipment from Cytiva, a global provider of technologies and services for the manufacture of therapeutics.

A growing and more integrated company

Diamyd Medical is working to reduce the human suffering and economic burden caused by diabetes by developing novel drugs that target the mechanisms underlying the disease. A growing number of employees who collaborate with a global network of clinics and researchers form the core of the company.

Diamyd Medical's operations comply with regulations and industry standards that naturally integrate several of the most significant sustainability topics. The company is organized according to a model with a number of employees at the core of the company who collaborate with a global network of clinics and researchers. The model is based on long-term partnerships, internal excellence and cost efficiency.



Employee growth in Umeå and Stockholm
Diamyd Medical is a knowledge-intensive company and reliant on attracting and retaining individuals with a high level of expertise and experience. During the financial year, the number of employees increased from 11 to 19. Some of this growth was due to new recruitments at the company's new manufacturing facility in Umeå.

The establishment was possible despite the ongoing pandemic and is an important step in the company's focus to become an integrated pharmaceutical company.

Alongside of establishing the company's facility in Umeå, Diamyd Medical has added further excellence in clinical development and data analysis to its operations at the head office in Stockholm.

Diamyd Medical strives to provide a safe and secure workplace that develops its employees. A positive company culture promotes job satisfaction, good relationships, low sickness absence and low employee turnover.

In Stockholm, the office has been upgraded to even better meet the needs of the operations.

Scientific Advisory Board
Diamyd Medical has access to specialized knowledge in its fields of research through a scientific and medical advisory board comprising some of the world's leading experts in diabetes. The advisory board communicates regularly and discusses results achieved and any future plans for research and development.

The advisory board is a key source of information for the company, and individual members are regularly consulted about any medical or scientific issues arising in the company. In addition, the members serve as ambassadors for Diamyd Medical in contact with academic and company-sponsored researchers. The scientific advisory board is led by Mark Atkinson, a Board member of Diamyd Medical.

"A patient perspective is important in Board work"

Dr. Karin Hehenberger, CEO of the patient engagement platform Lyfebulb, was co-opted to Diamyd Medical's Board during the year. With her impressive resume and personal experience of type 1 diabetes, she will make a significant contribution to the Board's work.

Karin Hehenberger received her MD and PhD in molecular medicine from the Karolinska Institute before moving on to research at Joslin Diabetes Center at Harvard Medical School. It was her own experience that inspired her to choose a career path focused on the prevention of autoimmune diseases. At the age of 16, she was a promising tennis player and a member of the Swedish tennis team, when she was diagnosed with type 1 diabetes. The disease put a stop to her tennis career.

After Harvard, Karin had a successful career in the US with leading medical and financial positions at companies including Eyetech Pharmaceuticals, Coronado BioSciences, Johnson & Johnson and McKinsey. She has also been a senior partner in several large private equity funds for life sciences.

"It feels inspiring now to be working with a well-established company that is trying to cure and prevent type 1 diabetes. As a member of Diamyd Medical's Board, I can use my experience of financing and leading small companies to success in the US market. But most of all, I can contribute a patient perspective, which I think is important in Board work," she says.

Major value for patients

When Karin thinks back on her own teenage years and how difficult it was to control her blood sugar levels, she sees huge potential value in Diamyd® for patients. Clinical results suggest that Diamyd® could delay both the onset of type 1 diabetes in a large subpopulation, and keep blood sugar levels under control when the disease actually develops.

"If the body could maintain some of its endogenous insulin production, that would reduce the severity of the disease and make it easier to control here and now for the patient, with fewer injections and less worry. It would also reduce the risk of long-term complications. That would make such an incredible difference for children and young people living with type 1 diabetes," she says.

Just over a decade ago, Karin was affected by serious complications herself. She was saved by a kidney transplant from her father, and then a pancreas transplant.

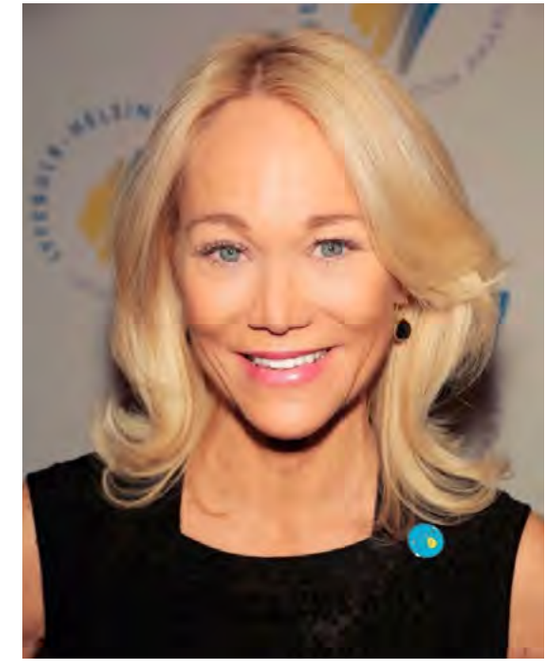
"Everything changed dramatically for me. As a transplant recipient, I have to take immunosuppressive drugs – which obviously affects my life – but after so many decades, I was no longer living with type 1 diabetes. I realized then how much my daily life had been affected by the disease and all the things I had to plan and think about. We love to say how a happy and healthy lifestyle is possible despite diabetes, but you are still very constrained and limited, which lowers your quality of life," she says.

Her own platform

She also realized that patients living with chronic conditions must be seen and able to make their voices heard. To give them a platform, and to encourage the pharmaceutical industry and healthcare to listen to the patient perspective, she founded Lyfebulb, and became the CEO, in early 2015.

"Lyfebulb is a platform for patient engagement that organizes communities for people with various chronic diseases such as type 1 diabetes, MS and chronic kidney disease. But we also work to include patients in the early stages of development for all types of new drugs and products. We also support patient entrepreneurs – those affected by the disease as a patient or a loved one who have good ideas and want to be involved in the development of new products and solutions," she says.

The new Board member's contact with the patient community is invaluable for Diamyd Medical. Patient engagement is crucial for the upcoming Phase III trial to evaluate the safety and efficacy of Diamyd® and for the future



authorization by US and European regulatory authorities.

