

A composite image serving as the background for the cover. The left side shows a female scientist in a white lab coat and blue gloves, looking up and holding a small white card or chip. The right side features a detailed anatomical illustration of a kidney with various internal structures and blood vessels.

ANNUAL REPORT

2021

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# The year in brief

## Significant events in 2021

- Idogen appointed highly reputable scientific advisors in transplantation: Bo-Göran Ericzon, professor of Transplant Surgery at Karolinska Institutet and Jan Holgersson, professor of Transplant Immunology at the University of Gothenburg.
- Additional payment of MSEK 3 from the EU Commission for the company's IDO 8 project as part of the Horizon 2020.
- The European Patent Office (EPO) granted a patent to protect the company's tolerogenic cell therapy in Europe.
- Idogen generated proceeds of MSEK 9.9 before issue costs, in October, where shares were subscribed with the support of subscription warrants (T04).
- Together with its partner, Radboud University Medical Center (RUMC), Idogen successfully concluded optimization and qualification of the GMP manufacturing process ahead of the first clinical trial application for its tolerogenic cell therapy, IDO 8.
- Idogen submitted an application to the Swedish Medical Products Agency (MPA) to initiate a clinical Phase 1/2a study to obtain safety data and signals of clinical effects among hemophilia patients with antibodies to their treatment with Factor VIII.
- Idogen's Board of Directors proposed a 100% guaranteed rights issue that would generate MSEK 50.4 for the company before costs.

## Significant events after year-end

- Idogen also submitted a clinical trial application for IDO 8 to NoMA, the Norwegian Medicines Agency.
- A rights issue was approved at an Extraordinary General Shareholder Meeting on January 20. The rights issue was conducted in February and subscribed at 100%, generating MSEK 50.4 gross for the company.
- Idogen's Chief Scientific Officer, Åsa Schiött, presented the company's tolerogenic cell therapy platform at the 5th Antigen-Specific Immune Tolerance Summit on January 27.
- On March 18, Idogen receives approval from the Swedish Medical Products Agency to start its clinical phase 1/2a study for IDO 8, a completely new type of cell therapy for patients with severe hemophilia A who has developed antibodies against their vital coagulation factor VIII treatment.



# CEO comment

After an intense year of preparation, we are now about to enter the clinical phase with our most advanced cell therapy treatment IDO 8. The drug candidate aims to treat patients with hemophilia A who have developed antibodies against the standard treatment with coagulation factor VIII, so that they again can tolerate their vital treatment.

**H**emophilia – more specifically, hemophilia A – is an hereditary illness in which the patient suffers from a lack of coagulation factor VIII, which means that the ability of the blood to coagulate is impaired. A simple injury could give rise to severe bleeding that is difficult to stop. The current standard treatment consists of administering coagulation factor VIII to patients; however, one third of these patients develop neutralizing antibodies against the treatment, rendering it ineffective. Idogen develops cell therapies that are targeted at preventing the body's immune response from attacking biological drugs of this type, but such therapies could also prevent the body's immune system from attacking transplanted organs or the body's own cells and tissues. Our ambition is to revolutionize treatment in several diseases and conditions in which the immune system is erroneously activated.

## Optimized manufacture in place

In 2021, we successfully finished optimizing the manufacturing process that will be used in the first clinical trial of IDO 8. Through the optimization process, our Dutch partner Radboud University Medical Center (RUMC), maximized the antigen levels loaded in our cell therapy. These are the antigens which we aim to will induce tolerance to – a key characteristic of the product for achieving a robust treatment effect. This means that we have now an established process for the manufacture of our cell therapy, which can support our clinical trials.

The cell therapy will be customized for each individual patient in RUMC's GMP-certified facility. The treatment uses the patient's own cells (monocytes), which are subsequently developed into tolerogenic dendritic cells using our unique tolerance inducer in combination with the specific antigen, which the body's immune response is expected to learn to tolerate. For the IDO 8 study, that antigen will be factor VIII. In March 2022, we received approval from the Swedish Medical



Products Agency to start our clinical phase 1/2a study with IDO 8 to evaluate safety but also to measure any signals of treatment effect in patients. At the same time we are also awaiting information from the Norwegian Medicines Agency, where we submitted an application in January to be able to recruit patients for the study also in Norway. The plan is to start the study and start patient recruitment during the second quarter this year. We also intend to submit applications to additional European countries where we have established that it will be feasible for the trial to be conducted.

## Patent protection has been further strengthened

The value of IDO 8 was further boosted at the beginning of 2021, when the European Patents Office approved a patent that will protect the use of the product until 2036. A corresponding patent application is currently being processed

*2021 was truly a year of successful deliverables – we checked off several important milestones in developing IDO 8*

in the US. Moreover, we have filed a broad international patent application (PCT) with the potential to protect our entire innovative technology platform for tolerogenic cell therapies. In addition to the platform technology itself, this patent application also covers the manufacturing process and the use of the cell therapy in a number of different indications, which could be valid through to 2040 provided that it is approved. With a strong patent portfolio, we have a solid ground for future business negotiations with commercial partners.

## Expanded points of contact with outstanding hematologists and cell therapy experts

In conjunction with our preparations for the clinical trial, we have worked on expanding our network among leading hematologists and increasing awareness of our technology in order to put IDO 8 on the map. In January 2022, Idogen was invited to present its technology platform for tolerogenic cell therapy at the 5th Antigen-Specific Immune Tolerance Summit, where leading researchers in the field took part: from US universities to representatives of major pharmaceutical companies and innovative biotech companies. The presentation provided us with an excellent opportunity to speak about our scientific progress as well as being able

to appreciate the level of interest that exists in creating antigen-specific tolerance in the treatment of several serious conditions and illnesses. The company plans to participate in further scientific conferences over the coming year.

## Strengthened capital base

This year, we began strengthening our cash and bank balances ahead of the start of our clinical trial with IDO 8 and the continued preclinical development of IDO T, which is being developed to reduce the risk of tissue rejection after transplants. The fully guaranteed rights issue closed in mid-February and initially generated a capital contribution of MSEK 50.4 before costs, with the possibility of an additional contribution of MSEK 42.0 in September when the associated subscription warrants can be exercised. Through this round of investments, it is pleasing to be able to welcome new investors and to confirm that our existing owners remain confident in our development of tolerogenic cell therapies.

## Increased focus on IDO T

The progress in the IDO 8 project has also strengthened our scientific conviction that tolerogenic dendritic cells can be used as a platform technology to produce several treatments for many serious conditions and illnesses. Once IDO 8 goes to the clinic, we will be able to focus more specifically on the preclinical development of IDO T, which has the potential to become a tolerance-inducing treatment, aiming to prevent the immune system from attacking transplanted organs and thus rejecting them. The plan for IDO T is to use our platform technology for designing tolerance inducers, establishing preclinical proof-of-concept for the treatment and subsequently submitting an application for a first in man clinical trial in 2023.

Moreover, the clinical trial with IDO 8 will provide crucial safety information that can be leveraged for the IDO T development program.

2021 was truly a year of successful deliverables – we checked off several important milestones in developing IDO 8 and preparing it for clinical trials. In parallel, we have made advances with IDO T and we are looking forward to making the same journey with our transplantation program.

**Anders Karlsson** | Chief Executive Officer

# Idogen in brief

Idogen is a Swedish biotechnology company based in Lund. Idogen develops tolerogenic cell therapies to counteract attacks by the patient's immune system on biological agents, transplanted organs or the body's own cells or tissue. The term 'tolerogenic' refers to the immune system's selective tolerance of a specific pathogenic or immuno-stimulatory antigen following treatment with Idogen's cell therapy. Idogen's most advanced product candidate, IDO 8, is designed for patients with severe hemophilia A who have developed neutralizing antibodies against their life-saving therapy with coagulation factor VIII (FVIII). The company is also developing IDO T – a tolerogenic cell therapy to prevent transplanted organ rejection, initially in kidney transplantation with a living donor. IDO T is expected to improve transplant survival and reduce the need for immunosuppressive drugs, which will reduce the risk of cancer and infections. A third therapeutic area that Idogen regards as especially interesting is IDO AID, for the treatment of various types of severe and unusual autoimmune diseases.

## Vision

Idogen's vision is to revolutionize the treatment of a range of diseases and conditions in the event of unwanted activation of the body's immune system. The company has identified a major medical need for treatment in the case of autoimmune diseases, organ rejection and in patients

who have developed anti-biologic antibodies against, for example, factor VIII or therapeutic antibodies. Idogen's ambition is to launch the first tolerogenic cell therapy with long-lasting effects for the treatment of patients with major unmet medical needs.

## Business concept and objectives

Idogen intends to continue developing the company's first two programs into clinical proof-of-concept. Various types of partnerships or commercial agreements will be a crucial part of the further clinical development towards market approval and commercial products. With regard to autoimmune diseases, the company is more open to various types of partnerships.

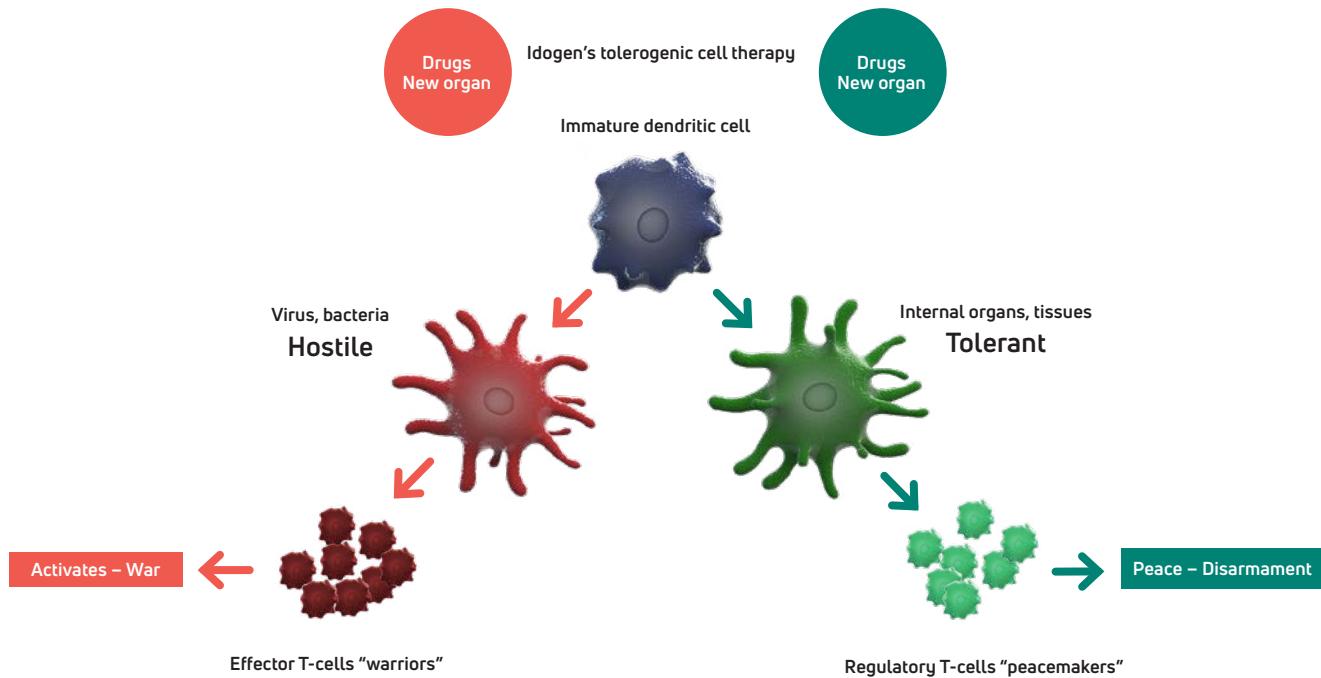


# Tolerogenic cell therapy – individualized treatment for each patient

## When the immune system has become your enemy

There are many situations where the body's immune system can cause damage instead of protecting us. One example is when it causes transplant rejection. Another is when the immune system neutralizes the

activity of biological drugs, for example, in the treatment of hemophilia with factor VIII. Yet another situation is in the case of various autoimmune diseases such as rheumatoid arthritis, inflammatory bowel diseases, type 1 diabetes and multiple sclerosis (MS), where the immune system attacks the body's own proteins or antigens.



*Dendritic cells control other immune system cells' recognition of, and reaction to, what belongs in the body and what is foreign. The dendritic cells that recognise bacteria or viruses activate our immune system (red) and those that recognize the body's own cells stop the body from attacking its own tissues and induce tolerance (green). The goal of Idogen's cell therapy is to teach the immune system so as to counteract undesirable activation while leaving the rest of the immune system unaffected.*





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**Idogen's technology is a platform that could be adapted to various medical conditions by making minor changes.**

## Idogen's technology

**T**he ability to produce new treatments that maintain a properly functioning immune system, meaning one that protects and defends the body from invasion by foreign organisms – such as viruses, bacteria and tumors – would revolutionize life for patients with severe chronic illnesses. Idogen wants to be part of this revolution by developing new cell therapies – a type of treatment that differs from conventional medical therapies. Instead of administering a chemical substance to the body, the patient is treated with their own cells, which first obtain their unique tolerogenic profile outside the body before being returned to the patient.

Idogen's treatment is based on dendritic cells – a type of white blood cell – that plays a central role in the immune system because they control other immune system cells' recognition of what belongs in the body (self) and what is foreign (non-self). When we are exposed to bacteria or viruses, the dendritic cells trigger our immune response.

At the same time, they ensure that the immune system does not attack our own body. The dendritic cells that prevent the immune system from attacking the body's own, healthy cells are called tolerogenic. The aim of Idogen's technology is to develop tolerogenic dendritic cells that are programmed to tolerate the immune system to defined molecules or antigens.

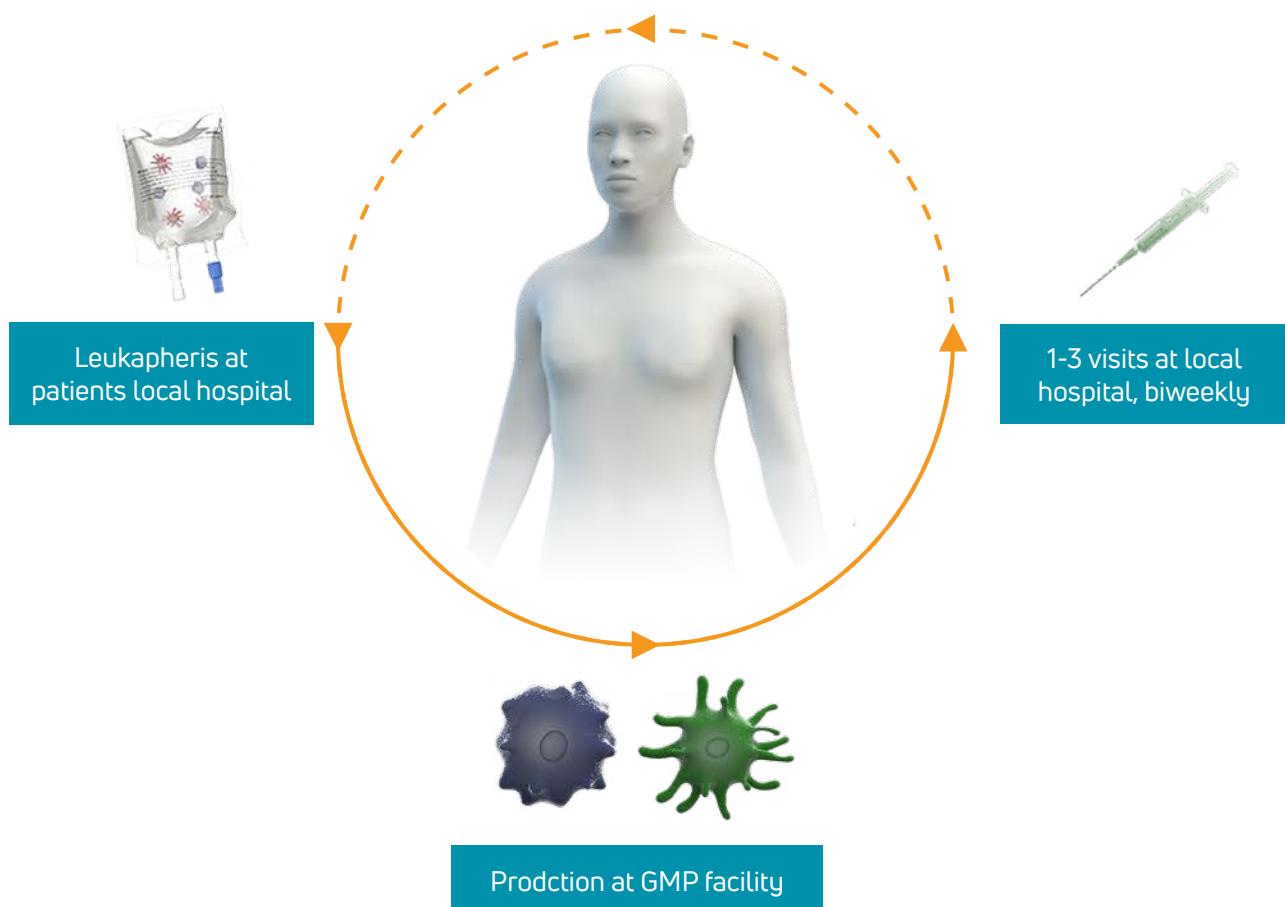
The technology in Idogen's therapy entails treating cells from the patient's blood outside the body and developing them into tolerogenic dendritic cells in a unique and – in the company's opinion – patentable manner. These tolerogenic dendritic cells are then returned to the patient. In the body, tolerogenic dendritic cells have the capacity to specifically counteract harmful immune responses and induce tolerance. This means the undesirable activation of the immune system is prevented while the immune system in general is not affected, which maintains defenses against such threats as viruses, bacteria and cancer.