To clarify the value of Diamyd®, we need to show how difficult it really is to be living with type 1 diabetes and the prevalence of long-term risks for the patients. That's something that I, along with many others patients, can testify to," says Karin Hehenberger.

The 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, 2021, the number of shares in Diamyd Medical was 71,569,796, comprising 69,013,573 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, 2021), the share capital amounted to SEK 7,258,812.

Share performance

The last price paid at August 31, 2021 was SEK 33.70 (39.55), generating a market cap of MSEK 2,326 (2,636) for Diamyd Medical calculated on the number of Class B shares. The highest price paid was SEK 74.70 (49.90). The lowest price paid was SEK 24.60 (6.29). The average share price was SEK 39.08 (19.11).

During the financial year, 117,743,208 (95,276,942) Class B shares were traded on Nasdaq First North Growth Market for a total value of MSEK 4,713 (1,827).

New 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 from SEK 2,400,000 to SEK 71,569,796 and the share capital by SEK 243,414 to SEK 7,258,812. The issue was fully registered with the Swedish Companies Registration Office on May 20, 2021.

Ownership structure

At August 31, 2021, the number of shareholders was 16,247 (12,402). The ten largest owners of Diamyd Medical held shares corresponding to 41.1% of the capital and 55.5% of the votes.

Share performance, 2020/2021

Dividend

The Board proposes that no dividend be paid for the 2020/2021 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.

Data per share

	2020/21	2019/20
Share price, August 31	33.7	39.6
Share performance, %	-6	374
Equity per share, SEK	2.6	1.0
Result per share, SEK	0.9	0.1
Average no. of shares	69,794 454	69,169 796
No. of shares at August 31	71,569 796	69,169 796

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
Total		**7,258,812**	**2,556,223**	**69,013,573**	**7,258,812**

[1)] Offset issues.

[2)] Warrant redemption scheme.

Ownership structure by size of holding at August 31, 2021

Holding	No. of shareholders	Class A shares	Class B shares	Holding (%)	Votes (%)	Market cap (KSEK)
1 – 500	9,667	0	1,451,22	2.03	1.53	48,906
501 – 1,000	2,013	0	1,604,344	2.24	1.70	54,066
1,001 – 5,000	3,063	0	7,321,138	10.23	7.74	246,722
5,001 – 10,000	702	0	5,259,277	7.35	5.56	177,238
10,001 – 15,000	279	0	3,508,022	4.90	3.71	118,220
15,001 – 20,000	144	0	2,583,595	3.61	2.73	87,067
20,001 –	379	2,556,223	47,285,976	69.64	77.03	1,593,537
Total	**16,247**	**2,556,223**	**69,013,573**	**100**	**100**	**2,325,757**

Ownership structure by size of holding at August 31, 2021

Name	Class A shares	Class B shares	Holding (%)	Votes (%)
Försäkringsaktiebolaget, Avanza Pension	0	9,319,631	13.02	9.85
Essen-Möller, Anders	2,556,223	5,313,040	11.00	32.65
Lindkvist, Bertil	0	6,227,800	8.70	6.58
Nordnet Pensionsförsäkring AB	0	2,680,413	3.75	2.83
Swedbank Försäkring AB	0	734,099	1.03	0.78
Konstruktions och Försäljningsaktiebolag	0	725,000	1.01	0.77
Arandi Development AB	0	512,000	0.7	0.54
Schéle, Sven	0	435,000	0.61	0.46
Relbo Aktiebolag	0	475,550	0.66	0.50
Lindberg, Mikael	0	463,632	0.6	0.49
Total, ten largest owners	**2,556,223**	**26,886,165**	**41.14**	**55.46**
Other shareholders	0	42,127,408	58.86	41.76
Total	**2,556,223**	**69,013,573**	**100**	**100**

Source: Euroclear and Diamyd Medical AB

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, 2020-August 31, 2021.

ACTIVITIES

Diamyd Medical develops precision medicine therapies for type 1 diabetes. The diabetes vaccine Diamyd® is an antigen-specific immunotherapy for the preservation of endogenous insulin production. Significant results have been shown in a large genetically predefined patient group in a large-scale meta-analysis as well as in the Company's European Phase IIb trial DIAGNODE-2, where the diabetes vaccine was administered directly into a lymph node in children and young adults with recently diagnosed type 1 diabetes. Preparations for a confirmatory Phase III trial are on-going. A vaccine manufacturing facility is being set up in Umeå for the manufacture of recombinant GAD65, the active ingredient in the therapeutic diabetes vaccine Diamyd®. Diamyd Medical also develops the GABA-based investigational drug Remygen® as a therapy for regeneration of endogenous insulin production and to improve hormonal response to hypoglycaemia. 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. Diamyd Medical's Class B shares are traded on Nasdaq First North Growth Market under the DMYD B ticker. The Company's Certified Adviser is FNCA Sweden AB.

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 for the treatment of autoimmune diabetes (type 1 diabetes). Clinical data demonstrates the potential of the diabetes vaccine Diamyd® to suppress or halt the autoimmune destruction of insulin-producing beta cells. 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 significantly reduce the complications of autoimmune diabetes.

Remygen® is Diamyd Medical's own formulation of GABA, a primary neurotransmitter that is also present in the pancreatic islets of Langerhans. GABA has been shown to affect the release of insulin and glucagon in both healthy volunteers and patients. Preclinical studies have presented strong evidence that GABA stimulates the formation and function of the insulin and glucagon-secreting cells in the pancreas. Preclinical studies have also shown that GABA modulators such as Alprazolam can increase the positive effect of GABA on the insulin-producing cells.

Clinical trials

Intralymphatic immunotherapy with Diamyd®

DIAGNODE-3 is an upcoming Phase III trial scheduled to commence at the end of 2021 and conclude at the end of 2025. The trial will include about 330 people aged 12-28 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 in Europe and the US. 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.

GADinLADA The main aim of the trial is to assess the safety of intralymphatic treatment with Diamyd® in patients with LADA (Latent Autoimmune Diabetes in Adults). The patients have been recruited in Norway at the Norwegian University of Science and Technology (NTNU) in Trondheim, in partnership with St. Olavs Hospital (Trondheim University Hospital) and in Sweden at Center for Diabetes, Akademiskt specialistcentrum, an academic specialist unit operated in partnership with Region Stockholm, the Karolinska Institute and the Karolinska University Hospital. The trial participants are aged 30-70 years, have been diagnosed with LADA within the past 18 months but are not yet on insulin therapy. The sponsor is the Norwegian University of Science and Technology with Ingrid K Hals as the sponsor's representative. Diamyd Medical is contributing the investigational drug, expertise and some financial support for immunological analyses and determination of HLA haplotypes. The plan is to announce the first results from the trial in early 2022.