In June 2019, the company announced that a new and more effective tolerance inducer had been developed. This newly developed method is a combination of different substances that by themselves have a limited effect, but when they are combined yield a synergistically powerful effect. Efforts to document this unique combination of compounds subsequently continued until a priority patent application could be filed on December 13, 2019. The patent application covers Idogen's entire technology platform for tolerogenic cell therapy. The patent application is a first step towards global protection. One year later, on December 10, 2020, the final international application (PCT) was filed. If granted, the patent will provide market exclusivity until 2040.

The company has chosen to manufacture its cell therapy in collaboration with an external party for clinical trials with its product candidate IDO 8 in hemophilia patients. Since November 2019, the manufacturing process has been developed in partnership with Radboud University Medical

Center (RUMC) in Nijmegen, the Netherlands. RUMC is an internationally renowned center with a great deal of know-how concerning dendritic cells and is therefore particularly suited to scaling up production for Idogen's cell therapy. In the autumn of 2021, RUMC successfully optimized the manufacturing process and scaled up IDO 8 production, and Idogen is thus ready to commence manufacturing the study material for the impending Phase 1/2a trial.

The initial trial in human subjects will be conducted in hemophilia A patients who have developed neutralizing antibodies against their life-saving treatment with FVIII. In December 2021, Idogen submitted an application to receive carry out a phase 1/2a study with IDO 8 to the Swedish Medical Products Agency. The company announced on March 18 this year the approval of the application. The corresponding application for the Norwegian Medical Products Agency, NoMA, was submitted January 3 this year.



*Idogen's therapy entails treating cells from the patient's blood outside the body for development into tolerogenic dendritic cells. These programmed dendritic cells are then returned to the patient as a cell therapy in order to specifically counteract a harmful immune response and induce tolerance, without affecting the normal functions of the immune system.*

# Manufacture of drugs for clinical testing

Idogen signed a license agreement in November 2019 with RUMC in the Netherlands. Since then, RUMC has successfully upgraded the manufacture of Idogen's tolerogenic cell therapy in compliance with Good Manufacturing Practice (GMP). Professor Jolanda de Vries and her colleagues at RUMC are global leaders in the field and have more than 20 years of experience in conducting research and working practically with manufacturing cell therapy based on dendritic cells, mainly in oncology.

Their extensive knowledge of taking a dendritic cell-based therapy to the patient constitutes an important complement to the internal expertise built up at Idogen. In the second half of 2021, Idogen optimized the manufacturing process for its initial product candidate, IDO 8, in partnership with RUMC for the purpose of achieving the best therapy results possible in the clinical study. Patient recruitment in the study will begin during the second quarter of 2022.

The company is also a partner in a Vinnova-financed project, the CAMP cell and gene therapy initiative, which has been awarded total funding of MSEK 48 over a period of six years to establish Sweden as a leader in biological agents. Idogen participates in CAMP together with such companies as AstraZeneca, Novartis, Celgene/BMS, Gilead/Kite, Roche and Pfizer as well as all of Sweden's universities, health care regions and research institutions.



In the second half of 2021, Idogen optimized the manufacturing process for its initial product candidate, IDO 8, in partnership with RUMC for the purpose of achieving the best therapy results possible



IDO 8 is Idogen's most advanced project, with the objective of developing a tolerogenic cell therapy for patients with severe hemophilia A who have developed neutralizing antibodies against their ongoing treatment.

# ido 8

## IDO 8 – When the body's immune system attacks factor VIII, a critical medicine

IDO 8 is Idogen's most advanced development program, with the objective of developing a tolerogenic cell therapy for patients with severe hemophilia A who have developed neutralizing antibodies against their ongoing treatment. Hemophilia A is caused by a hereditary lack of coagulation factor VIII, and the standard treatment for patients with a severe form of hemophilia is to treat them with drugs that consist of the missing coagulation factor. Approximately 30% of the patients treated with factor VIII, however, develop neutralizing antibodies, or inhibitors, which inhibit the effect of the coagulation factor and render the treatment ineffective. This complication can often be managed by intensifying factor VIII treatment to induce tolerance, which means frequent injections of a high dose of factor VIII. This is the recommended treatment today under guidelines from the World Hemophilia Federation (WHF) and can last anywhere from six months up to three years. Unfortunately, these antibodies remain in approximately one third of patients, which leaves them without an alternative for a therapy that could prevent bleeding. Idogen's initial development

program, IDO 8, is aimed at meeting the need among these patients. The goal of IDO 8 is to treat these patients with tolerogenic cell therapy, thereby inducing long-term tolerance for FVIII and thus recovering the desired effect of the life-saving treatment with factor VIII.

Hemophilia A is a rare disease and Idogen has been granted European orphan drug designation for the treatment – a key step for the company since orphan drug designation provides several regulatory advantages such as less extensive requirements for clinical trials, scientific guidance from the regulator during development and ten-year market exclusivity in Europe after launch. Idogen also intends to apply for orphan drug designation for hemophilia A in the US and Japan as well. In the US, orphan drug designation would entail seven years of market exclusivity after launch. The company is working to be ready to recruit the first patient in the Phase 1/2a clinical trial in the second quarter of 2022.



*In 2021, Idogen's research team prepared thoroughly ahead of the clinical trial for IDO 8. The focus has been on finalizing the preclinical documentation ahead of the Phase I/IIa trial, planned to begin in the second quarter of 2022.*

# ido T

### IDO T – When the body's immune system attacks a transplanted organ

**I**dogen intends to use the same method that has now been developed for the treatment of hemophilia in other therapeutic areas with only minor adjustments to the production process. Therefore, the company is now also developing IDO T, a product candidate for transplantation. The treatment could work for several types of organs, and the company intends to focus initially on kidney transplantation. The basic principle is to "teach" the immune system to recognize and tolerate the transplanted organ so that it is not rejected in conjunction with the transplantation. This could eventually increase the lifespan of the transplanted organ and reduce or eliminate entirely the need for treatment, often lifelong, with immunosuppressive drugs that do not selectively suppress the immune system. A successful product would be expected to decrease the side effects that result from the immunosuppressive treatment itself such as cancer and severe infections.

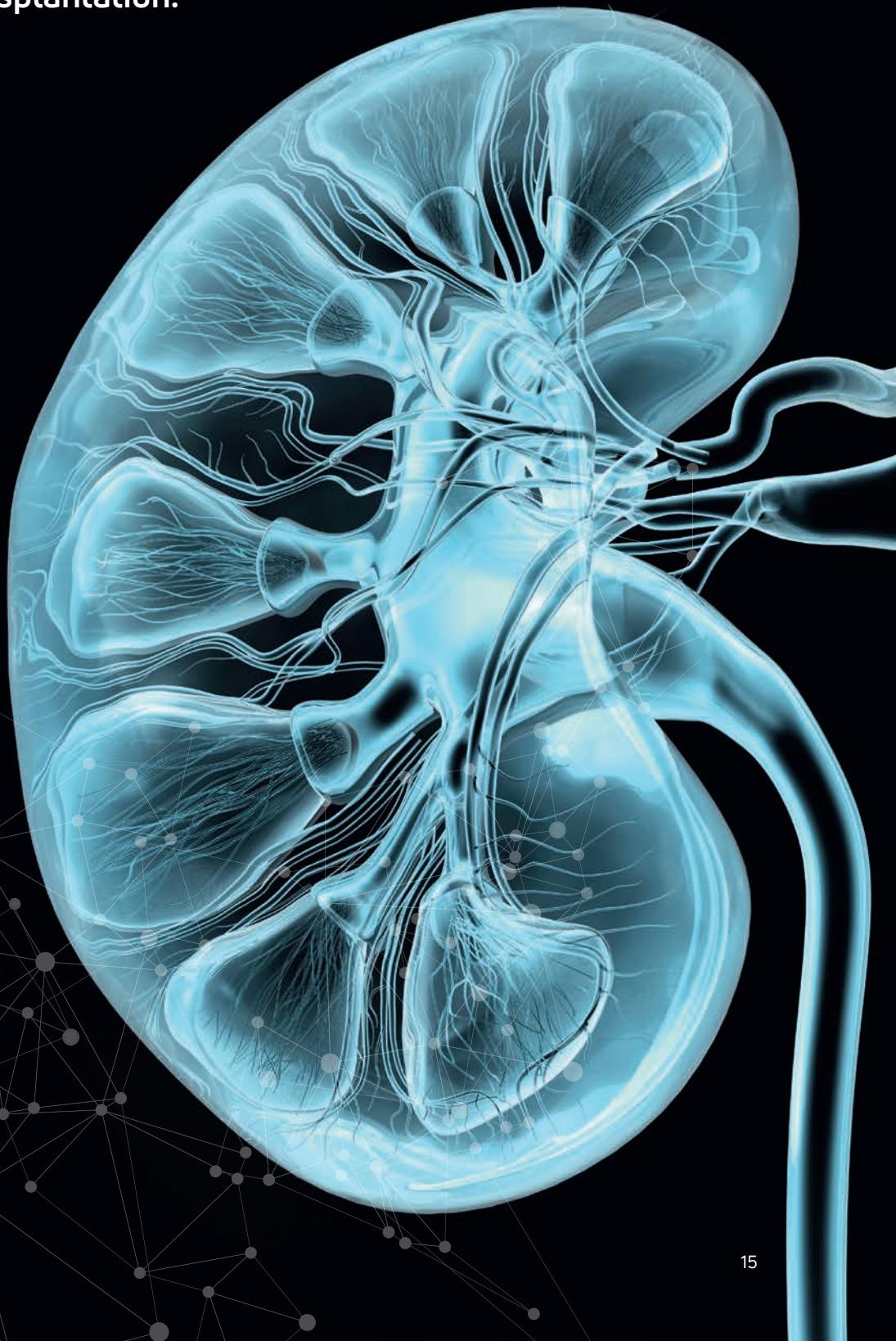
The company is of the opinion that there is a great need

for a long-acting, efficient and safe treatment that induces tolerance for the transplanted organ in order to avoid the risk of organ rejection. Initially, Idogen intends to target patients about to undergo kidney transplantation with organs from living donors. With a living donor, there is often the possibility of planning the transplant well in advance and therefore also being able to plan for the production of the prophylactic treatment using Idogen's cell therapy. The cells from the organ donor are added to the patient's own cells together with Idogen's proprietary tolerance inducer in conjunction with the transplantation being performed. This means that the tolerogenic cell therapy that facilitates tolerance for the transplanted kidney can be built up in the patient in parallel with the transplantation. The development work for IDO T is pursued with the aim to submit an application for a clinical phase 1/2a study before the end of 2023.



*In January 2020, the Crown Princess Couple were able to see in real time how Idogen's researchers develop our tolerogenic cell therapy.*

**Idogen is now also developing  
IDO T, a product candidate  
for kidney transplantation.**



# ido AID

## IDO AID – When the body's immune system attacks the body's own cells and tissues

Idogen has also planned a third therapeutic area focused on severe and rare autoimmune diseases, IDO AID. Idogen has identified a group of autoimmune diseases where there is a major unmet medical need and a treatment could be granted orphan drug designation.

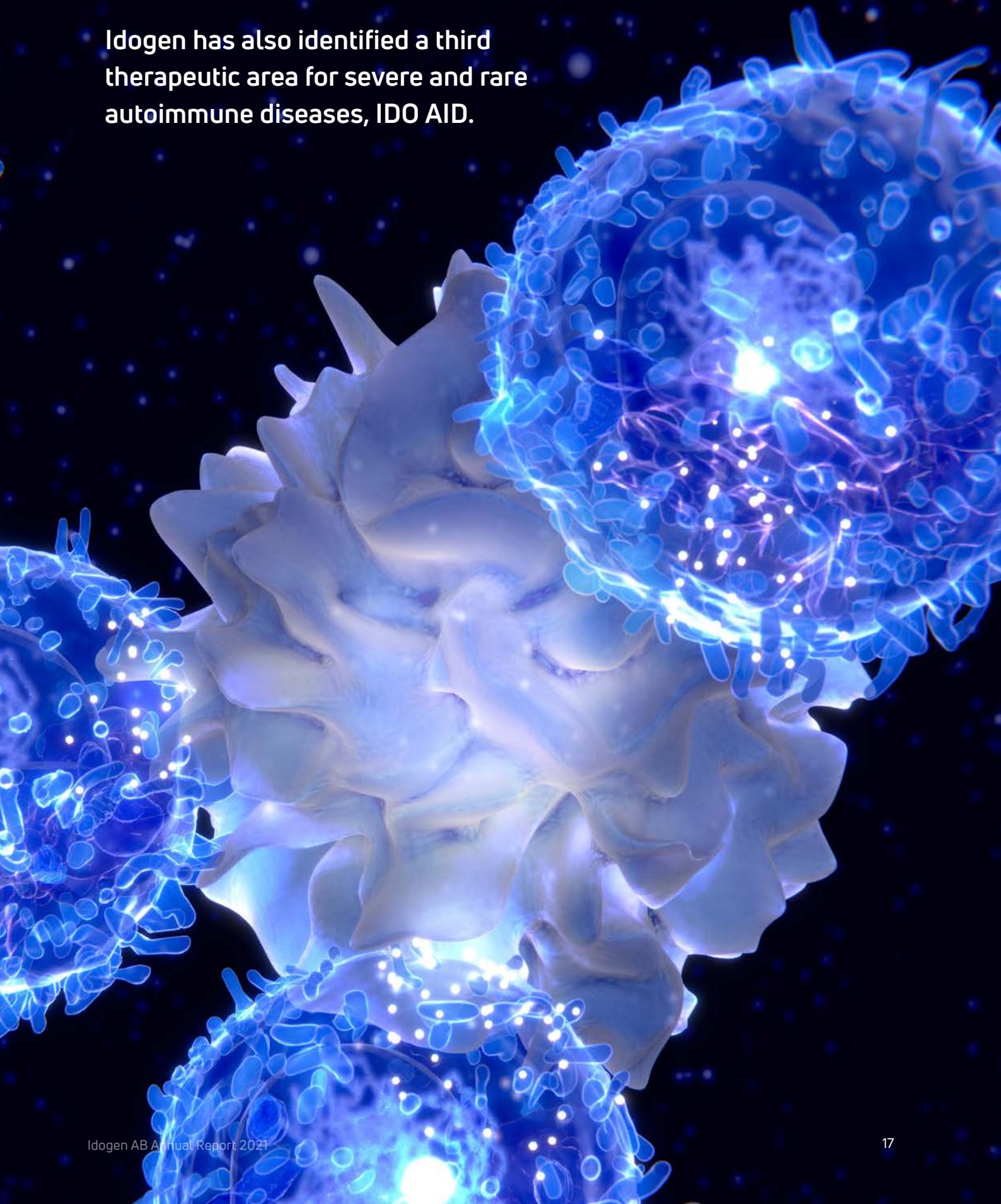
Patients with autoimmune diseases are often treated for long periods of time with powerful broad-spectrum immunosuppressive drugs. However, the effect on the underlying disease is rarely optimal and at the same time,

the treatment can lead to undesirable side effects in a manner similar to that in conjunction with transplantation. The medical need for improved therapies is therefore high. By drastically shortening the treatment, Idogen's tolerogenic cell therapy could reduce the need for immunosuppressive drugs, with improvements to patient health as a result. The company is looking for partners in these fields of therapy to move further.



*Every day, Idogen works to give patients around the world the chance at freer, healthier lives.*

Idogen has also identified a third therapeutic area for severe and rare autoimmune diseases, IDO AID.



# Market

Idogen develops tolerogenic cell therapies for the purpose of treating unwanted activation of the immune system. The company is currently active in the following areas: treatment of patients with severe hemophilia A who have developed neutralizing antibodies against their life-saving therapy with coagulation factor VIII, organ rejection in conjunction with transplantation, and severe autoimmune diseases, in which the individual's own immune system attacks the body's own tissue. The markets for these areas are described below.

## Hemophilia A and treatment against pharmaceutical antibodies

Hemophilia is caused by a lack of coagulation factors, and the current standard treatment for patients with a severe form of hemophilia is to treat with the missing coagulation factor, which for hemophilia A is factor VIII<sup>1</sup>. Approximately 30% of the patients treated with factor VIII develop neutralizing antibodies, or inhibitors, rendering the treatment ineffective. This complication can often be managed by intensifying the factor VIII treatment to induce tolerance (for factor VIII), which entails frequent injections of a high dosage of factor VIII.<sup>2</sup> The treatment, which can last anywhere from six months to three years, is stressful for patients – who often are children. In addition, it is very expensive due to the high price of factor VIII. Unfortunately, the antibodies remain in about 30% of these patients, leaving the patients unable to prevent bleeding through treatment with factor VIII.

Patients with remaining neutralizing antibodies are currently treated with short-term pharmaceuticals that can only manage acute bleeding, at a cost of as much as MSEK 3–8 per patient per year. The annual cost of this short-term treatment is over EUR 800,000 in the US, over EUR 350,000 in France and over EUR 550,000 in Germany, the three largest global pharmaceutical markets for hemophilia A.<sup>3</sup> In addition to the extremely high cost of the short-term treatment, there are high hospital-related costs owing to serious complications from repeated bleeding in the joints, which often results in surgery on the joints.

Idogen's initial development program, IDO 8, is intended to treat this group of vulnerable patients. By providing treatment with individual tolerogenic cell therapy, the hope is to be able to develop a long-term tolerance for factor VIII, thereby being able to continue treatment without developing neutralizing antibodies.

## New therapy alternatives

In November 2017, Roche's drug Hemlibra® was approved by the US FDA for treatment of patients with hemophilia A. The drug is now approved in more than 100 countries throughout the world, including Europe and Japan.<sup>4</sup> In 2020, Hemlibra had sales of approximately SEK 20.5 billion (approx. USD 2.3 billion), which is an increase of 68% on the preceding year.<sup>5</sup> The price tag for a year's treatment with Hemlibra is estimated to be close to MSEK 4. Hemlibra can be used as a preventive treatment for hemophilia A in cases where the patient has developed antibodies and normal replacement therapy with factor VIII can therefore not be administered. Hemlibra works using a mechanism that mimics that of factor VIII, which allows the blood to coagulate without factor VIII.<sup>6</sup> The prophylactic effect of Hemlibra compared with factor VIII has been discussed and several studies show that the hemostatic effect of Hemlibra is lower than can be achieved through replacement with factor VIII, although an effective reduction in the number of bleedings can be attained.<sup>7</sup> The bleedings that arise despite treatment with Hemlibra are treated most effectively using factor VIII and, accordingly, the highest priority, according to international recommendations, remains the attempt to induce immune tolerance.<sup>8</sup> Following the induction of tolerance, the patient can again be treated using factor VIII in the event of bleeding but can also continue preventive treatment with the factor that is missing from the blood.

For episodes of acute bleeding, factor VIII remains the preferred treatment, and consequently the company is of the opinion that there is still a medical need for being able to treat hemophilia A patients by inducing tolerance and thus continue treatment with factor VIII i.e., it affects the patient's immune system to such an extent that it does not generate antibodies that neutralize the effect of factor VIII treatment.



1. Internetmedicin, Hemofili (blödarsjuka typ A och B), 2019.
2. Delignat S, Rayes J, Russick J, Kaveri S.V., Lacroix-Desmazes, S and The ABIRISK consortium. Inhibitor Formation in Congenital Hemophilia A: an Immunological Perspective, *Seminars in Thrombosis & Hemostasis*, 2018.
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4. Roche, Hemlibra® (emicizumab).
5. Roche, Annual report 2020.
6. Kitazawa T, Esaki K, Tachibana T, Ishii S, Soeda T, Muto A, et al. Factor VIIIamimetic cofactor activity of a bispecific antibody to factors IX/IXa and X/Xa, emicizumab, depends on its ability to bridge the antigens. *Thrombosis and stasis*. 2017;117(7):1348-57.
7. Grandoni et al. *philia* 2021 Mar; Vol. 27 (2), pp. 321-328.
8. WFH (World Federation for Hemophilia), *Guidelines for the Management of Hemophilia*, 3rd edition, 2020.



Globally, there are an estimated 157,000 patients with hemophilia A<sup>1</sup>. According to data from Datamonitor, about a third of these, 52,300 patients, are in North America, Europe and Japan – countries where cell therapy currently has already been introduced, though for other indications entirely. Of the total number of hemophilia A, patients in the named markets, it is estimated that approximately 12% – or 6,280 patients – remain defined as difficult to treat after developing neutralizing antibodies to VIII, despite intensified treatment with high doses of factor VIII (immune tolerance induction, or ITI). These 6,280 patients comprise the initial target market for IDO 8, and it is from this selected patient cohort that the company intends to recruit adult patients for the initial clinical trial.

### Addressable market, hemophilia A



Global number of patients with hemophilia A

North America, Europe and Japan 1/3

Patients with inhibitors on ITI

*Of the total number of hemophilia A patients in the world, approximately one third of these are estimated are found in North America, Europe and Japan.<sup>1</sup> Initially, Idogen will start clinical trials on the European market, which accounts for just over half of the 52,300 patients in North America, Europe and Japan. See picture to the left.*

1. Analysis conducted by Monocle Strategy & Communication (MSC) based on data from Datamonitor. Target markets include North America, Europe and Japan. Europe includes the following countries: EU5 (FR, DE, IT, ES, UK), AT, BE, DK, FI, NL, NO, PT, SE & CH

2. Global Data, PharmaPoint. Hemophilia A and B recombinant factor replacement therapy – Global drug forecast and market analysis to 2024, 2015.

3. Report Global Hemophilia Treatment Market Global Industry Insights, Trends, Outlook and Opportunity Analysis, 2019-2027. Coherent Market Insights.

Idogen's technology also has potential for development as a treatment to reduce the risk of organ and cell rejection after transplantation. The basic principle in this case is to "teach" the patient's immune system to recognize and tolerate the transplanted organ rather than attack it. This could eventually reduce the need after transplantation for the current, often lifelong, treatment with preparations that inhibit all types of immune system functionality. The greatest and most serious complication is when the transplant recipient's immune system attacks, destroys and rejects the donated organ. To prevent this, the transplanted patients – with few exceptions – are given lifelong treatment with a combination of immunosuppressive drugs that suppress the immune defense, but at the same time the risk of undesirable side effects such as cancer and infections increases. While the number of patients who retain a functional transplanted kidney during the first year after transplantation has increased in recent decades, there has not been any decisive improvement in the long-term survival of transplants.<sup>1,2</sup> The company is therefore of the opinion that transplantation is a therapeutic area with a significant medical need. Idogen's tolerogenic cell therapy could provide possibilities for both improving transplant survival and reducing the need for and use of immunosuppressive drugs.

Kidney transplantation is the most common type of organ transplantation, and the number of kidney transplants has increased over the last few years, from approximately

72,000 globally in 2010 to approximately 100,000 in 2019<sup>3</sup>. In 2020, significantly fewer kidney transplants – approximately 20,000 – were conducted globally. The reason for this was the COVID-19 pandemic, which prevented the medical sector from performing these operations<sup>4</sup>. This decline was also noted in Sweden, but only with a reduction of about 50 operations.<sup>5</sup>

In Europe, the number of kidney transplants amounted to approximately 22,000 in 2010 and increased to more than 28,000 in 2019, an increase of approximately 30% over a ten-year period. The figure for North and South America increased from approximately 22,800 transplants to approximately 39,500 during the same period, an increase in excess of 40% for the period. These regions also saw a drastic reduction during 2020 due to the COVID-19 pandemic, with levels comparable to the beginning of the decade.<sup>4</sup>

An average calculated on Idogen's potential markets shows that approximately 26% of all kidney transplants occur from living donors.<sup>3</sup> This is the group of transplants that Idogen will initially focus on. Access to a related living donor gives time for the manufacture of the recipient's cell therapy ahead of organ harvest and transplantation. The market for IDO T for kidney transplants with a living donor is estimated to have a potential annual market value of approximately USD 2–4 billion.<sup>7</sup>

## Addressable market, kidney transplantation<sup>6</sup>

44 000

Total number kidney transplants per year

11 252

Number kidney transplants per year Living donors

*Of the total market of approximately 100 000 kidney transplants per year, 44 000 patients are estimated to receive transplants in Idogen's addressable markets (North America, Europe and Japan). Of these, 26% are performed with living donors – 11 252 per year.*



1. Afzali B, Taylor AL, Goldsmith DJA. *What we CAN do about chronic allograft nephropathy: Role of immunosuppressive modulations*. Kidney International, 2005.
2. Wang JH, Skeans MA, Israni AK. *Current status of kidney transplant outcomes: dying to survive*. Adv Chronic Kidney Dis, 2016.
3. Global observation on donation and transplantation, 2010–2020.
4. Aubert et.al., *The Lancet* 2021: 10: 709–719.
5. Njurförbundet, *Rekord i antal njurtransplantationer*, 2020.
6. MSC estimation of the IDO-T market size. This estimation was based on research from sources including, among others, Datamonitor and the 2018 WHO-ONT report. Data is based on 2018 figures. Target markets include North America, Japan and Europe. Europe include DE, UK, FR, ES, IT, AT, BE, DK, FI, NL, NO, PT, SE & CH.
7. Evaluate Pharma och Nordea.

With autoimmune diseases, the individual's immune system attacks their own cells and tissues, the targeted cells/tissues defines the autoimmune disease. By reprogramming the immune system with Idogen's technology to instead tolerate the so-called antigens in the body, the autoimmune response would cease. Today, there are more than 100 autoimmune diseases that are treated with symptom-suppressing drugs for the specific tissue instead of treating the basic cause of the problem<sup>1</sup>. This means Idogen sees great potential for the company's cell therapy in autoimmune diseases.

Idogen's method is particularly suited for autoimmune diseases where there is a well-defined antigen and where the reaction is driven by T cells. This means the company has identified a number of diseases with the potential to be treated with IDO AID.



1. Mia et al. J Autoimmune 2017: 83: 95-112.se

# Market trends for cell therapies

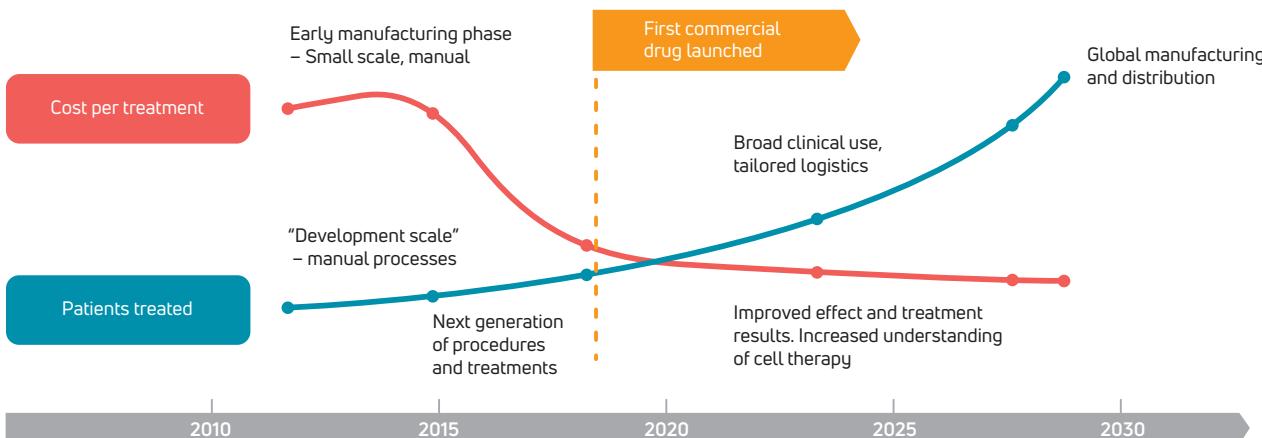
Newer technologies for treating severe diseases are making their way into medical care, with major new possibilities for doctors and patients, especially where there is significant medical need. Examples of these new technologies are advanced therapy medicinal products (ATMP), which over the long term will change how we view medical care and which diseases are curable. The advantages over traditional drug therapies are numerous. Where traditional drugs often only slow the course of a disease, or continually compensate for deficiencies in the body's biological and chemical processes through lifelong treatments, cell and gene therapies have the potential to correct whatever has gone wrong once and for all.

The goal of Idogen's cell therapy is to become that exact kind of corrective treatment. Cell therapies are a recent addition to treatments for severe diseases and to date only a handful of products have already made it all the way to commercial products. In 2017, Novartis received approval from the US Food and Drug Administration for its

Kymriah® CAR-T cell therapy against cancer. The following year, Novartis also received approval in Europe. The approval is regarded as an historic milestone in the establishment of cell therapies, reducing uncertainty among those investors who were previously doubtful about this area. Leading regulatory agencies currently predict that a large number of cell and gene therapy treatments will be registered over the next few years.

In recent years, a number of smaller cell therapy companies have signed commercial license agreements with global pharmaceutical companies under attractive terms. The acquisition of TxCell by Sangamo Therapeutics is one example. The company has developed a CAR-treg platform, which uses cell therapy to provide a local immunosuppressive effect for the treatment not only of conditions including organ rejection in conjunction with transplantation but also Crohn's disease and multiple sclerosis. TxCell was still in the preclinical stage at the time of acquisition, and the purchase price totalled MUSD 84.<sup>1</sup>

## Cell therapy – from early phase to clinical use



Where cell and gene therapy was once a treatment used extremely selectively for a few diseases around the world, there are now products commercially available for severely ill patients with great medical need (Reference : Regional Personnel (2019) "Where are the Biggest Talent Gaps in Cell and Gene Therapy." Available at: <https://regionalpersonnel.com/where-are-the-biggest-talent-gaps-in-cell-and-gene-therapy>)

1. <https://investor.sangamo.com/news-releases/news-release-details/sangamo-announces-completion-txcell-acquisition>.

Leading regulatory agencies currently predict that a large number of cell and gene therapy treatments will be registered over the next few years.



# Interview with Principal Investigator in Idogen's clinical study with IDO 8

Idogen is on the threshold of a clinical phase 1/2a study with cell therapy IDO 8 in patients with severe hemophilia A who have developed antibodies to their substitution therapy with coagulation factor VIII.

Professor Jan Astermark, who will be the Principal Investigator in the clinical study, gives an introduction to the treatment of hemophilia A and the medical need of these patients.

(Article in collaboration with Biostock)

Professor Jan Astermark

## Background

### A large proportion of hemophilia A patients develop antibodies to their treatment

Hemophilia A is caused by a lack of FVIII, a glycoprotein needed for the blood to coagulate. Severe hemophilia A is usually treated every two or three days with an injection of factor concentrate containing the missing coagulation factor.

However, the immune system can recognise the substitution treatment as something foreign and harmful, which leads to that about a third of the patients develop inhibitory antibodies, so-called inhibitors, which inactivate FVIII and render the treatment ineffective. This means that patients no longer respond to FVIII treatment, which increases the tendency to bleed.

### IDO 8 to enable treatment with FVIII again

Idogen wants to counteract this problem with the cell therapy IDO 8, which is intended to prevent the immune system from attacking FVIII, and thereby enable the patient to be treated with FVIII again.