Investigator-initiated clinical trial with Remygen®

ReGenerate-1 is an open-label investigator-initiated clinical trial in approximately 36 patients aged 18-50 who have had type 1 diabetes for more than five years and have low to non-existing insulin production. The trial is taking place at Uppsala University Hospital with Professor Per-Ola Carlsson as Coordinating Investigator. The trial comprises two studies – an initial safety and dose-escalation study with six patients, and the actual main study comprising a total of 36 patients, who will be followed for up to nine months depending on their dose expansion cohort. The primary goal is to assess the safety of Remygen® as well as the combination of Remygen® and the GABA receptor modulator Alprazolam. The trial will also investigate whether Remygen® alone, or in combination with Alprazolam, can affect the protective mechanisms that prevent low blood sugar levels and restore insulin secretory capacity, which could eventually mean that patients can regain or increase their endogenous insulin production.

In November 2019, a positive safety profile for Remygen® based on the initial safety and dose-escalation study led to the go-ahead for the currently ongoing main study of ReGenerate-1. The entire trial is expected to end in 2022 and interim results will be read out on several occasions beforehand.

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 therapeutic diabetes vaccine Diamyd®. The facility comprises clean rooms, laboratories and office premises, enabling control, predictability and scalability in the manufacturing technology for the active ingredient in the Diamyd® vaccine. Small-scale experimental production of GAD65 was established during the year. Large-scale production will primarily be installed with equipment from Cytiva. In September, Diamyd Medical announced that the company was acquiring the property with the manufacturing facility. The aim of the acquisition was 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 currently leases, and the total site area of 9,000 m². Ownership of the property was transferred on October 31.

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, 2021, Diamyd Medical's share of capital and voting rights in the company was approximately 12.5% measured at cost, or about MSEK 31.0. Diamyd Medical also owns 20% of the shares in the artificial intelligence company MainlyAI AB. At August 31, the carrying amount was MSEK 1.2.

SIGNIFICANT EVENTS DURING THE FINANCIAL YEAR

Diamyd Medical announced topline results from the placebo-controlled Phase IIb DIAGNODE-2 trial, where the diabetes vaccine Diamyd® (GAD-alum) was injected directly into the lymph node of people recently diagnosed with type 1 diabetes. In line with earlier large-scale analysis of trials with subcutaneous injections of Diamyd®, the results for a total of 109 patients showed a statistically significant effect in the defined HLA (Human Leukocyte Antigen) subpopulation of trial participants. Specifically, the trial showed beta cell function preservation 15 months after diagnosis, as measured by mixed-meal stimulated C-peptide response. The primary efficacy parameter, defined as mixed-meal stimulated C-peptide response for the entire trial population, was not achieved. No serious adverse events were reported in the trial. Based on these results, Diamyd Medical will focus on the HLA subpopulation in the upcoming pivotal Phase III program.

Diamyd Medical received funds corresponding to MSEK 148 from Medtronic PLC's acquisition of Companion Medical, Inc.

Diamyd Medical's participation of approximately MSEK 19.3 was fully subscribed in a rights issue in the associate NextCell Pharma AB.

Diamyd Medical, in a partnership with Mainly.AI and KTH, was granted funding by VINNOVA for AI-driven sustainable production. The project will design, test and build a structure for sustainable production using artificial intelligence (AI) for Diamyd Medical's production facility in Umeå.

The first immunological results from DIAGNODE-2 showed that the immune response differs significantly between genetically defined patient subpopulations for several immunological parameters following treatment with the diabetes vaccine Diamyd® (GAD-alum). The results are in line with a previously observed difference in clinical response (announced in September 2020) between people who are positive or negative for the HLA DR3-DQ2 genotype.

Diamyd Medical and the Critical Path Institute entered into a data sharing collaboration to develop advanced drug development data sets for type 1 diabetes. The aim of the collaboration is to significantly improve the scientific community's insight into type 1 diabetes (T1D) through Diamyd Medical's contribution of fully anonymized data from a European Phase III trial to the Trial Outcome Markers Initiative (TOMI-T1D) integrated database.

A large-scale meta-analysis published in August 2020 and based on data from Phase III and Phase II trials in Europe and the US with the Diamyd® diabetes vaccine (GAD/alum), was updated with data from the European Phase IIb DIAGNODE-2 trial announced in September 2020. The meta-analysis thereby included data from 627 individual patients and gave further support for a positive and statistically significant dose-dependent treatment response for preservation of endogenous insulin production in people with type 1 diabetes who carry the HLA DR3-DQ2 haplotype.

Following a review of safety data, an independent Data and Safety Monitoring Board (DSMB) approved a planned continuation of the ReGenerate-1 investigator-initiated clinical trial, where Diamyd Medical's GABA-based investigational

drug Remygen® is given in combination with the GABA receptor modulator drug Alprazolam.

Diamyd Medical invested MSEK 1.2 in MainlyAI AB, generating a 20% ownership stake and a position on the company's Board. The aim of the investment was to facilitate Mainly.AI's strategic focus on AI use, where the first project will address sustainable production in the pharmaceutical sector.

Diamyd Medical announced that the upcoming Phase III trial with Diamyd® in newly diagnosed type 1 diabetes is based on the first precision medicine method in this field. The trial is designed to confirm the safety and efficacy results for Diamyd® in people newly diagnosed with type 1 diabetes who also carry the HLA DR3-DQ2 genotype.

Diamyd Medical chose Cytiva's FlexFactory platform for the production of type 1 diabetes vaccine with a precision medicine focus in Umeå. A directed share issue of new shares totaling MSEK 60 was completed. Investors subscribed for 2,400,000 Class B shares at a per-share price of SEK 25. The offering raised gross proceeds of MSEK 60 for the company.