The company plans to start a clinical phase 1/2a with IDO 8 during the second quarter of 2022. The Principal Investigator for the study will be Jan Astermark, Professor of Clinical Coagulation Medicine at Lund University, as well as Chief Physician and Head of the Coagulation Unit at the Skåne University Hospital in Malmö.

## Interview with Professor Jan Astermark

Professor Astermark's many years of research have primarily been focused on hereditary bleeding disorders and how to optimize the treatment of hemophilia patients. He has been involved in the training of professionals worldwide and has a wide, international network of contacts in the field. In the below interview with BioStock, Jan Astermark talks more about the standard treatment for hemophilia A today and why there is a need for new drugs.

#### Jan, first of all, what is hemophilia A?

Hemophilia A is the most common form of hemophilia and is due to a congenital deficiency of factor VIII (FVIII), which is a protein that is needed to stop bleeding if, for example, you injure yourself. Patients have either a total absence of FVIII or a partial deficiency of FVIII. The disease is therefore divided into mild, moderate and severe hemophilia A.

#### How do you treat hemophilia A today?

Patients with severe hemophilia A have an immeasurable level of FVIII and are treated preventively with intravenous injections of FVIII preparations, so-called factor concentrates. The treatment starts at the age of one

year and is given about once a week in the beginning, and then increases to about every other day. The FVIII treatment creates good protection against bleeding and prevents joint injuries that are otherwise a major problem in these patients. Without preventive treatment with FVIII, there is a high risk of deformed joints and severe bleeding.

#### Many patients develop inhibitory antibodies to FVIII. How extensive would you say this problem is?

If the body has never seen the coagulation factor before, it is not that unexpected that the immune system can react by producing antibodies to the factor concentrate fairly quickly after starting the treatment.

The antibodies counteract the effect of FVIII, which means that the treatment no longer works. This is noticeable when the patient suddenly begins to bleed abnormally. The treatment thus no longer has a hemostatic effect.

Unfortunately, antibodies to FVIII are a fairly common problem affecting about one-third of patients with severe hemophilia A.

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**Patients with antibodies are treated with an intensified treatment with FVIII to induce tolerance, which is also called Immune Tolerance Induction (ITI). Could you tell us a little more about this?**

With the help of immune tolerance treatment, an attempt is made to get rid of the antibodies. The patients are often treated with relatively high doses of the FVIII preparation for a longer period, up to several years, to "exhaust" the immune system. In about two-thirds of cases, this succeeds and the patient becomes tolerant, while the remaining third have to live with antibodies that prevent them from being treated with FVIII.

The immune tolerance treatment can be very stressful for both the child and the family because you usually give daily doses of a lot of factor concentrate. A port-a-cath or the like may be needed to provide the treatment. As if that was not enough, the child also has an increased risk of bleeding.

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**Are there other treatment options for patients with FVIII inhibitory antibodies?**

There are currently a few other treatment options that can improve the situation for hemophilia A patients who do not get rid of their antibodies. For example, bleeding can be treated with recombinant factor VIIa, which is a so-called bypass product.

The treatment can also be given for preventive purposes but is not as effective as FVIII in this respect. Then there is Hemlibra, a relatively new drug that contains an antibody that has been developed to function as FVIII. The advantage of Hemlibra is that it is given subcutaneously about once a week, instead of injections into the vessels several times a week.

However, none of these treatment options provides adequate protection against bleeding. Should the patient undergo surgery or be seriously injured, additional medication must be added. Basically, factor concentrate is the best treatment because it contains the protein that the patient lacks.

Since hemophilia A is a genetic disease, it is also conceivable that some of the patients could be treated with gene therapy, which is under development today.

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**What drives doctors to participate in clinical trials with new drugs in hemophilia?**

There is definitely a great need to make patients tolerant to the treatment that contains the protein they lack and need, i.e. FVIII.

We in healthcare always wants to have the patient's best interest at heart. I want to be able to offer all my hemophilia A patients, including those with antibodies to FVIII, the best possible treatment. Therefore, I choose to participate in research and clinical trials in the field.

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**What do you think is particularly interesting about Idogen's development of cell therapy to treat antibodies to FVIII?**

Idogen is developing a treatment with a completely new mechanism

for creating tolerance to FVIII in patients with hemophilia A. Research on why and how the immune system produces antibodies to FVIII and what can be done to counteract this has been going on for a long time. Idogen uses the knowledge about which regulatory molecules and cells that are involved in the immune response to be able to reset the immune system so that it does not react to the factor concentrate.

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**What effect do you want to achieve with IDO 8?**

Idogen's cell therapy is aimed at hemophilia A patients who have difficulty getting rid of their antibodies to FVIII with immune tolerance therapy. It would be extremely valuable if we could succeed in making these patients tolerant to FVIII. Then you would be sure that treatment with FVIII provides effective protection against bleeding and that the effect of FVIII is easy to measure when the patient is bleeding or needs surgery.

In the upcoming clinical phase 1/2a study with IDO 8, which is a First-in-Human study, we want to see that the treatment quenches the immune response to FVIII and that the antibody reaction disappears. The goal is for IDO 8 to enable the immune system to accept FVIII so that the patient can once again be treated with factor concentrate.

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**What is the interest in research and development in hemophilia A?**

Hemophilia is a relatively costly disease for society that in many cases has a significant impact on patients' life situation. There is, therefore, a great socio-economic interest in optimising the treatment and counteracting injuries and bleeding in these patients.

In general, there is great interest in research and development of new treatments in the area. I do not know of any other company, or research group, that uses the same technology as Idogen, so it will be extremely exciting to be a part of their development.

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**"Hemophilia is a relatively costly disease for society that in many cases has a significant impact on patients' life situation.**

**There is, therefore, a great socio-economic interest in optimising the treatment and counteracting injuries and bleeding in these patients."**





Professor Bo-Göran Ericzon

# Interview with Leading transplantation surgeon about Idogen's cell therapy IDO T

The preclinical development work is progressing for Idogen's cell therapy IDO T, which is intended to prevent organ rejection in transplants, primarily kidney transplants with a living donor. Bo-Göran Ericzon, professor of Transplant Surgery at Karolinska Institutet, gives an introduction to medical treatment in organ transplantation and his view on the value of innovative treatments in the field of transplantation.

(Article in collaboration with Biostock)

## Background

### The first transplant

The first successful human organ transplant, a kidney transplant on identical twins, was performed in 1954 in the US by Joseph Murphy. Ten years later, in 1964, the first kidney transplant in Sweden was performed by Curt Franksson, head of surgery at the Seraphim Hospital in Stockholm. Back then, organ rejection was a common problem and many transplants failed.

In the 1980s, the first so-called calcineurin inhibitor, ciclosporin, was launched on the market, which was later followed by tacrolimus in the 1990s. The introduction of these immunosuppressive drugs, that inhibit the activity of T cells, led to significantly fewer organ rejections and better transplant results.

### Medical need remains

Today, few acute organ rejections occur in the early phase and in the first year, largely due to significant advances in the field of transplantation and immunosuppressive treatment. However, the long-term survival of the transplant has not improved much during these years. One of the reasons is that the immunosuppressive drugs effectively inhibit the immune system's activity, giving rise

to an increased risk of infections, cardiovascular diseases and cancer that can have a negative impact on the survival of the transplanted patient in the long term.

### IDO T may reduce the need for immunosuppressive therapy

A possible solution to the problem of organ rejection and unwanted side effects from immunosuppressive drugs would be to induce tolerance in the recipient of the donated organ in connection with the transplant. This could allow a lowering of the dose of immunosuppressive drugs after the initial treatment, without the organ being attacked by the immune system.

This is what Idogen wants to make possible with its cell therapy IDO T. If the product candidate succeeds in achieving the desired effect, it could improve transplant survival and reduce the need for immunosuppressive treatment, and perhaps even – after a few years – eliminate the need for immunosuppressive drugs.



# Interview with Professor Bo-Göran Ericzon

Idogen has in connection with the development of its tolerogenic cell therapy IDO T, developed a collaboration with leading medical and scientific advisors. One of them is Bo-Göran Ericzon, MD, Ph.D., Professor of Transplant Surgery and Head of the Division of Transplant Surgery at CLINTEC at the Karolinska Institute since 2000. He has also been President of the European Society of Organ Transplantation (ESOT) during 1997–1999.

Professor Ericzon has been focused on liver transplantation for metabolic liver disorders and liver transplantation in combination with allogenic bone marrow transplantation

for the treatment of cancer. In 2008, his team performed the first hepatocyte transplantation in Scandinavia. Professor Ericzon is the author of more than 300 peer-reviewed publications and book chapters, and he is also a member of several international scientific committees. In recent years, his research has been focused on tolerance induction in organ transplantation.

In the interview below, Bo-Göran answers questions about organ transplantation and gives his view on Idogen's drug development, as well as the need for new treatments within the transplant area.

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**Could you start by briefly telling us what organ rejection is and what symptoms the patient exhibits when this occurs?**

When an organ is transplanted from a donor to a recipient, the recipient's immune system will react because the body does not recognize the foreign organ. An inflammation occurs which counteracts the donated organ – the function of the organ is decreased and the organ is at risk of being rejected.

The symptoms that the patient exhibits depend on which organ has been transplanted, but overall, you see a deterioration in the patient's general condition and function of the organ. Common symptoms include fever as well as swelling and tenderness around the transplant. For example, if it is a kidney transplant, urine production may decrease and the creatinine level in the blood may rise.

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**How common is it that the donated organ is rejected and how do you treat patients to counteract this?**

It can be expected that about a quarter of all patients gets a small

rejection in the first week after the transplant. This is treated by adjusting the immunosuppressive medication to a higher dose. However, short-term organ rejection, so-called acute organ rejection, is not the biggest problem in this case. The main problem lies in the long-term organ rejection, the so-called chronic rejection, and the immunosuppressive drugs required to prevent it.

Chronic organ rejection slowly impairs the function of the organ over a very long time, up to many years. To get the immune system to accept the transplanted organ, patients are currently treated with lifelong immunosuppressive medication that is associated with several side effects.

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**How do you treat patients who are transplanted to prevent organ rejection?**

Today, there are a number of different drugs that are given in a combination to prevent organ rejection. You usually start by giving 2–3 different drugs, and then remove some of them over time. However, patients will always need to have some type of medication, usually one of the

calcineurin inhibitors tacrolimus or ciclosporin for lifelong immunosuppressive treatment to prevent organ rejection.

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**When ciclosporin and tacrolimus were introduced in the 1980s and 1990s, there was a clear improvement in transplant outcomes. What are the benefits and shortcomings of this type of immunosuppressive drug?**

These two drugs revolutionised the treatment of transplanted patients. They enabled more patients to be transplanted and also with significantly better results. The tissue similarity between donor and recipient no longer became as important.

The main disadvantage of ciclosporin and tacrolimus is that they are given as a lifelong treatment. When you take a drug for so many years, even several decades, the side effects become particularly noticeable. One of the most problematic side effects is the negative impact on kidney function, i.e. nephrotoxicity. This is particularly problematic if the patient has gone through a kidney transplant, the most common organ transplant today.

Immunosuppressive drugs also give rise to an increased risk of infection, especially at the beginning of medication, as well as an increased risk of cardiovascular disease and cancer in the long-term. These types of side effects occur because of the treatment's suppression of the entire immune system, and not just specifically the immune cells' reaction to the donor's tissue antigen.

#### **What medical advances have been made in the field in recent years?**

Relatively little progress has been made in this area since the calcineurin inhibitors came in the 1980s and 1990s. Some examples of other drugs used today are mycophenol acid, everolimus and belatacept as well as some antibodies to lymphocytes. However, ciclosporin and tacrolimus still form the basis of treatment.

**Given what you have told us so far, it seems that there is a need for new treatments to further improve transplant survival. Could you tell us a bit more about this?**

Above all, the side effects need to be fewer and milder. There is a need for new treatments with the same or better effect as today's medication, but without the degree of side effects that they cause.

At the same time, transplant survival does not reach optimal levels today either. A kidney transplant patient may need to return to dialysis or get a new kidney after 20 years. Also from this perspective, it would be desirable to have better treatment options.

**There are several new treatment methods in development, such as Idogen's cell therapy which aims**

**to create tolerance for the donated organ instead of inhibiting the immune system. From your perspective, what benefits could such a treatment bring?**

It would be very beneficial if such cell therapy could teach the recipient's immune cells to accept the organ, without affecting the immune system in general. I see great benefits in getting away from pharmacological immunosuppression, i.e., the drugs that broadly inhibit the immune system.

In general, it is about utilizing the cells' own knowledge and understanding of how to manage and protect the body's organs.

**You are part of Idogen's Scientific Advisory Board. What was it about the IDO T project that attracted your interest?**

What interested me was the concept of using the recipient's cells and teaching them to protect the transplanted organ, thus avoiding lifelong immunosuppression that weakens the patient's immune system. It would be very beneficial to be able to de-escalate to perhaps one or two years of treatment with immunosuppressive drugs given their side effects.

In addition, Idogen's IDO T program is similar to the track we are on in our research at Karolinska Institutet, within liver transplants. When working to teach the body's immune cells not to react to the donor-specific cells, it is important to keep the rest of the immune system intact, so that it can protect against, for example, infections and cancer. You can think of several different methods for this and today we do not know if we will succeed, the medical profession needs to test several different solutions.

#### **What is your role in the IDO T project?**

I will contribute with my knowledge and expertise, particularly when Idogen will test IDO T in "real life" in clinical trials in humans.

#### **What is your vision for future treatment for patients undergoing organ transplantation?**

– An ideal situation would be if we could use the recipient's cells, together with the transplanted organ, to create a condition where the patient only needs to be treated with immunosuppressive drugs during a transitional phase. Completely getting rid of the immunosuppressive medication can be difficult, but it would be a fantastic step forward if we could at least scale back the use and eliminate them in the long term, given their side effects.

**"I see great benefits in getting away from pharmacological immunosuppression, i.e., the drugs that broadly inhibit the immune system."**

## Future and strategy

**Idogen's intention is to enter into commercial license agreements based on the clinical trial results in each development program. In recent years, a number of smaller cell therapy companies have signed commercial license agreements with global pharmaceutical companies under attractive terms.**

Cell therapies are a recent addition to treatments for severe diseases and to date a handful of therapies have already made it all the way to becoming a marketed product. A highly promising cell therapy developed by Novartis, one of the largest pharmaceutical companies in the world, was approved for the treatment of cancer in the US in 2017 and Europe in 2018. The approval is regarded as an historic milestone for the establishment of cell therapies, reducing uncertainty among those investors who were previously doubtful about this area. Idogen has analyzed the European market and conducted a survey of the US market regarding potential products that could be developed using our platform for tolerogenic cell therapy. The company is of the opinion that there is a great potential market for the treatment of hemophilia A patients who have developed inhibitors against factor VIII, since current treatment guidelines in North America and Europe still recommend inducing tolerance for the first-line treatment with factor VIII. The potential is even greater in kidney transplantation, since over 11,000 patients yearly receive transplants from living donors at Idogen's addressable markets for tolerogenic cell therapy.

At present, there are already several established regulatory programs whose purpose is to speed up the development and time to market of new treatments with substantial

medical potential for patients. One initiative is PRIME (priority medicines), which was launched by the European Medicines Agency (EMA) in 2016. Another is accelerated approval at the FDA, which entails early market approval for pharmaceutical candidates that demonstrate promising results from treating seriously ill patients who have no other treatment alternatives. The company's ambition is to evaluate these regulatory opportunities in parallel with completion of the first clinical trial of IDO 8.

Idogen was awarded research funding of MEUR 2.9 by Horizon 2020 (the EU Framework Programme for Research and Innovation), for development of the company's tolerogenic cell therapy for the treatment of patients suffering from severe hemophilia. The EU grant SME Instrument Phase 2 has the overarching target of conducting preclinical safety studies, creating processes for manufacturing tolerogenic cell therapy for clinical trials and conducting the first phase 1/2a clinical trial in patients with hemophilia A and neutralizing antibodies against factor VIII. Idogen was awarded the grant in intense competition with other companies, which is proof of the company's quality, and the grant has been a vital contribution in financing the development of the product candidate IDO 8.



## Patents

Idogen's patent portfolio is an important asset and comprises a crucial obstacle for competitors to copying and commercializing the company's technology. A strong patent portfolio is a precondition for future potential licenses and partnerships. The patents are also key to maintaining a lead over potential future competitors and safeguarding the value of the company.

At present, Idogen's patent portfolio consists of two patent families. The first patent family describes the treatment of antibodies targeting the treatment with factor VIII within hemophilia A, as well as methods for the treatment of antibodies targeted at drugs (anti drug antibodies) for the treatment of several other medical conditions. A patent for this family was granted in Europe in July 2021, expiring in March 2036, and covers the application of some aspects of Idogen's technology for antibodies that have been developed against substitute treatment with factor VIII and factor IX. An application for this patent family is also being processed in the US.

The second – and, in the company's opinion, the more important – patent family comprises an international (PCT) patent application, which describes and asserts Idogen's existing technology and its applications. This PCT application covers all of Idogen's technology platform for tolerogenic cell therapy and pertains to the production process, the cell products created by the production process and treatment methods based on these cell products. The patent application for this second patent family has priority as of December 13, 2019 and was expanded to an international patent application under the Patent Cooperation Treaty (PCT) for global coverage in December 2020. When granted, this second patent could potentially provide patent protection until December 2040.



# Idogen's historical milestones

2021

- In December, an application was submitted to the Swedish Medical Products Agency (MPA) regarding the start of a clinical Phase 1/2a study to obtain safety data and signals of clinical effects among hemophilia patients with antibodies to their treatment with Factor VIII.
- In December, the optimization and qualification of the GMP manufacturing process was successfully concluded for the first clinical trial with its tolerogenic cell therapy, IDO 8.
- In September, Idogen announced its decision to optimize the manufacturing process for IDO 8 with the aim of maximizing the potential improved effects in the impending clinical Phase 1/2a study.

2020

- In September, Idogen announced that the ongoing coronavirus pandemic had affected the IDO 8 project. The planned start of the first clinical trial of the tolerogenic cell therapy IDO 8 was postponed six months, from the first to the second half of 2021.
- In June, Idogen's shares were listed on Nasdaq First North Growth Market following a transfer from Spotlight.



2019

- In November, Idogen announced the conclusion of a license agreement with the Radboud University Medical Center for the production of IDO 8 cell therapy for hemophilia, where the patient has developed neutralizing antibodies against their critical treatment with blood coagulation factor VIII (FVIII).
- In December, Idogen announced that the company had filed a patent application for its novel tolerogenic cell therapy.
- Anders Karlsson became new CEO from August 20 following the resignation of Lars Hedbys in June.

2018

- In January, the EU paid the first portion of the Horizon 2020 research funding, an amount of MEUR 1.2, and another MEUR 0.3 was paid in December.
- Idogen expanded its project portfolio with projects in autoimmune diseases.



2016

- Idogen shows Proof-of-Concept in an animal model of hemophilia A. Treatment with tolerogenic dendritic cells results in a lower incidence of neutralizing antibodies against factor VIII and the treatment has a long-lasting effect.

2015

- The company determined a development strategy and initial evidence – patients with antibodies to hemophilia A – and filed its third patent application related to antibodies against biological agents.
- The company's share was listed on Aktie Torget (later Spotlight).

2008

- Ventac Partners and the four professors Leif G. Salford, Bengt Widegren, Bertil Persson and Hans-Olov Sjögren founded Idogen in Lund.



# Board of Directors

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According to Idogen's Articles of Association, the Board shall consist of a minimum of three and a maximum of eight ordinary Board members.

The company's Board currently consists of five ordinary Board members, including the Chairman. The current Board was elected at the Annual General Meeting on May 11, 2021, for the period until the end of the 2022 AGM.

**Agneta Edberg**  
Chairman of the Board since 2016

Agneta Edberg, born 1956, has more than 25 years of experience from senior positions in the life sciences. Agneta currently works as a consultant and CEO through her own company, A Edberg Consulting AB. Agneta Edberg's previous positions include Managing Director and Vice President of Mylan AB, Nordic countries; Managing Director SLF; Business Unit Director, Pfizer; Marketing Director, Pharmacia; Managing Director, NM Pharma and COO Bactiguard. Agneta Edberg has a health economics degree from Stockholm School of Economics and a biomedical degree from Mid Sweden University in Sundsvall.

**Other ongoing assignments:**  
Chairman of the Board of Amferia AB, CathPrint AB and Elicera AB; Board member of Apotek Produktion & Laboratorier AB, XNK Pharmaceuticals AB, Svenska Läkemedelsförsäkringen AB, CAMP and NextGenNK.

**Holding:** 157,257 shares and 195,360 T05.

Independent in relation to the company and its management and the company's major shareholders.

**Leif G. Salford**  
Board member since 2009

Leif G. Salford, born 1941, is one of Idogen's founders. Leif G. Salford is professor emeritus of neurosurgery and former Head of the Rausing Laboratory for Translational Neuro-oncology at Lund University. Leif G. Salford has conducted neurosurgery research at Cornell Medical Center in New York, Kuwait University, the University of Gothenburg and Lund University. He has held a number of key positions, including chief physician at Sahlgrenska University Hospital, Head of Division and member of the Hospital Board at Skåne University Hospital in Lund, Prefect for the Department of Clinical Sciences at Lund University and Chairman of the World Federation of Neurosurgical Societies (WFNS) Neuro-oncology Committee and the European Association of Neuro-Oncology (EANO).

**Other ongoing assignments:** -

**Holding:** 182,581 shares and 117,660 T05.

Independent in relation to the company and its management and the company's major shareholders.

## Board of Directors

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**Sharon Longhurst**  
Board member since 2020

Sharon Longhurst, born 1969, has 20 years of experience in manufacturing and quality control of various biological pharmaceuticals, both as head of operations and as consultant. Sharon has also worked for six years as a reviewer at the UK Medicines and Healthcare products Regulatory Agency and held positions of responsibility for the quality assessment of chemistry, manufacturing and control (CMC) in EU applications for the approval of cell and gene therapies. She has also worked as a consultant for producing biological pharmaceuticals and represented the UK as deputy chair of the EMA Gene Therapy Working Party program for the European Medicines Agency. Sharon Longhurst has a background in virology and previously worked as head of CMC at Immunum AB (publ) for four years; she is now VP Development at GADETA BV.

**Other ongoing assignments:** -

**Holding:** 92,400 shares and 126,000 T05.

Independent in relation to the company and its management and the company's major shareholders.



**Christina Herder**  
Board member since 2017

Christina Herder, born 1961, has more than 25 years of experience from drug discovery and business development in the pharmaceutical industry. Christina Herder's previous positions include several senior positions at Swedish Orphan Biovitrum AB (Sobi) (publ) and Biovitrum. Christina Herder currently serves as Executive Vice President, Chief Operating Officer at Medivir AB (listed on Nasdaq Stockholm). Christina Herder was previously Chief Executive Officer of the pharmaceutical company Modus Therapeutics AB. Christina Herder holds a Ph.D. in Physical Chemistry from the Royal Institute of Technology in Stockholm and an Executive MBA from Stockholm University.

**Other ongoing assignments:**

Board member of PCI Biotech Holding A/S, Elicera Therapeutics AB and Beactica AB. Deputy Board member of Glycovisc Biotech AB.

**Holding:** 62,718 shares and 99,000 T05.

Independent in relation to the company and its management and the company's major shareholders.



**Lennart Svensson**  
Board member since 2021

Lennart Svensson, born 1961, has 30 years of experience of qualified work as CFO. Lennart Svensson's most recent position was as CFO of Midsona AB, listed on Nasdaq Stockholm (Mid Cap), where he worked for 12 years and took part in, for example, strategic transition, numerous acquisitions and the raising of capital. Lennart's previous experience includes senior positions in Ericsson in Sweden and internationally, which culminated in Ericsson Mobile Platforms AB in Lund. Lennart Svensson holds an M.Sc. in Economics and Business from Stockholm University.

**Other ongoing assignments:**  
Owner and Board member of Logidox AB.

**Holding:** 99,000 shares and 198,000 T05.

Independent in relation to the company and its management and the company's major shareholders

# Management

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**Anders Karlsson**  
Chief Executive Officer  
since 2019.

Anders Karlsson, born 1964, has broad international experience in life sciences from both pharmaceutical and medical technology companies. Anders Karlsson was CEO of Novartis (Norway) 2003-2006, and then CEO of the medical technology companies AbSorber AB, Olerup International AB and Olerup SSP AB 2007-2011. In 2011, he was appointed CEO of Allenex AB, listed on Nasdaq Stockholm, which develops, manufactures and sells products globally for transplant diagnostics. In 2016, Allenex was acquired by CareDx Inc., listed on Nasdaq in the US. Until 2019, Anders Karlsson served as Managing Director of CareDx International AB with responsibility for CareDx Inc's global operations outside the US, and has been a member of the company's global Management Team. Anders Karlsson holds an MBA from Henley Business School, University of Reading, UK and executive education from London Business School and Harvard.

**Other ongoing assignments:** -

**Holding:** 604,000 shares, 858,000 T05, 120,000 subscription warrants (20/23) and 230,000 subscription warrants (21/24).



**Ingvar Karlsson**  
CFO since 2016.

Ingvar Karlsson, born 1956, works as a CFO consultant and has extensive experience from qualified positions in several major companies. Before stepping into the role of CFO of Idogen, Ingvar Karlsson was CFO of Lekolar Group. Prior to that, he was CFO of Doro AB, which is listed on Nasdaq Stockholm. His previous assignments include controller at Gambro Group. Ingvar Karlsson holds an M.Sc. in Economics and Business from Lund University.

**Other ongoing assignments:**

Board member of Oxcia AB (publ) and CFO in Elicera Therapeutics AB (publ).

**Holding:** 349,383 shares, 496,000 T05, 30,000 subscription warrants (20/23) and 60,000 subscription warrants (21/24).



**Åsa Schiött**  
CSO since 2020.

Åsa Schiött, born 1967, has many years of experience within drug development by working in the biotech and pharmaceutical industry for more than 20 years. Åsa has worked in small and medium sized biotech companies within the immunological areas of vaccine, cancer and transplantation. She has led several development projects, from non-clinical safety studies to the completion of clinical phase II trials as a senior project manager. She has been involved in EU marketing authorization applications and US IND applications and has knowledge of document requirements, data standards e.g., eCTD and CDISC, etc. Åsa holds a PhD in Tumor Immunology and a Post Doc in Immunology from the Tumor Immunology and Immunotechnology departments of Lund University, respectively. Åsa has substantial research experience within immunology, including dendritic cells, but also transplantation.

**Other ongoing assignments:** -

**Holding:** 103,524 shares, 147,048 T05, 30,000 subscription warrants (20/23) and 60,000 subscription warrants (21/24).

# Management

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**Dennis Henriksen**  
CTO since 2014.

Dennis Henriksen, born 1962, has over 20 years of experience from senior positions in small and medium-sized biotech companies, including several years as Vice President of BioNebraska Inc., with responsibility for the company's research and development. He has long experience in developing and implementing cGMP in small and medium-sized biotech companies. Dennis Henriksen holds an M.Sc. in Chemical Engineering from Copenhagen Technical University and Ph.D. in Bioorganic Chemistry from Copenhagen University.

**Other ongoing assignments:**  
Board member of K/S Lower Cardiff Road and ViFoyer ApS.

**Holding:** 12,343 shares.



**Neil Thomas**  
CBO and Patent Manager  
since 2014.

Neil Thomas, born 1971, has been working in the biotech sector for over 20 years, with extensive experience in company formation, capital raising, IP portfolio management, business development and licensing. He was previously Head of Business Development & IP at Genetrix and Head of IP & Technology at BioXell. His experience also includes positions at European patent agencies based in London, and Board assignments at several life science companies. Neil Thomas holds a B.Sc. in Biological Sciences from the University of Birmingham and a Ph.D. in Biochemistry and Molecular Biology from Durham University in the UK.

**Other ongoing assignments:**  
Board member of ZipPrime OÜ.

**Holding:** 3,143 shares.



**Hanjing Xie**  
CMO since 2022

Hanjing Xie, born in 1970, is a medical doctor and triple board certified in hematology, oncology and internal medicine and has had over 20 years of clinical experience mostly from Karolinska University Hospital. She has a PhD in clinical pharmacology from Karolinska Institute and is an associate professor in oncology. Hanjing has been active in the pharmaceutical industry since 2015 and has held a number of meritorious senior positions in the pharmaceutical industry such as Senior Medical Advisor at Bayer (2015-2018), Head of the Clinical Trial Unit at Capio St. Görans Hospital (2018-2020) and Senior Medical Study Director at Oncopeptides (2020-2022). Hanjing Xie contributes with extensive experience and solid knowledge in hematology, clinical treatment with novel immunotherapy/cell therapy in oncology, as well as broad experience in clinical development inclusive conducting clinical trials both in the early and later phases of product development.

**Other ongoing assignments:** -

**Holdings:** -

# Management

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**Vicki Venizelos**

CRO since 2020.

Vicki Venizelos, born 1967, has held various CMC and regulatory roles in the biotechnology and pharmaceutical industry for more than 20 years. She began applying her experience in the field of ATMP development 14 years ago. Companies Vicki has worked for range from small to medium size biotechnology companies through to large multinationals, where she has helped enable first-in-human studies (FIH) through to further clinical development, EU marketing authorization applications and US biologics license applications. Vicki holds a B.Sc. in Chemistry and Microbiology from the University of South Australia, and business education from the Rotterdam University of Applied Sciences. Apart from her role at Idogen, Vicki is the owner of a CMC and regulatory consultancy company based in Leiden, the Netherlands.

**Other ongoing assignments:** -

**Holding:** 10,000 subscription warrants (20/23)  
and 40,000 subscription warrants (21/24).



# Scientific Advisory Board

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## Rolf Ljung, MD, PhD

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Rolf Ljung is a senior professor of pediatrics at Lund University and a former chief physician in pediatric hematology with a special focus on coagulation at Skåne University Hospital. His research focuses on bleeding and coagulation diseases in children and in particular genetic and clinical studies in hemophilia. An important work has been to map the genetic variation in the disease, among other things to be able to predict the risk of developing antibodies to treatment. Ljung is also the scientific chairman of the European Pediatric Network for philia Management (PedNet) and the International Network on Pediatric Hemophilia (INPH).



## Jan Holgersson, MD, PhD

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Jan Holgersson works as a Professor of Transplant Immunology at the University of Gothenburg and Head of Clinical Immunology and Transfusion Medicine as well as Head of the Tissue Typing and Stem Cell Laboratory at Sahlgrenska Hospital in Gothenburg.

His research focuses on understanding the immunological mechanisms behind the rejection of transplanted organs and tissues. An important element has been to develop diagnostics for the detection and semiquantification of antibodies against blood group ABH antigen and other tissue antigens (non-HLA).

Jan Holgersson is also Chairman of the Board of VERIGRAFT AB.



## Michaela Sharpe, PhD

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Michaela Sharpe is a leading expert in non-clinical safety assessment of advanced therapy medicinal products (ATMP) and vaccines with over 18 years of experience in the biotechnology and pharmaceutical sectors. She has designed tailored non-clinical strategies for over 35 complex therapies to facilitate the development of clinical trials; including pluripotent stem cell therapies, somatic cell therapies, immunotherapies, genetically modified cell therapies, tissue engineering products, and prophylactic and therapeutic vaccines. In addition, she has an in-depth understanding of non-clinical regulatory requirements for regulators (MHRA, EMA and FDA) for ATMP, vaccines and GLP regulations.



## Jolanda de Vries, PhD

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Jolanda de Vries is Professor in the Department of Tumor Immunology at the Nijmegen Center for Molecular Life Sciences. She was one of the pioneers in translating dendritic cell biology into potential clinical applications. The first Phase I / II clinical trials in which patients were vaccinated with dendritic cells (DC) loaded with tumor-specific peptides were initiated in 1997. Her primary scientific interest continues in line with DC immunotherapy and in particular migration and imaging of DC. For example, in-vivo imaging of ex-vivo-labeled cells by MRI (Nature Biotechnology 2005). She recently completed the first plasmacytoid DC vaccination study.

# Scientific Advisory Board

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## Bo-Göran Ericzon, MD, PhD

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Professor of Transplant Surgery at Karolinska Institutet, Stockholm and Head of the Division of Transplant Surgery, Department of Clinical Sciences, Intervention and Technology (CLINTEC) at Karolinska Institutet since 2000. Research and clinical scholarship at the University of Pittsburgh, Pennsylvania, PA, USA. Doctoral degree from Karolinska Institutet 1993.