The Phase II GADinLADA clinical trial, where the Diamyd® diabetes vaccine is injected directly into the lymph node of patients with the autoimmune form of diabetes LADA (Latent Autoimmune Diabetes in Adults), was fully recruited. The plan is to announce the first results from the trial in early 2022.

Diamyd Medical contracted the global contract research company (CRO) ICON PLC for DIAGNODE-3, a placebo-controlled Phase III trial with the Diamyd® diabetes vaccine and a precision medicine focus. The trial is designed to confirm the safety and efficacy results for Diamyd® in people newly diagnosed with type 1 diabetes, and who also carry the genetically defined HLA DR3-DQ2 haplotype.

Karen Hehenberger, MD, PhD, joined the Board as a co-opted member and will be recommended for election to the Board at the next AGM. Dr. Hehenberger has extensive experience of senior medical and financial positions in diabetes and other chronic diseases.

The peer-reviewed medical journal Diabetes Care published the results from DIAGNODE-2, a Phase IIb trial that evaluated intralymphatic administration of Diamyd Medical's lead drug candidate Diamyd® (GAD-alum) in individuals recently diagnosed with type 1 diabetes. The results showed that, in line with a published large-scale meta-analysis of clinical data, while no treatment benefit was seen in the full patient population, three intralymphatic injections of Diamyd® showed a significant and positive effect on the preservation of insulin producing capacity in the predefined subpopulation of people who carry the HLA DR3-DQ2 haplotype. In this subpopulation of patients, more than 50% greater preservation of insulin producing capacity was observed 15 months from baseline in those who received active treatment compared to placebo.

A scientific abstract describing the results from a meta-analysis based on data from more than 600 people with type 1 diabetes who participated in clinical trials with Diamyd® (GAD-alum) was selected for an oral presentation on October 1 at the Annual Meeting of the European Association for the Study of Diabetes (EASD).

A 24-month follow-up of DIAGNODE-2, the Phase IIb clinical trial with Diamyd®, indicated a continued positive treatment effect after 15 months. 50 of the 109 people in DIAGNODE-2 who participated in a follow-up study of the trial were followed for a total of 24 months. The actively treated trial participants who carried HLA DR3-DQ2, a total of 15 people, followed their expected trajectory from 15 to 24 months, thus no decreasing treatment effect compared with the pattern up to 15 months. As also expected, the safety profile at 24 months was good, with no difference in adverse effects between those who were actively treated and those who received a placebo.

The European Patent Office announced that Diamyd Medical's patent application for the prevention and treatment of autoimmune diabetes in people carrying the HLA DR3-DQ2 genotype would be granted. The patent remains valid until 2035 and provides uniform protection in Europe for the treatment or prevention of genetically defined autoimmune diabetes with GAD, which is the active ingredient in the therapeutic Diamyd® diabetes vaccine. The approved patent claims apply to the patient population that has shown a clinical response to treatment with Diamyd®, which is the same patient population for which the Phase III DIAGNODE-3 trial is designed.

As part of its interaction with regulatory authorities, Diamyd Medical performed two new analyses of a large meta-analysis data set comprising 627 people who had participated in four earlier placebo-controlled trials to study the safety and efficacy of the therapeutic Diamyd® diabetes vaccine. Both analyses support the clinical relevance and significance of the positive treatment effects of Diamyd®, which further supports the design of the Phase III DIAGNODE-3 trial.

Small-scale experimental production of the recombinant human GAD65 protein, the active ingredient in the therapeutic Diamyd® diabetes vaccine, was established at the manufacturing facility in Umeå. Large-scale production primarily installed with equipment from Cytiva. The future cGMP-certified manufacturing process in the facility at Umeå is a key element of Diamyd Medical's regulatory strategy for possible future conditional and fast-tracked marketing authorizations.

SIGNIFICANT EVENTS AFTER THE END OF THE FINANCIAL YEAR

A directed share issue of 5,357,143 new Class B shares at a subscription price of SEK 28 was completed. 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. The offering was subscribed by Swedish institutional and qualified retail investors.

Diamyd Medical acquired the property in Umeå where the company is establishing production of the recombinant GAD65 protein, the active ingredient in the therapeutic Diamyd® diabetes vaccine. 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 currently leases, 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 Food

and Drug Administration (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.

A new analysis showing the effect of the Diamyd® diabetes vaccine (GAD-alum) on reducing the time a patient has high blood sugar levels was selected for presentation at the Annual International Society of Pediatric and Adolescent Diabetes (ISPAD) conference on October 13–15, 2021. The analysis is based on data from continuous glucose monitoring (CGM) and was presented by Professor Johnny Ludvigsson, Coordinating Investigator for the DIAGNODE-2 clinical 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.

The clinical results from the dose-escalation study of the investigator-initiated Phase I/II ReGenerate-1 clinical trial that is studying Remygen® (GABA) in people with lifelong type 1 diabetes were published in the peer-reviewed medical journal BMJ Open Diabetes & Care. As previously announced, the patent-pending findings showed that Remygen® improved protective mechanisms in episodes of low blood sugar (hypoglycemia), indicating its potential use as a treatment for the prevention of hypoglycemic episodes.

The FDA requested additional data to support Diamyd Medical's application for the Phase III DIAGNODE-3 trial. Remaining issues, largely related to the production of the investigational drug, must be clarified before the FDA's decision to place DIAGNODE-3 on a clinical hold in the US can be lifted. Considering the delay this may entail, Diamyd Medical will begin to initiate and complete the trial in Europe, while interaction with the FDA continues.

FINANCIAL INFORMATION

Revenues

Revenues amounted to MSEK 0.4 (44.3). The decrease is attributable to a non-recurring payment of approximately MSEK 43 from a previous manufacturer of GAD65 in the preceding year. See also Note 3.

Earnings

Net result for the year amounted to MSEK 60.0 (9.7). The year-on-change was mainly attributable to the non-recurring effect of a gain on divestment of the holding in Companion Medical (MSEK 144.4), the payment of (-43.0) from a previous GAD65 manufacturer in the preceding year, higher research and development costs (-43.1) and higher personnel costs (-7.0).

Financial position

At August 31, 2021, cash and cash equivalents and short-term investments amounted to MSEK 139.4 (68.4). Equity amounted to MSEK 189.3 (72.5).

Result from other shares and participations

At August 31, 2021, Diamyd Medical had an ownership interest of approximately 12.5% in NextCell Pharma AB. The carrying amount of the holding amounted to MSEK 31.0 at the same date. In November 2020, Diamyd Medical increased its holding in the company by investing its pro-rata participation in the company's rights issue, entailing an investment of approximately MSEK 19.3. Diamyd Medical also owns 20% of the shares in the artificial intelligence company MainlyAI AB. At August 31, the carrying amount was MSEK 1.2. Diamyd Medical did not receive any dividends from its holdings during the year.

ORGANIZATION

At August 31, 2021, the company had 19 (11) employees and the average number of employees during the year was 14 (7) people. The increase was mainly attributable to the manufacturing unit in Umeå and expansion of the clinical activities in Stockholm. Personnel costs amounted to MSEK -16.2 (-9.2). 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.

Share-related risk
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 August 1, 2021 and August 31, 2021, the lowest price paid for the company's share was SEK 24.60 and the highest price paid was SEK 74.70. The share price may fluctuate due to the variation in earnings reported quarterly, 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 the Diamyd® diabetes vaccine. 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. During the year, Dr. Karin Hehenberger was co-opted to the Board and will be recommended for election to the Board at the next AGM.

The Board held 18 minuted meetings during the 2020/2021 financial year. The matters addressed included production and other investment-related issues, financing, regulatory issues and the upcoming 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, 2021, the number of shares in Diamyd Medical was 71,569,796, comprising 69,013,573 Class B shares (ten votes 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, 2021), the share capital amounted to SEK 7,258,812.

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 2,400,000 to 71,569,796, and the share capital by SEK 243,414 to SEK 7,258,812. The issue was fully registered with the Swedish Companies Registration Office on May 28, 2021.

OWNERSHIP STRUCTURE

At August 31, 2021, the number of shareholders was 16,247, an increase of 31% during the year. The ten largest owners of Diamyd Medical held shares corresponding to 41.1% of the capital and 55.5% of the votes. Both Class A and Class B shares are freely transferable. The shareholder who holds more than 10% of the voting rights is Anders Essen-Möller, with 32.6% of the votes.

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 139.4. After the end of the financial year, Diamyd Medical raised gross proceeds of MSEK 150 by implementing a directed share issue in September 2021.
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 company's non-restricted equity amounts to the following:

SEK	
Share premium reserve	248,895,155
Retained earnings	-127,141,128
Result for the year	60,045,645
Non-restricted equity	**181,799,672**

The Board proposes that the company's retained earnings of SEK 181,799,672 be carried forward. The company's earnings for the financial year and financial position at August 31, 2021 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 2020/2021 financial year.

Multi-year overview

KSEK	2020/21	2019/20	2018/19	2017/18	2016/17	2015/16	2014/15	2013/14
Net income	253	341	1 568	726	922	757	513	443
R&D costs	-56,860	-13,810	-22,359	-29,118	-12,871	-6,220	-9,686	-5,465
Personnel costs	-16,174	-9,195	-7,891	-7,831	-7,031	-7,671	-7,366	-6,716
Result for the year	60,046	9,709	-36,610	-43,953	-25,555	-32,008	-21,397	-16,034
Cash flow from operating activities	-109,468	16,880	-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	139,376	68,362	56,714	44,112	85,726	31,396	29,727	35,675
Equity ratio, %	94	81	85	78	88	77	85	87
Profit/loss per share, before and after dilution, SEK	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.

Income statement

KSEK	Note	Aug 31, 2021	Aug 31, 2020
OPERATING INCOME			
Net income		253	341
Other operating income		191	784
Other compensation and income	3	-	43,174
TOTAL OPERATING INCOME		**444**	**44,298**
OPERATING EXPENSES			
External research and development costs		-56,860	-13,810
External patent and license costs		-2,501	-4,488
Personnel costs	4	-16,174	-9,195
Other external costs	5,6,7	-9,457	-6,858
Other operating expenses		-551	-59
Amortization/depreciation and impairment of assets	8, 11	-782	-149
TOTAL OPERATING EXPENSES		**-86,324**	**-34,559**
OPERATING RESULT		**-85,880**	**9,739**
Gain on sale of financial asset		144,414	-
Interest income and similar profit items		1,965	500
Interest expense and similar loss items		-453	-530
RESULT AFTER NET FINANCIAL ITEMS		**60,046**	**9,709**
Income tax	10	-	-
RESULT FOR THE YEAR		**60,046**	**9,709**

Balance sheet

KSEK	Note	Aug 31, 2021	Aug 31, 2020
Assets			
Fixed assets			
Intangible assets			
Patents	8	65	205
Tangible assets			
Machinery and inventory	11	5,553	1,970
Financial assets			
Participations in associates	12	32,220	11,743
Other long-term securities	13	–	2,827
Other long-term receivables	14	626	626
TOTAL FIXED ASSETS		**38,464**	**17,370**
CURRENT ASSETS			
Accounts receivable		51	79
Other current receivables		1,594	3,594
Prepaid expenses and accrued income	15	21,953	358
Short-term investments		-	9,995
Cash and cash equivalents		139,376	58,367
TOTAL CURRENT ASSETS		**162,974**	**72,394**
TOTAL ASSETS		**201,438**	**89,764**

KSEK	Note	Aug 31, 2021	Aug 31, 2020
EQUITY AND LIABILITIES			
Equity			
Share capital	16	7,259	7,015
Statutory reserve		200	200
Share premium reserve		248,895	192,414
Retained earnings		-127,141	-136,850
Result for the period		60,046	9,709
TOTAL EQUITY		**189,258**	**72,489**
PROVISIONS			
Pensions and other commitments	17	777	777
Total long-term liabilities		**777**	**777**
CURRENT LIABILITIES			
Trade payables		5,572	7,254
Other current liabilities		1,039	699
Accrued expenses and deferred income	18	4,792	8,544
Total current liabilities		**11,402**	**16,497**
TOTAL EQUITY AND LIABILITIES		**201,438**	**89,764**