Professor Ericzon's main research interest is related to liver transplantation for metabolic liver diseases and liver transplantation in combination with allogeneic bone marrow transplantation for the treatment of advanced cancer.

Between 1997 and 1999, Bo Göran Ericzon was President of the European Society of Organ Transplantation (ESOT).



## Richard Williams, PhD

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Richard Williams is a senior researcher and group leader at the Kennedy Institute of Rheumatology, Oxford University, and conducts outstanding basic research on the enzyme IDO1 and rheumatoid arthritis. The Kennedy Institute is a world-renowned institute in rheumatoid arthritis and research from there has led to the development of the most important drug treatment for rheumatoid arthritis. Richard Williams was recently named editor of the scientific journal *Arthritis Research & Therapy*.

## Leif G Salford, MD, PhD, Founder

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Leif G. Salford is one of the founders of Idogen and professor emeritus of neurosurgery and former head of the Rausing Laboratory for Translational Neuro oncology at Lund University. His scientific work combines immune and gene therapy against the most malignant brain tumors and he has also been noted for his work on the effect of electromagnetic radiation on the blood-brain barrier. Professor Salford has conducted research in neurosurgery at Lund University, University of Gothenburg, Kuwait University and Cornell Medical Center in New York. Leif G Salford has been chairman of e.g. World Federation of Neurosurgical Societies (WFNS) Committee on Neuro-Oncology and for the European Association for Neuro-Oncology (EANO).



## Hans-Olov Sjögren, MD, PhD, Founder

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Hans-Olov Sjögren is one of the founders of Idogen and professor emeritus in tumor immunology at Lund University. Through his research at Karolinska Institutet in Stockholm, Fred Hutchinson's Cancer Center in Seattle and the Wallenberg Laboratory and the Biomedical Center at Lund University, he has contributed substantially to increasing the understanding of immune responses to cancer both in experimental models and in patients. Professor Sjögren's research focuses on the mechanism that balances immune activation and inhibition in tumor disease and led to the discovery of a molecular tool to increase an immunosuppressive mechanism, the principle on which Idogen now builds.

# The share

Idogen AB is a public limited company and has been listed on Nasdaq First North Growth Market since June 4, 2020. Idogen was previously listed on the Spotlight Stockmarket starting on June 12, 2015. During 2021, the number of shareholders increased from some 3,900 to approximately 4,000. It is not possible to specify the exact number of shareholders because a number of shareholders have their shares in endowment policies, which means an exact number cannot be specified. The share price declined from SEK 3.00 at the beginning of 2021 to SEK 1.23 at the end of December 2021 after the company announced the rights issue on December 17, 2021.

In May 2020, a 10:1 reverse split was carried out.

## Ownership Structure

Specification of ten largest shareholders at December 31, 2021.

Name	No. of shares	Proportion of votes and shares, %
Avanza Pension AB	1 448 934	6,3
Tobias Ekman	1 120 000	4,8
Nordnet Pension AB	757 816	3,3
Gunvald Berger	722 320	3,1
Semelin kapitalförvaltning AB	456 695	2,0
Elias Tezaris	447 868	1,9
Niklas Wallet	415 000	1,8
Håkan Blomqvist	400 000	1,7
Danske Bank Luxemburg	383 263	1,7
Per Eliasson	351 903	1,5
Others	16 566 676	71,8
<b>Total</b>	<b>23 070 475</b>	<b>100,00</b>

## Share Capital

- The share capital is to amount to at least SEK 12,768,000 and at most SEK 51,072,000.
- The number of shares shall not be fewer than 18,240,000 and not exceed 72,960,000.
- The registered share capital is SEK 16,149,332.50.
- There is one class of share. Each share carries the same rights to a share in the company's assets and provides entitlement to one vote at General Shareholder Meetings. One share carries one vote.
- The company's shareholder register is managed by Euroclear Sweden AB (previously VPC AB), Box 7822, SE-103 97 Stockholm.

## Share Capital Trend

Year	Event	Quotient value	Increase in number of shares	Increase in share capital	Total number of shares	Total share capital
2008	Formation of the company	1	100,000	100,000.00	100,000	100,000.00
2012	New share issue	1	27,660	27,660.00	127,660	127,660.00
2013	New share issue	1	1,596	1,596.00	129,256	129,256.00
2014	New share issue	1	64,628	64,628.00	193,884	193,884.00
2015	New share issue	1	14,403	14,403.00	208,287	208,287.00
2015	Bonus issue	2,45	-	302,016.15	208,287	510,303.15
2015	Share split 35:1	0,07	7,081,758	-	7,290,045	510,303.15
2015	Rights issue	0,07	2,500,000	175,000.00	9,790,045	685,303.15
2016	Warrants of series TO 1	0,07	2,432,544	170,278.08	12,222,589	855,581.23
2017	New share issue	0,07	8,555,883	598,911.81	20,778,472	1,454,493.04
2018	Warrants of series TO 2	0,07	3,318	232.26	20,781,790	1,454,725.30
2018	New share issue	0,07	27,709,743	1,939,682.01	48,491,533	3,394,407.31
2020	New share issue	0,07	42,725,000	2,990,750.00	91,216,533	6,385,157.31
2020	New share issue	0,07	7	0.49	91,216,540	6,385,157.80
2020	Reverse split 10:1	0,07	-82,094,866	-	9,121,654	6,385,157.80
2020	New share issue	0,70	9,121,654	6,385,157.80	18,243,308	12,770,315.60
2021	Warrants of series TO 4	0,70	4,827,167	3,379,016.90	23,070,475	16,149,332.50

# Directors' Report

The Board of Directors and the CEO of Idogen AB (Corp. Reg. No. 556756–8521) hereby submit their annual report for the financial year January 1, 2021 to December 31, 2021.

Unless otherwise stated, all amounts are in KSEK and figures in parentheses pertain to the corresponding period of the preceding year.

## Information About The Operations

Idogen AB (publ) has its registered office in the municipality of Lund and is a biotechnological research and development company. Idogen develops tolerogenic cell therapies to prevent the patient's immune system from attacking biological agents, transplanted organs or the body's own cells or tissues. The term 'tolerogenic' refers to the immune system's selective tolerance of a specific pathogenic or immunostimulatory antigen following treatment with Idogen's therapy. Idogen's intention is to revolutionize the treatment of several disorders in which the body's immune

system does not function as it should, and for which there is a major unmet medical need – such as in autoimmune diseases, organ rejection after transplantation and in patients who have developed anti-biologic antibodies. The company was formed in 2008 around an immunological discovery at Lund University.

## Ownership Structure

Idogen AB is a public limited company and has been listed on Nasdaq First North Growth Market (Ticker: IDOGEN) since June 5, 2020. Prior to this, the share was listed on Spotlight since June 12, 2015. During the year, Idogen added about 100 new shareholders. In total, there were approximately 4,000 shareholders at year-end. Idogen's largest shareholder is Avanza Pension with 1,448,934 shares (6.3% of the votes and capital). For further information, refer to the page 45 concerning the share and to the company's website.

## Financial Overview

### Multi-year comparison

	2021	2020	2019	2018	2017
Net sales, KSEK	-	-	-	-	-
Other operating income, KSEK	13,915	8,113	4,192	3,766	0
Operating expenses, KSEK	-52,880	-34,266	-37,018	-31,627	-21,299
Operating loss, KSEK	-38,965	-26,153	-32,826	-27,861	-21,299
Loss for the year, KSEK	-38,854	-26,822	-32,694	-27,634	-21,322
Average number of shares	19,274,867	8,068,161	4,849,153	2,184,317	1,620,752
Average number of warrants	9,723,279	500,890	210,967	1,179,071	796,986
Loss per share before dilution	-2.02	-3.32	-6.74	-12.70	-13.20
Loss per share after dilution	-2.02	-3.32	-6.74	-12.70	-13.20
Cash flow from operating activities, KSEK	-40,190	-28,081	-34,974	-10,394	-19,906
Balance sheet total, KSEK	23,069	50,843	31,189	71,674	44,187
Working capital, KSEK	9,775	38,507	14,844	42,306	33,894
Acid-test ratio, KSEK	181	482	216	305	888
Equity/assets ratio, %	47.6	79.9	58.8	71.2	90.3
Return on equity, %	neg.	neg.	neg.	neg.	neg.

#### **Definitions of key figures:**

##### Working capital

Total current assets (including cash and bank balances) less current liabilities.

##### Acid-test ratio

Total current assets (including cash and cash equivalents) relative to current liabilities.

##### Equity/assets ratio

Shareholders' equity in relation to balance sheet total.

##### Earnings per share before dilution

Profit after tax divided by average number of shares for the period. The number of shares has been recalculated for the reverse split in 2020 (10:1) and earnings per share are therefore comparable.

## **Financial Development**

### **Operating income and profit/loss**

#### *Other operating income*

Other operating income for the period amounted to KSEK 13,915 (8,113).

#### *Operating loss*

Operating loss for the period totaled KSEK -38,965 (-26,153), a change of KSEK -12,812 compared with the year-earlier period.

Recognition of EU research funding and other minor support generated a higher positive contribution of KSEK 5,802, while expenses rose KSEK 18,614.

#### *Profit/loss for the period*

Loss for the period totaled KSEK -38,854 (-26,822). Loss per share was SEK -2.02 (-3.32).

### **Liquidity and cash flow**

- Cash flow from operating activities was KSEK -40,190 (-28,081).
- Cash flow from investing activities was KSEK -510 (0).
- Cash flow from financing activities was KSEK 9,220 (49,115).
- Cash flow for the period was KSEK -31,480 (pos: 21,033).
- At the end of the period, the company's cash and cash equivalents amounted to KSEK 15,560 (47,041).

### **Horizon 2020**

In May 2017, Idogen was granted research funding of MEUR 2.86 (just over MSEK 29) from Horizon 2020 (the EU Framework Program for Research and Innovation) to develop the company's tolerogenic cell therapy, for the treatment of patients with severe hemophilia who have developed anti-factor VIII neutralizing antibodies during treatment.

In April 2021, MEUR 0.3 (approximately MSEK 3) was paid out. Most of the outstanding amount (MEUR 0.43 – approximately MSEK 4.5) is expected to be paid out in 2022.

The amounts received were recognized as deferred income. Costs arising from the project are recognized over time. The entire Horizon grant has been recognized in profit or loss as of the closing of the 2021 annual accounts.

### **Financial position**

At December 31, 2021, the equity/assets ratio was 48% (80) and equity amounted to KSEK 10,987 (40,621).

At December 31, 2021, total assets amounted to KSEK 23,069 (50,843).

## **Subscription Warrants T04**

In conjunction with the new share issue in December 2020, Idogen issued 9,121,654 units each consisting of one (1) share and one (1) subscription warrant. Each subscription warrant carried entitlement to subscribe to one (1) new share in the company at a redemption price of seventy (70) percent of the volume-weighted average price of the company's share during the period from September 6, 2021 through September 17, 2021, which was set at a price of SEK 2.06 per share.

The final outcome showed that the exercise rate amounted to 52.9%, corresponding to 4,827,167 new shares.

Through exercise of the subscription warrants, Idogen raised proceeds of MSEK 9.9 before issue costs. The total number of shares in Idogen increased by 4,827,167, from 18,243,308 to 23,070,475. The share capital in Idogen increased by SEK 3,379,016.90, from SEK 12,770,315.60 to SEK 16,149,332.50.

## **Investments**

Idogen invested in lab equipment. Investments for the period amounted to MSEK 0.5 (0.0).

## **Accounting Policies**

The annual accounts are prepared according to the Swedish Annual Accounts Act and RFR 2 (Swedish Financial Reporting Board) Accounting for Legal Entities. Since the company is not included in any group, IFRS-compliant financial statements are not applicable.

It is stated in RFR 2 that a Parent Company must apply IFRS as adopted by the EU as far as this is possible within the framework of the Swedish Annual Accounts Act and the Swedish Pension Obligations Vesting Act, and with consideration for the relationship between accounting and

taxation. The recommendation sets out the exceptions and additions to IFRS that may be applied.

## Significant Events During The Year

A significant milestone was reached during the year as Idogen submitted an application to the Swedish Medical Products Agency (MPA) regarding the start of a clinical Phase 1/2a study to obtain safety data and signals of clinical effects among hemophilia patients with antibodies to their treatment with factor VIII. Immediately after the new year – on January 3, 2022 – Idogen also filed an application for a clinical trial with IDO 8 to NoMA, the Norwegian Medicines Agency. This was preceded by extremely intensive preclinical efforts during the year.

The COVID-19 pandemic affected the tempo of development efforts at the Radboud University Medical Center. In September, Idogen initiated new activities in order to maximize the effect of the tolerogenic cell therapy IDO 8 before the start of the first patient study, which was successfully carried out and concluded in December.

During the year, activities to support the IDO T development in kidney transplantation were also initiated through Idogen bringing renowned scientific advisors into the company. Preclinical efforts were initiated during the year.

The European Patent Office (EPO) granted a European patent to protect the company's tolerogenic cell therapy.

The financing of Idogen consisted of two elements: a further partial payment of MSEK 3 from the EU Commission (for the company's project as part of the Horizon 2020 call for submissions) and Idogen's generation of MSEK 9.9 in proceeds before issue costs when shares were subscribed for with the support of subscription warrants (TO4). At the end of year, Idogen's Board of Directors proposed a rights issue that generated proceeds for the company of approximately MSEK 41 after issue costs.

## Significant Events After Year-End

The Extraordinary General Shareholder Meeting held on January 20 approved the Board's proposal of a rights issue of MSEK 50.4 before issue costs.

The share issue was carried out in February.

No significant events that affect the annual accounts occurred after the end of the financial year.

## Research And Development

IDO 8 is Idogen's most advanced project, aimed at developing a tolerogenic cell therapy for patients with severe hemophilia who lack adequate treatment after developing antibodies

against their treatment, Factor VIII. The company has chosen to focus on hemophilia as first therapeutic area due to the major unmet medical need in these patients and because the disease has a well-defined antigen, presenting opportunities to develop an effective treatment for this patient cohort.

Since Idogen's tolerogenic cell therapy is based on a platform technology, this means that a similar method that is now being developed for the treatment of hemophilia, could also be used in other fields of therapy after minor adjustments to the method. The company has therefore made a strategic decision to commence parallel development of a product candidate for kidney transplantation, IDO T. The basic principle is to "teach" the patient's immune system to recognize and accept the transplanted organ rather than attack it, causing ultimately, organ rejection.

Idogen is also working in the therapeutic area of autoimmune diseases with the aim of identifying potential treatments for patients with substantial unmet medical need in this field. The umbrella designation for this project is IDO AID.

## Employees And Organization

At December 31, 2021, the number of employees (FTE) was 10 (9).

Idogen's organization comprises all of the competencies and experience required to run the company. Close collaboration has been established with a number of consultants with key competences (e.g. patents, preclinical, clinical trials, cell therapy, drug development, regulatory expertise for manufacturing, documentation, quality assurance, finance and legal matters).

## Remuneration Of Senior Executives

As a general principle, Idogen will pay market-based and competitive salaries. Employee benefits comprise salaries, bonuses and pensions as well as company cars. Fees to consultants comprise daily/hourly rates. Remuneration is presented in Note 8 (Remuneration of the Board of Directors) and Note 9 (Salaries, other remuneration and social security expenses). The applicable remuneration policy is available in the Corporate Governance Report.

## Incentive Plans

The 2020 General Shareholder Meeting resolved to introduce a rolling incentive plan for management. The 2021 General Shareholder Meeting passed a resolution in line with the resolution from 2020. There are thus two warrants programs for management. The warrants were assessed in accordance with the Black-Scholes model, using an external party's calculation of the warrant

prices. The warrants were purchased at the market price set according to the assessment.

The 2020/2023 warrants program with 250,000 subscription warrants at a market price of SEK 8.90 per share, and the 2021/2024 warrants program with 455,000 subscription warrants at a market price of SEK 5.90 per share. After the right issue 2022 a recalculation has taken place. For 2020/2023 the signing price is 8.69 and the number of warrants is 256,000. For 2021/2024 the signing price is 5.65 and the number of warrants is 456,920.

In addition to the plan, there is a three-year "stay put" program for those persons in the company who subscribed for warrants.