Cash flow statement

KSEK	Note	Sep-Aug 2020/21	Sep-Aug 2019/20
OPERATING ACTIVITIES			
Operating result		-85,880	9,739
Interest received		0	31
Interest paid		-71	-26
Non-cash flow items			
Amortization/depreciation		782	149
Other non-cash flow items		362	-
CASH FLOW BEFORE CHANGES IN WORKING CAPITAL		**-84,806**	**9,893**
Increase (-) decrease (+) receivables		-19,566	1,134
Increase (+) decrease (-) liabilities		-5,095	5,853
TOTAL CASH FLOW FROM OPERATING ACTIVITIES		**-109,468**	**16,880**
INVESTING ACTIVITIES			
Investments in machinery and equipment		-4,225	-1,979
Investments in financial assets		-20,477	-3,217
Divestment of financial asset		2,827	-
Gain on sale of financial asset	9	144,414	-
Matured short-term investments		9,995	40,001
Investments in short-term investments		0	-29,984
CASH FLOW FROM INVESTING ACTIVITIES		**132,533**	**4,821**
FINANCING ACTIVITIES			
New issue		60,000	-
Issue expenses		-3,276	-
CASH FLOW FROM FINANCING ACTIVITIES		**56,724**	**-**
CASH FLOW FOR THE PERIOD		79,789	21,701
Total cash and cash equivalents at the beginning of the period		58,367	36,702
Effects of currency translation on cash and cash equivalents		1,221	-35
TOTAL CASH AND CASH EQUIVALENTS AT THE END OF THE PERIOD		**139,376**	**58,367**

Change in equity

KSEK	Share capital	Statutory reserve	Share premium reserve	Other non-restricted equity	Total equity
OPENING BALANCE SEPTEMBER 1, 2019	**7,015**	**200**	**192,414**	**-136,851**	**62,780**
Result for the period	-	-	-	9,709	9,709
CLOSING BALANCE AUGUST 31, 2020	**7,015**	**200**	**192,414**	**-127,140**	**72,489**
OPENING BALANCE SEPTEMBER 1, 2020	**7,015**	**200**	**192,414**	**-127,140**	**72,489**
Result for the period	-	-	-	60,046	60,046
New 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**

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

Revenue recognition
Operating income is mainly derived from sales of recombinant GAD for preclinical research. 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.

Associates
Associates are measured 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.

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.

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.

Financial assets

Participations in associates amount to KSEK 32,220, and consist of shares in NextCell Pharma AB and MainlyAI AB. The holdings were tested for impairment, but there was no indication that the holdings were impaired.

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 Other compensation and income

In the preceding financial year, an amount of MUSD 5 was received from Protein Sciences Corporation. The proceeds pertained to the repayment of an advance invoice of MUSD 0.5 (approximately MSEK 4.8), of which half was recognized as research and development costs and the remainder as prepaid expense. The remaining MUSD 4.5 was received as support for relocation of the manufacturing process. The payment affected operating income by an amount corresponding to MSEK 43.2.

NOTE 4 Personnel costs

Average no. of employees	2020/21	2019/20
Of whom women	9	4
Of whom men	5	3
Total	**14**	**7**

Gender representation on Board	31 aug 2021		31 aug 2020	
	Women	**Men**	**Women**	**Men**
Board	2	4	1	4
Management Team	4	2	3	2
Total	**6**	**6**	**4**	**6**

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	0	47	197
Anders Essen-Möller, Board member [1]	1,026	0	10	1,036
Maria-Teresa Essen-Möller, Board member	100	0	31	131
Torbjörn Bäckström, Board member	100	0	10	110
Mark Atkinson, Board member [2]	205	0	0	205
Karin Hehenberger, co-opted Board member [3]	100	0	0	100
Ulf Hannelius, President and CEO [4]	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**

[1] *Of the amount, 100 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] *The amount refers to consulting fees. See also Note 5.*
[4] *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 2019/2020 KSEK	Salary/fees and other compensation	Pension costs	Social security contributions	Total
Erik Nerpin, Chairman	150	0	47	197
Anders Essen-Möller, Board member	1,026	0	10	1,036
Maria-Teresa Essen-Möller, Board member	100	0	31	131
Torbjörn Bäckström, Board member	100	0	10	110
Mark Atkinson, Board member	100	0	0	100
Ulf Hannelius, President and CEO	1,725	328	542	2,595
Other employees	4,388	688	916	5,992
Total	**7,589**	**1,016**	**1,557**	**10,162**

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 1,040 (748). 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 105 (-) for consulting services. Co-opted Board member Karin Hehenberger received compensation of KSEK 100 for consulting services. The Arm's Length principle was applied to pricing.

KSEK	2020/21	2019/20
Consulting fees and salaries to related parties	1,040	748
Consulting fees to Board members	1,131	926

NOTE 6 Auditor's fees

KSEK	2020/21	2019/20
BDO Mälardalen AB		
Audit assignments	300	170
Total	**300**	**170**

NOTE 7 Leases

KSEK	2020/21	2019/20
Lease payments, incl. rent during the year	1,156	815
FFuture lease payments incl. rent are due for payment as follows:		
Within 1 year	1,542	1,158
Within 2-5 years	3,737	1,191
Total	**5,279**	**2,349**

At August 31, 2021, the company had one rental agreement for office premises in Stockholm with a remaining term of three years, and one rental agreement for office and lab premises in Umeå with a remaining term of 13 years and nine months.

NOTE 8 Patents

KSEK	Aug 31, 2021	Aug 31, 2020
Opening cost	11,076	11,076
Purchases	-	-
Sales/disposals	-	-
Closing accumulated costs	**11,076**	**11,076**
Amortization for the year	139	-140
Closing accumulated amortization	**-11,012**	**-10,872**
Closing carrying amount	**65**	**205**

NOTE 9 Interest income and similar profit items

During the year, the divestment of shares in Companion Medical, Inc generated a gain, including a currency translation effect, corresponding to a total of SEK 144.4.