## Environmental Information

At present, Idogen AB conducts operations that are subject to neither permit nor reporting requirements.

## Risk Management

### Risks specific to the company

#### *Risks related to preclinical and clinical trials*

Before a treatment can be launched on the market, safety and efficacy when treating patients must be verified for each individual indication, which is often preceded by demonstration in preclinical studies. Idogen has concluded the preliminary preclinical studies for the company's most advanced research project – IDO 8 – and filed a clinical trial application in December 2021 with the relevant authorities for the start of the planned Phase I/IIa clinical trial with IDO 8 for patients who have developed inhibitors that counteract the effect of their regular treatment with coagulation factor VIII (FVIII). Provided that the necessary regulatory approval is received, the clinical trial with IDO 8 is expected to commence in the second quarter of 2022. IDO T is still undergoing preclinical studies with the goal of filing an application for the start of clinical trials in late 2023.

Since Idogen is at the end of the preclinical stage, there is no guarantee that the drug candidate will successfully pass through to clinical trials. Results from preclinical studies are not always predictive of outcomes in clinical trials. Accordingly, there is always a risk that the planned studies will not demonstrate sufficient safety and efficacy for the treatments to continue in clinical development and ultimately receive market authorisation and be launched on the market. There is also a risk that authorities consider data from the preclinical studies underlying clinical trial applications to be lacking in evidence.

The fact that the company is in preclinical stage could make it difficult to evaluate Idogen's sales potential, since Idogen may either pursue development jointly with partners or out-license/sell some parts of the development. On the basis of the above, there is a risk that income, in full or in part, will not materialize, which could have a highly adverse effect on Idogen's earnings capacity.

Clinical trials are associated with considerable uncertainty and risk in respect of schedules and trial results. Idogen may also be required to conduct more extensive clinical trials than the company's Board deems sufficient at present, which could give rise to a high impact on the company's costs, depending on the design of such trials, and delayed commercialization. There is also a risk that the partners conducting these preclinical studies and clinical trials are unable to maintain the clinical and regulatory quality required for any future out-licensing, partnerships, sales or regulatory approval.

The company considers the likelihood that the risks described above will occur as high.

#### *Impact of COVID-19 on the company's operations and planned clinical trials*

The COVID-19 pandemic has resulted in, for example, several clinical trials being cancelled, delayed or postponed until a future date as a consequence of a heavy burden on health care as well as guidelines and restrictions from bodies such as the European Medicines Agency (EMA) and local authorities. The need from companies that wish to conduct clinical trials is increasing in pace with restrictions in health care being eased. However, various clinical trials are competing with the capacity of ordinary health care. In addition, a so-called "health care debt" has also arisen as a result of the COVID-19 pandemic that has put additional pressure on companies' desire to conduct clinical trials.

As an example of the actual impact on the company's operations, the COVID-19 pandemic has resulted in a delay in the start of the IDO 8 clinical phase 1/2a clinical trial as a consequence of temporary limitations in capacity at our manufacturing partner Radboud University Medical Center (RUMC). Altogether, the COVID-19 pandemic has had – and could also have in the future – negative consequences for the company's operations. Depending on the continued spread of COVID-19 at both the local and global level – for example, as the result of new mutations, renewed increases of the spread of infection in society, reduced vaccination rates and reduced efficacy of the vaccine against new variants, the issuance of new guidelines or

restrictions, lockdowns or similar – there is a risk that the company's planned clinical trials will be delayed or will be more expensive than the company planned and that the results from the clinical trials will be delayed for this reason, which could have a medium-high adverse impact on the company's operations and future prospects.

The company considers the likelihood that the risk described above will occur as medium-high.

#### ***Risks related to patient enrolment***

The plan is to initiate the company's future clinical Phase I/Illa clinical trial with IDO 8 in the second quarter of 2022. The company and any potential partners are dependent on the ability to enrol participants in order to conduct the clinical trial.

For IDO 8, the number of eligible participating patients is limited and the treatment is centralized to major leading centres for the treatment of coagulation disorders. In the event that patients cannot be enrolled in the company's clinical trial in accordance with the existing schedule, this could lead to the company needing to include more study centres. The need to include more centres could in turn lead to a delay in the company's clinical trial. There is also a risk of competition from other clinical trials that are in progress or that could be initiated in parallel. Delays and interruptions to the company's study, or competition from other studies, could mean that the company's efforts at development become more costly than the company had planned, and that expected proceeds from sales are delayed and put off into the future – which would have a medium-high adverse impact on the company's operations and future prospects.

The company believes that the likelihood of occurrence of the risk described above is high.

#### ***There is a risk of side effects***

Since Idogen has not yet begun clinical trials, there is no documentation of side effects in humans in conjunction with treatment using the company's drug candidate. There is therefore a risk that patients taking part in Idogen's planned clinical trials suffer from side effects. Potential side effects may delay or stop the continued development and limit or prevent commercial use and thereby lead to increased costs and have a highly adverse impact on the company's future earnings capacity. Another consequence is that the company may be taken to court by patients suffering side effects, after which the company may be liable for compensation. There is a high probability that each planned study will have limitations to the scope

and upper limits of its insurance cover. There is therefore a risk that the company's insurance cover does not fully cover possible future legal demands, which could have a highly adverse impact on the company's costs.

The company considers the likelihood that the risks described above will occur as medium-high.

#### ***No drugs launched to date***

To date, none of Idogen's drugs have been launched in the market, either on the company's initiative or through partners, and the company has therefore not yet generated any proceeds from sales. This is why it may be difficult to evaluate the company's sales potential. Idogen's most advanced development project, IDO 8, will begin clinical trials in the second quarter of 2022. In the preclinical and clinical phase, there are serious risks that include discontinuing the development of the company's drug candidates before the products have become commercially viable or available in the market. There is therefore a risk that the company's income, in full or in part, could not materialize, which in turn could have a medium-high or severe adverse effect on the company's earnings capacity and profitability.

The company considers the likelihood that the risks described above will occur as medium-high.

#### ***Risks related to license agreements and manufacturing process***

Idogen's treatment consists of an autologous cell therapy. For the manufacture of the company's tolerogenic cell therapy under Good Manufacturing Practice (GMP) standards, the company has chosen an ongoing partnership with Radboud University Medical Center (RUMC).

This partnership ensures the manufacture of cells ahead of the company's impending clinical trials. Idogen is – and will be, going forward – dependent on partners and other players for the manufacture and delivery of the company's current and future products. There is a risk that RUMC, or other existing or future business partners, will choose to discontinue their collaboration with the company or will be unable to continue their partnership on favourable terms for the company, and that in such a situation Idogen would be unable to replace that partner in an adequate manner as regards time, quality, or finance. Nor can it be guaranteed that the company's partners or other players will fully meet the quality requirements that the company or relevant authorities impose. In the event any of the above risks occur, Idogen deems it would have a highly adverse effect on the operations in the form of delays as well as a possible limited or loss of income.

The company considers the likelihood that the risks described above will occur as medium-high.

#### ***Risk related to key individuals and qualified personnel***

Idogen has built up an organization with qualified individuals to create the best possible conditions to develop and commercialize the company's projects. However, Idogen is still run by a relatively small organization and the company's future growth is to a large extent dependent on the knowledge, experience and commitment of company management and other key individuals. The company may fail to retain these key individuals and to recruit new qualified staff in the future, which could have a medium-high impact on the company's ability to commercialize any of the drug candidates and thereby impact the company's profitability and future earnings capacity. New recruitments may also take a considerable amount of time to complete. Should any of the company's key individuals leave the company, this could lead to delays to or the disruption of Idogen's operations and continued development. It is particularly important in this respect that employees view Idogen as a professional and stimulating employer. To achieve this, demands will be made on professional Board work, professional management, the achievement of performance forecasts and that the company applies market-based financial incentive schemes.

The company considers the likelihood that the risks described above will occur as medium-high.

#### **Industry-related risks**

##### ***Risks related to competitors in the market for cell therapies***

Since Idogen's concept is based on inducing immunological tolerance using the body's own cells, which is a relatively new field, the competitive situation can be difficult to assess. The company is not aware of any companies that are working with the same technology, but the company is aware of a number of businesses, universities and research institutions that are conducting research and development into immunological tolerance. For example, the Company has identified research in this field at institutions including Newcastle University in the UK, the University of Queensland in Australia and the Hospital Clinic de Barcelona in Spain. Furthermore, the company could also meet competition from other fields and concepts that could potentially be used to treat the same indications, such as products based on nanoparticles.

Extensive investment and development by a competitor could give rise to risks in the form of limited or loss of income for the company. In addition, companies with

global operations and considerably stronger resources than Idogen, that are currently active in related areas could decide to establish a position in Idogen's business area. Although Idogen assesses that the price that can be charged for the products should provide a reasonable margin to cover the costs, it can be difficult to make a preliminary assessment of the price level and costs at an early stage of development, especially when some large drug development companies may have larger organizations which means they can set more competitive prices on competing drugs. Lower price levels could have a medium-high to high impact on Idogen's earnings capacity and future profitability.

Competition in the various therapeutic areas, such as hemophilia A and kidney transplantation, could also come from products that act in ways other than via immunological tolerance. One such product is Roche's Hemlibra, which has another mechanism of action and is used to prevent the frequency of bleeding episodes in patients with hemophilia A who have developed antibodies against FVIII. More intense competition could have an adverse impact on Idogen's ability to commercialize any of its drug projects and, therefore, a high adverse effect on the company's profitability and future earnings capacity.

The company considers the likelihood that the risks described above will occur as high.

#### **Financial risks**

##### ***Risks related to the company's continuing financing needs***

At present, the company has not launched any treatment either individually or via partners, and has not therefore conducted sales or generated any revenue. Idogen's development plans for drug projects entail increased costs for the company. To implement the development plans, Idogen requires financing.

For the continued development of the company's tolerogenic cell therapy, Idogen will be dependent on financing which is why there is a risk that Idogen may continue to turn to the general public to raise capital even in the future. There is a risk that any additional capital cannot be obtained on favourable terms, that the capital obtained is insufficient to finance the company's development, or that such capital cannot be obtained at all. This could mean that development is temporarily ceased, or that the company is forced to conduct operations at a slower pace than desired, which could have a serious negative impact on company's ability to commercialize the drug candidates in accordance with the current plan and a high negative impact on the company's ability to generate income.

Time and cost aspects may be difficult to determine with accuracy in advance from a development perspective. This entails a risk that planned development will be more costly than planned. Any setbacks in results and/or delays in clinical trials could have a medium-high to severe impact on time to the company's income generation which, in turn, could increase the need for additional funds.

The company considers the likelihood that the risks described above will occur as high.

### Legal and regulatory risks

#### *Risks related to the intellectual property rights*

Idogen has had one patent granted, and patent applications pending in two patent families. Patents and other intellectual property rights have a limited lifetime, and there is a risk that current and/or future patent portfolios and other intellectual property rights held by the company will not provide adequate commercial protection. Should the company be forced to defend its patent rights from use by a competitor, this could give rise to significant costs, which could have a material adverse effect on Idogen's operations, earnings and financial position. In addition, there is always a risk in this type of operation that Idogen may, or may allegedly, infringe a patent held by a third party. Possible infringement of a third-party patent could also limit opportunities for one or more of the company's potential future partners to freely use Idogen's therapy. Due to the uncertainty associated with patent protection, the outcome of such disputes is difficult to predict. Negative outcomes in disputes over intellectual property rights can lead to lost protection, a ban on the continued use of a particular right or an obligation to pay damages. Moreover, the costs of a dispute, even one with a positive outcome for the company, could be significant, which could have a highly adverse effect on Idogen's profitability. In addition, the aforementioned could result in difficulties and/or lead to delays in future launches or possible out-licensing/sales. Moreover, there is a risk that the company's pending patent applications, and possible future patent applications, will not be granted or only be granted in certain countries, which would affect Idogen's opportunities for the continued development of its drug projects to a great degree.

The company considers the likelihood that the risks described above will occur as medium-high.

#### *Risks related to regulatory approval and registration*

Before commencing clinical trials and marketing and selling treatments, Idogen must obtain regulatory approval and registration in each market from, for example, ethics

committees, the Food and Drug Administration (FDA) in the US and the European Medicines Agency (EMA) in Europe. Should Idogen, directly or indirectly via possible future partners, be unable to obtain the necessary regulatory approval and registration, this could have a negative effect on the company in the form of delayed or, in the worst case, cancelled clinical trials. Views on the company's proposed design of upcoming trials could also lead to delays and/or increased costs for Idogen. The currently applicable rules and interpretations may be changed in the future, which could affect the ability of the company or its possible future partners to meet various regulatory requirements. Moreover, approvals and registrations may also be revoked. Therefore, changes in rules and interpretations and revoked approvals and registration also constitute future risk factors, which could have a medium-high to high adverse effect on Idogen's ability to commercialize and sell any of its drug projects.

The company considers the likelihood that the risks described above will occur as medium-high.

### Risks related to the share

#### *Future new share issues may lead to the dilution of holdings and have an adverse impact on the share price*

Idogen remains at an early clinical development phase and is yet to generate revenue. It is difficult to make a preliminary assessment of when the company can become profitable. Idogen requires additional financing to enable the continued development of the company's drug projects. If new financing is provided through shareholder capital, the new share issues would lead to the dilution of holdings in Idogen for current shareholders, when they do not take part in any such issues. As the date and conditions for any future new share issues will depend on Idogen's situation and market conditions at that time, the company cannot predict or estimate the amounts, date or other conditions for such issues. Such share issues may have a medium-high to high adverse impact on Idogen's share price depending on the conditions for any new share issues.

The company considers the likelihood that the risks described above will occur as high.

#### *Limited liquidity in the share*

There is a risk that an effective and liquid market fails to develop for the company's shares and share-based securities, which could lead to difficulties for a shareholder who wishes to change their holding of shares at the desired time and price. Limited liquidity entails a risk that the listed buy and sell price for the company's shares

does not provide a fair reflection of the value of a large shareholding. Share liquidity is influenced by a number of factors, some of which are investor specific, such as the size of the security holding relative to the share turnover. If active and liquid trading does not develop or is sustainable with Idogen's shares, this may entail difficulties for shareholders who wish to divest their shares at a desired date or at a price that would have been available if the shares had better liquidity.

The company considers the likelihood that the risks described above will occur as medium-high.

## Future Development

Idogen is developing future treatments consisting of cell therapy. The company has now transitioned the production of tolerogenic dendritic cells to a process that can robustly generate clinical trial material for each individual patient in accordance with GMP standards.

## Board Of Directors

The Board of Director's overall mission is to be responsible for the company's organization and administration of the company's affairs. When conducting its mission, the Board has to satisfy the interests of all shareholders. According to the Articles of Association, the Board of Directors should have at least three and not more than eight members.

Members of the Board are elected annually at the Annual General Meeting (AGM) for the period until the end of the next AGM.

The Board held 14 meetings (18) during the year. The Board monitored research findings closely during the year and continuously allocated more resources. During the year, the Board devoted considerable time to the financing of projects.

## 2021 AGM

The Annual General Meeting (AGM) was held on May 11, 2021. Due to COVID-19, the AGM was held in virtual form with postal voting.

Board members Agneta Edberg (Chairman), Leif G. Salford, Sharon Longhurst and Christina Herder were re-elected. The Board was expanded by one member, and Lennart Svensson was elected as new Board member.

The first Corporate Governance Report was presented to the AGM, and approved. The final requirement for compliance with the Swedish Corporate Governance Code was thereby also met.

The Articles of Association were adjusted, and the maximum number of shares was raised to 72,960,000.

The AGM also authorized the Board to implement a private placement totaling a maximum of 4,560,827 shares.

Furthermore, the AGM resolved to continue the multi-year warrants program for management and other employees (second year). A total of 455,000 warrants were issued to eight employees and consultants for subscription of new shares in June 2024 at a price of SEK 5.79 per share.

## Extraordinary Meeting In January 2022

On January 20, 2022, the Board of Directors held an Extraordinary General Meeting that approved the Board's proposal of a rights issue of units containing three shares and six subscription warrants for SEK 3.06 per unit. Each existing share will receive five unit rights, and seven unit rights provide entitlement to subscribe for a unit. The rights issue is underwritten to 100%.

Subscription for the shares took place from January 27 to February 10. Idogen raised MSEK 41 in capital after issue costs.