NOTE 10 Income tax

KSEK	2020/21	2019/20
Current tax		-
Reconciliation of effective tax		
Profit before tax	60,046	9,710
Tax expense 21.4%	-12,850	-2,078
Tax effect of:		
Non-deductible expenses	-8	-10
Non-taxable income	30,905	-
Other unrecognized expenses	-701	-
Loss carryforwards incurred during the year	-17,346	2,088
Loss carryforwards utilized during the year		
Tax expense	**-**	**-**

NOTE 11 Tangible assets

KSEK	Aug 31, 2021	Aug 31, 2020
Opening cost	3,118	1,139
Purchases	4,225	1,979
Sales/disposals	-	-
Closing accumulated costs	**7,343**	**3,118**
Depreciation for the year	-632	-10
Closing accumulated depreciation	**-1,790**	**-1,148**
Closing carrying amount	**5,553**	**1,970**

NOTE 12 Participations in associates

KSEK Company	Corp. Reg. No.	Registered office	Votes, %	Share of capital, %	Aug 31, 2021 Carrying amount	Aug 31, 2020 Carrying amount
NextCell Pharma AB	556965-8361	Huddinge, Region Stockholm	12.5	12.5	31,020	11,743
Information about equity and earnings						
Equity according to most recently adopted financial statements					26,218	22,960
Result according to most recently adopted financial statements					-17,681	-21,451
Diamyd Medical's opening cost					11,743	8,526
Purchases					19,277	3,217
Impairment					-	-
Closing accumulated costs					**31,020**	**11,743**
Closing carrying amount					**31,020**	**11,743**
MainlyAI AB	559258-7538	Stockholm, Region Stockholm	20.0	20.0	1,200	-
Information about equity and earnings						
Equity according to most recently adopted financial statements					2,225	-
Result according to most recently adopted financial statements					0	-
Diamyd Medical's opening cost					-	-
Purchases					1,200	-
Impairment					-	-
Closing accumulated costs					**1,200**	**-**
Closing carrying amount					**1,200**	**-**

NOTE 13 Other long-term securities

KSEK	Aug 31, 2021	Aug 31, 2020
Opening cost	-	2,827
Purchases	-	-
Sales/disposals	-	-
Closing accumulated costs	**-**	**2,827**
Closing carrying amount	**-**	**2,827**

The amount in the preceding year comprised a holding in Companion Medical, Inc., which was recognized at cost. See also Note 9.

NOTE 14 Other long-term receivables

KSEK	Aug 31, 2021	Aug 31, 2020
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 15 Prepaid expenses and accrued income

KSEK	2020/21	2019/20
Prepaid rent	14	10
Prepaid insurance premiums	557	97
Prepaid production costs	21,139	100
Other prepaid expenses	243	146
Other accrued income	-	4
Total	**21,953**	**358**

NOTE 16 Share capital

For a specification of changes in equity, refer to "Change in equity" on page 34. At August 31, 2021, the number of shares in Diamyd Medical comprised 69,013,573 Class B shares (ten votes 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 7,258,812 (7,015,398). The (rounded) quotient value was 0.1014 (0.1014). All shares issued are fully paid.

NOTE 17 Provisions

KSEK	Aug 31, 2021	Aug 31, 2020
Opening cost	777	777
Impairment	-	-
Closing accumulated costs	**777**	**777**
Closing carrying amount	**777**	**777**

At August 31, 2021, the amount comprised an endowment policy.

NOTE 18 Accrued expenses and deferred income

KSEK	2020/21	2019/20
Accrued vacation pay	1,612	957
Accrued social security contributions	506	301
Accrued interest expense	1	0
Accrued research costs	1,696	6,631
Other accrued expenses	977	656
Total	**4,792**	**8,544**

NOTE 19 Pledged assets

KSEK	2020/21	2019/20
Pledged assets	239	239
Total	**239**	**239**

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

NOTE 20 Significant events after the end of the financial year

- Diamyd Medical completed a directed share issue that raised gross proceeds of MSEK 150.
- An agreement was concluded to acquire the property in Umeå where the company is establishing GAD65 production.
- Start-up of the Phase III DIAGNODE-3 trial was placed on clinical hold by the FDA pending a clarification of some outstanding issues related to the investigational drug.
- The Swedish Medical Products Agency approved the start-up of DIAGNODE-3.
- A new analysis showing the effect of the Diamyd® diabetes vaccine was selected for presentation at the ISPAD conference on October 13-15, 2021.
- VINNOVA granted funding of MSEK 40 to Diamyd Medical and partners for a precision health project focused on the prevention of autoimmune diseases.
- The clinical results from the dose-escalation study of the Phase I/II ReGenerate-1 clinical trial were published in the peer-reviewed medical journal BMJ Open Diabetes & Care.
- The FDA requested additional data to support Diamyd Medical's application for the Phase III DIAGNODE-3 trial. Considering the delay this may entail, Diamyd Medical will begin to initiate and complete the trial in Europe, while interaction with the FDA continues.

NOTE 21 Appropriation of profit

The following profits are at the disposal of the AGM

SEK	
Share premium reserve	248,895,155
Retained earnings	-127,141,128
Profit for the year	60,045,645
	181,799,672

The Board and CEO propose that the following profits be carried forward SEK 181,799,672

Signatures of the Board of Directors and Chief Executive

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 company's operations, financial position and earnings and describes the material risks and uncertainties faced by the company. The company's income statements and balance sheets will be submitted to the Annual General Meeting on December 2, 2021 for adoption.

Stockholm, November 10, 2021

Erik Nerpin
Chairman

Torbjörn Bäckström
Board Member

Anders Essen-Möller
Board Member

Mark A. Atkinson
Board Member

Maria-Teresa Essen-Möller
Board Member

Karin Hehenberger
Co-opted Board Member

Ulf Hannelius
Chief Executive Officer

Our Auditor's Report was
submitted on November 10, 2021.
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

Opinions

We have audited the annual accounts of Diamyd Medical Aktiebolag for the financial year of September 1, 2020-August 31, 2021. The annual accounts of the company are included on pages 23-39 of this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of Diamyd Medical Aktiebolag as of August 31, 2021 and its 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.

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

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 Diamyd Medical Aktiebolag 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 and the Managing Director are responsible for the preparation of the annual 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 that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts, the Board of Directors and the Managing Director are responsible for the assessment of the company'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 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.

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, 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. 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 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 or, if such disclosures are inadequate, to modify our opinion about the annual 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 to cease to continue as a going concern.

- evaluate the overall presentation, structure and content of the annual accounts, including the disclosures, and whether the annual accounts represent the underlying transactions and events in a manner that achieves fair presentation.

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, we have also audited the administration of the Board of Directors and the Managing Director of Diamyd Medical Aktiebolag for the financial year of September 1, 2020-August 31, 2021 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 Diamyd Medical Aktiebolag 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 type of operations, size and risks place on the size of the company'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 financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

Auditor's responsibility

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

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

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

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

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

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

Stockholm, November 10, 2021
BDO Mälardalen AB

Johan Pharmanson
Authorized Public Accountant

Board of Directors

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 of Diamyd Medical 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, 2021: 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 principal 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, 2021: 2,556,223 Class A shares and 5,331,040 Class B shares. Holding in endowment policy: 1,545,000 Class B shares.

Maria-Teresa Essen-Möller
Board member
Born in 1970

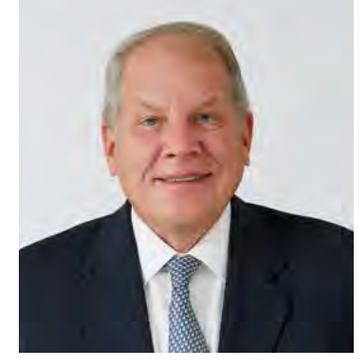
M.Sc. in Business Administration. Chief Commercial Officer at ScientificMed AB. Independent of the company, but not independent of its principal owner. Previous experience include CEO of Health Solutions AB, Digital Marketing Manager at Sanofi. Board member of Diamyd Medical since 2009.

Holding in Diamyd Medical at August 31, 2021: 463,998 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 April 2017. Head of Neurosteroid Research Centre in Umeå and Senior Professor at the Department of Clinical Science, Obstetrics and Gynecology at Umeå University.

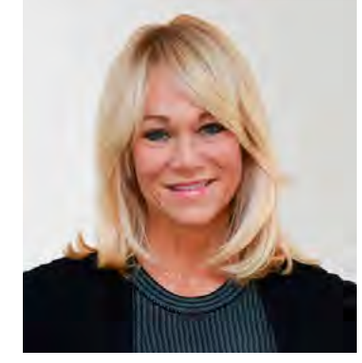
Holding in Diamyd Medical at August 31, 2021: 1,000 Class B shares via company.



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 November 2018.

Holding in Diamyd Medical at August 31, 2021: 16,750 Class B shares.



Karin Hehenberger
Co-opted Board member
Born in 1972

M.D., PhD, Karolinska Institute, post-doc at Joslin Diabetes Center, Harvard Medical School. Founder and CEO of Lyfebulb, Board member of 3B Future Health Ventures 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. Independent of the company and its principal owner. Co-opted Board member since April 2021.

Holding in Diamyd Medical at August 31, 2021: 10,000 Class B shares.

Management

Ulf Hannelius
CEO
Born in 1975

PhD in Molecular Biology from the Karolinska Institute in Stockholm and MBA from the Stockholm School of Economics. Prior experience from business development in the biotech and medtech industries, and from academic research in the fields of genetics and molecular biology. Ulf Hannelius joined Diamyd Medical in 2015, and has been CEO since 2016.

Holding in Diamyd Medical at August 31, 2021: 155,000 Class B shares.

Anna Styrud
Chief Financial Officer
Born in 1961

M.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. Anna Styrud joined Diamyd Medical in 2010.

Holding in Diamyd Medical at August 31, 2021: 105,000 Class B shares.

Martina Widman
Director Clinical Development
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, 2021: 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 Institute. Prior experience in managing technical development at several bio-tech companies. Anton Lindqvist joined Diamyd Medical in 2013.

Holding in Diamyd Medical at August 31, 2021: -

Maja Johansson
Site Manager, Umeå
Born in 1962

PhD in Biochemistry from Umeå University and Associate Professor in Neuroendocrinology. Prior experience from working in bio-tech companies. Maja Johansson joined Diamyd Medical in May 2020.

Holding in Diamyd Medical at August 31, 2021: -

Eva Karlström
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, 2021: -

Auditors
The Company's auditors are BDO Mälardalen AB, domiciled at Box 24193, 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 diabetes vaccine.
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 immune cells. 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 2 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 24, 2021, and are requested to notify Diamyd Medical of their intention to attend the meeting by November 26, 2021. 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 re-registration should be made to the bank or fund manager that manages the shares in good time before November 26, 2021. Shareholders may exercise their rights at the AGM by proxy. A power of attorney for a legal entity must be signed by an authorized signatory, and a copy of a current certificate of registration, stating the authorized signatory, must be attached.

VOTING IN ADVANCE
Shareholders may exercise their right to vote at the AGM by casting votes in advance (postal voting) as prescribed in Section 3 of the Swedish Act (2020:198) on Temporary Exceptions to Facilitate the Execution of General Meetings in Companies and Other Associations. The company urges shareholders to make use of this opportunity to reduce the number of people in physical attendance at the AGM and thereby mitigate the spread of COVID-19. A special form is used for advance voting. The form will be available on www.diamyd.com no later than two weeks prior to the AGM. Shareholders who exercise their right to vote by casting votes in advance are not required to give notice of their attendance at the AGM. The form for advance voting also applies as notification of attendance. The company must receive the completed form by Friday, November 26, 2021. Send the completed form to the address set out under 'Participation' above. Completed forms may also be submitted via e-mail to investor.relations@diamyd.com Corporate shareholders (legal entity) must attach a certificate of incorporation to the form. The same applies to shareholders who cast votes in advance via proxy. Shareholders may not include any special instructions or conditions on the form for advance voting. If so, the vote will be declared invalid. Further instructions and conditions are set out in the form for advance voting.

NOTICE OF ATTENDANCE
Notice of attendance can be made via the website www.diamyd.com, by mail to Diamyd Medical AB, Box 7349, 103 90 Stockholm, Sweden or by e-mail to investor.relations@diamyd.com The notice must include the shareholder's name, address, phone number, social security/corporate registration number and the name of any attending advisors.

DISTRIBUTION POLICY
The Annual Report is available in PDF format from www.diamyd.com. A printed copy of the Annual Report can also be mailed upon request. Requests for printed copies 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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FINANCIAL CALENDAR

Quaterly Report (Sep-Nov)	January 26, 2022
Quaterly Report (Sep-Feb)	Mars 30, 2022
Quaterly Report (Sep-May)	June 22, 2022
Year-end Report (Sep-Aug)	October 5, 2022

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