Through this issue, the number of shares in Idogen increased by 49,436,730, from 23,070,475 to 72,507,205 shares. The share capital in Idogen increased by SEK 34,605,711.00 to SEK 50,755,043.50.

In addition to shares, those who subscribed for shares also received warrant options (T05). Three subscription warrants provide entitlement to subscribe for a new share for 80% of the volume-weighted average rate between August 29 and September 9, though SEK 0.77 per share at the lowest and SEK 1.28 per share at the highest. Subscription will take place from September 15–29, 2022. At a maximum, Idogen could receive additional net proceeds of approximately MSEK 40.5. If the new shares are fully subscribed, the maximum number of shares in Idogen could increase by 32,957,820 to 105,465,025 shares. The share capital could increase by SEK 23,070,474.00 to SEK 73,825,517.50.

## 2022 Annual General Meeting

The Annual General Meeting will be held at 3:00 p.m. on May 4, 2022 in the main building of Spark Medicon Village in the Collaboration conference room, Scheletorget 1, Lund, Sweden.

Shareholders will be notified by announcement in Post- och Inrikes Tidningar (the Swedish Official Gazette) and on the

company's website, as well as by announcement in Svenska Dagbladet that notice has been given, no earlier than six weeks and no later than four weeks before the meeting.

Shareholders who wish to have a matter addressed by the AGM should send a written request to Idogen AB, Medicom Village, Scheelevägen 2, SE-223 81 Lund, Sweden at the latest six weeks prior to the meeting.

## Nomination Committee

In accordance with the AGM's decision, the three largest shareholders at the end of the third quarter of 2021 were asked to nominate their representatives for the Nomination Committee. Tobias Ekman (Chairman), Per Eliasson and Leif G. Salford were appointed to the Nomination Committee. The Nomination Committee's proposal was presented in November.

## Proposed Allocation Of Profit

The Board of Directors and Chief Executive Officer propose that no dividend (SEK 0.0/share, the same as in the preceding year) be paid for the financial year of January 1 – December 31, 2021.

## Proposed Appropriation Of Profit

Amounts in SEK

Funds available for distribution by the AGM:

Share premium reserve	82,408,479
Retained losses	-48,716,816
Profit/loss for the year	-38,854,477
	-5,162,814

The Board of Directors proposes that earnings be disposed as follows: Retained losses (48,716,816) and loss for the year (38,854,477) be settled against the share premium reserve and the remaining share premium reserve (-5,162,814) be carried forward

-5,162,814

Regarding the company's earnings and position in other respects, refer to the following income statements and balance sheets, the statement of changes in equity, the cash-flow statement and the accompanying notes and comments to the accounts.

# Income Statement

Amounts in KSEK	Note	2021	2020
<b>Net sales</b>			
Other operating income	5	13,915	8,113
<b>Total income</b>		<b>13,915</b>	<b>8,113</b>
<b>Operating expenses</b>			
Other external costs	6, 7	-38,828	-21,007
Employee benefit expenses	8, 9	-12,633	-11,934
Depreciation of tangible assets	12, 13	-1,418	-1,325
<b>Total operating expenses</b>		<b>-52,880</b>	<b>-34,266</b>
<b>Operating loss</b>		<b>-38,965</b>	<b>-26,153</b>
<b>Profit/loss from financial items</b>	10		
Other interest income and similar income		296	7
Other interest expenses and similar costs		-186	-677
<b>Total profit from financial items</b>		<b>110</b>	<b>-670</b>
<b>Loss after financial items</b>		<b>-38,854</b>	<b>-26,822</b>
Tax on profit/loss for the year	11	-	-
<b>Loss for the year</b>		<b>-38,854</b>	<b>-26,822</b>

# Statement Of Comprehensive Income

Amounts in KSEK

<b>Loss for the year</b>	<b>-38,854</b>	<b>-26,822</b>
<b>Other comprehensive income</b>	-	-
<b>Comprehensive income for the year</b>	<b>-38,854</b>	<b>-26,822</b>

# Balance Sheet

Amounts in KSEK	Note	Dec 31, 2021	Dec 31, 2020
<b>ASSETS</b>			
<b>FIXED ASSETS</b>			
Tangible assets	12,13		
Leasehold improvements		51	660
Equipment, tools, fixtures and fittings		1,161	1,459
<b>Total tangible assets</b>		<b>1,211</b>	<b>2,119</b>
<b>Total assets</b>		<b>1,211</b>	<b>2,119</b>
<b>CURRENT ASSETS</b>			
Current receivables			
Other receivables		1,266	975
Prepaid expenses and accrued income		5,031	707
<b>Total current receivables</b>		<b>6,297</b>	<b>1,682</b>
Cash and bank balances		15,560	47,041
<b>Total current assets</b>		<b>21,858</b>	<b>48,723</b>
<b>TOTAL ASSETS</b>		<b>23,069</b>	<b>50,843</b>
<b>EQUITY AND LIABILITIES</b>			
<b>EQUITY</b>	14		
Restricted equity			
Share capital		16,149	12,770
<b>Total restricted equity</b>		<b>16,149</b>	<b>12,770</b>
Non-restricted equity			
Share premium reserve		82,408	76,567
Profit brought forward		-48,716	-21,894
Profit/loss for the year		-38,854	-26,822
<b>Total non-restricted equity</b>		<b>-5,163</b>	<b>27,851</b>
<b>Total equity</b>		<b>10,986</b>	<b>40,621</b>
<b>Current liabilities</b>			
Accounts payable		1,924	1,588
Other liabilities		340	342
Accrued expenses and deferred income		9,819	8,291
<b>Total current liabilities</b>		<b>12,083</b>	<b>10,222</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>23,069</b>	<b>50,843</b>

## Statement Of Changes In Equity

Amounts in KSEK	Share capital	Share Premium reserve	Profit brought forward	Loss for the year	Total equity
<b>Opening balance January 1, 2020</b>	<b>3,394</b>	<b>36,829</b>	<b>10,800</b>	<b>-32,694</b>	<b>18,329</b>
Appropriation of profits as per AGM	-		-32,694	32,694	-
New share issues	9,376	50,605			59,983
Capital raising expenses		-10,866			-10,866
Comprehensive income for the year	-	-		-26,822	-26,822
<b>Closing balance December 31, 2020</b>	<b>12,770</b>	<b>76,567</b>	<b>-21,894</b>	<b>-26,822</b>	<b>40,621</b>

	Share capital	Share premium reserve	Other non-restricted equity	Loss for the year	Total equity
<b>Opening balance January 1, 2021</b>	<b>12,770</b>	<b>76,567</b>	<b>-21,894</b>	<b>-26,822</b>	<b>40,621</b>
Appropriation of profits as per AGM	-		-26,822	26,822	-
New share issues	3,379	6,756			10,134
Capital raising expenses		-915			-915
Comprehensive income for the year	-	-		-38,854	-38,854
<b>Closing balance December 31, 2021</b>	<b>16,149</b>	<b>82,408</b>	<b>-48,716</b>	<b>-38,854</b>	<b>-10,986</b>

### Disclosures on shareholdings

Number at January 1, 2021	18,243,308
Number at December 31, 2021	23,070,475
Number of warrants at December 31, 2021	675,000

# Statement Of Cash Flows

Amounts in KSEK	2021	2020
<b>Operating activities</b>		
Operating loss after financial items	-38,855	-26,823
Amortization that does not affect cash flow	1,418	1,325
<b>Cash flow from operating activities before changes in working capital</b>	<b>-37,436</b>	<b>-25,498</b>
Increase/decrease in other current receivables	-4,615	55
Increase/decrease in accounts payable	336	-595
Increase/decrease in other current operating liabilities	1,525	-2,043
<b>Cash flow from operating activities</b>	<b>-40,190</b>	<b>-28,081</b>
<b>Investing activities</b>		
Investment in intangible assets	-	-
Investment in tangible assets	-510	-
<b>Cash flow from investing activities</b>	<b>-510</b>	<b>-</b>
<b>Financing activities</b>		
New share issue	9,220	49,115
<b>Cash flow from financing activities</b>	<b>9,220</b>	<b>49,115</b>
<b>Cash flow for the year</b>	<b>-31,481</b>	<b>21,033</b>
<b>Cash and cash equivalents at the beginning of the year</b>	<b>47,041</b>	<b>26,008</b>
<b>Cash and cash equivalents at year-end</b>	<b>15,560</b>	<b>47,041</b>

# Notes with accounting policies and comments on the financial statements

## Note 1

### General information

Idogen AB is a limited liability company registered and headquartered in Sweden and with its head office in Lund (Medicon Village, Scheelevägen 2). The company's operations are presented in the Administration Report.

The annual report for the financial year ended on December 31, 2021 was approved by the Board of Directors on March 31, 2022 and will be presented for adoption to the AGM on May 4, 2022.

## Note 2

### Accounting policies

#### Summary of important accounting policies

The most important accounting policies applied in the preparation of this annual report are described below. These policies have been applied consistently for all years presented, unless otherwise indicated.

The company's functional currency is SEK (Swedish kronor), which is also the company's presentation currency. This means that the financial statements are presented in thousands of SEK. All amounts, unless otherwise stated, are specified in SEK.

#### 2.1 Basis for preparing the financial statements

The annual accounts are prepared according to the Swedish Annual Accounts Act and RFR 2 (Swedish Financial Reporting Board) Accounting for Legal Entities. Since the company is not included in any group, IFRS-compliant financial statements are not applicable.

It is stated in RFR 2 that a company must apply IFRS as adopted by the EU as far as this is possible within the framework of the Swedish Annual Accounts Act and the Swedish Pension Obligations Vesting Act, and with consideration for the relationship between accounting and taxation. The recommendation sets out the exceptions and additions to IFRS that may be applied.

The company has only one reportable operating segment.

#### Effects of new or changed IFRS standards on the company's accounting policies

##### Amended accounting policies

The changes in RFR 2, Accounting for Legal Entities, that were effective in earlier periods referred to IFRS 16 Leases.

This new lease standard mainly entails changes in how lessees recognize leases. A lessee is required to recognize all leases as assets and liabilities on the balance sheet, unless the lease term is 12 months or less or the underlying asset has a low value.

##### Adopted changes in RFR 2 that are not yet in effect

The Swedish Financial Reporting Board has also adopted a number of changes that are not yet in effect. These are not expected to affect Idogen.

#### 2.2 Foreign currencies

Monetary assets and liabilities denominated in foreign currency are reported using the closing rate. Transactions in foreign currency are restated using the exchange rate at the date of the transaction.

#### 2.3 Income taxes

Income tax recognition includes both current and deferred taxes. The tax is recognized in profit or loss, unless it pertains to items recognized directly in equity. In such cases, the tax is also recognized in equity.

Deferred tax is recognized according to the "balance sheet" method for all significant temporary differences.

A temporary difference exists when the carrying amount of an asset or liability is greater than its tax base. Deferred tax is calculated using the tax rate enacted by the balance-sheet date (the 2020 tax rate was lowered from 21.4% to 20.6% in 2021). Deferred tax assets are recognized to the extent it is probable that future taxable profit will be available against which the temporary differences can be utilized.

At December 31, 2021, deferred tax assets tax pertaining to unused tax loss carry forwards amounted to approximately MSEK 204 (166), which gave rise to a deferred tax asset of MSEK 42 (34). Deferred tax has not been recognized for the loss carry forwards because management cannot yet determine when the tax loss can be utilized against any future tax surplus. As a result, the company has no tax expense, nor measurement of deferred tax.

#### 2.4 Intangible assets

Because the company is in research stage, expenses are recognized as costs.

Development expenses are recognized as an intangible asset when they meet the following criteria:

- it is technically and commercially feasible to complete the intangible asset

- there is an intention and ability to sell or use the intangible asset
- it is probable that the asset will generate future economic benefits or lead to cost savings
- the expenditure can be measured reliably

The cost of an internally generated intangible asset comprises all directly attributable costs necessary to create, produce, and prepare the asset to be capable of operating in the manner intended by management. Internally generated intangible assets are amortized over their estimated useful lives.

No patent costs were capitalized since the costs relate to various patent applications.

## 2.5 Tangible assets

Tangible assets comprise expenses for improvements to leaseholds and equipment. Leasehold improvements on third party property are depreciated over the outstanding lease term for the premises. Equipment is depreciated according to plan.

Tangible assets are recognized at cost less depreciation. The cost includes expenses directly attributable to the acquisition of the asset.

The straight-line depreciation method is used over the estimated useful life of the asset as follows:

Expenses for improvements to third party property (lease term) ....	4 years
Equipment .....	5 years

## 2.6 Leases

All leases for which the company is the lessee are recognized as operating leases. Lease payments are recognized as a cost on a straight-line basis over the lease term.

## 2.7 Provisions

Provisions are recognized when the

company has, or may be considered to have, an obligation resulting from a past event and it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation. One condition is that the amount of the obligation can be estimated reliably.

## 2.8 Financial instruments

Due to the connection between accounting and taxation, the company has decided, in accordance with RFR2, not to apply IFRS 9 but instead to apply a method based on cost pursuant to the Annual Accounts Act.

### Receivables

Other receivables are recognized as current assets, since there are no items with a maturity later than 12 months, when they are recognized as fixed assets. Receivables are recognized at the amount expected to be received, after individual assessment.

### Cash and cash equivalents

Cash and cash equivalents cover cash on hand and bank balances, and cases where items classified as short-term investments have a maturity of less than three months.

### Liabilities

Liabilities are recognized at amortized cost with application of the effective interest method.

## 2.9 Employee benefits

Employee benefits are in the form of paid out salaries and earned holidays, with a reserve for social security expenses. Pension expense paid according to ITP1. The pension is a defined-contribution plan.

Remuneration of various people who are consultants is paid according to consultancy agreements, under which the individual consultant is responsible for salary, pension and social

security expenses, as well as for own work equipment.

There are two stock option programs for employees (refer further to pages 47–48). Share-based remuneration that is settled with equity instruments is measured at fair value at the point in time of allocation, which is the point in time when the company signs agreements on share-based remuneration. The fair value established at the point in time of allocation is recognized as stock option premium paid and recognized against the share premium reserve. Fair value has been calculated using the Black–Scholes model.

Any "stay put" bonus attributable to the share-based remuneration is capitalized in the same manner as the cost of the services received over the maturity of the stock option program.

## 2.10 Statement of cash flows

The cash flow statement is prepared using the indirect method. The recognized cash flow only includes transactions resulting in cash inflows and cash outflows. The company classifies cash and cash equivalents, in addition to liquid funds, as balances of liquid current assets that can easily be converted into a known cash amount and carry an insignificant risk of changes in the asset value.

## 2.11 Recognition of state support

State support is recognized as other operating income in the same period as the costs incurred for the project. In 2018, Idogen received support from the EU pertaining to Horizon 2020. The support was paid in advance in several tranches, and recognized as prepaid income. These have been settled on a quarterly basis in conjunction with the costs for the support arising. At the end of 2021, one payment from the EU remained. However, costs corresponding to this

support have already been paid, and this portion will thereby be recognized as accrued income.

## Note 3

### Estimates and assessments

Preparing the financial statements in accordance with RFR 2 requires that company management make judgments, estimates and assumptions that affect the carrying amounts of assets and liabilities, other information provided in the annual accounts and the income and expenses recognized during the period. Estimates, assessments and assumptions are reviewed regularly. The actual outcome may differ from these assessments, estimates and assumptions. The estimates and assumptions with a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities are primarily intangible assets. Where there is an indication of impairment of an asset, the recoverable amount of the asset is determined. If the carrying amount of the asset exceeds its recoverable amount, the carrying amount of the asset is reduced to its recoverable amount.

## Note 4

### Financial risk management

The company is exposed to various types of financial risks that could give rise to variations in profit/loss for the year, cash flow and shareholders' equity. In addition, the company is exposed to financing and liquidity risk.

The financial risks can primarily be divided into the following categories: market risk (including currency risk, interest-rate risk and price risk), credit risk and financing and liquidity risk.

#### Currency risk

Future sales may be denominated in both SEK and foreign currency. The various purchases are denominated in SEK and foreign currency (increased portion). At present, Idogen is not exposed to any significant currency risk and has no activities designed to delay the effects of currency fluctuations.

The EU grant paid in EUR results in a currency risk that is reduced by exchanging some parts of the grant into SEK and by paying project costs in EUR.

#### Interest-rate risk

Idogen has no loans but has considerable amounts of cash which are currently not interest bearing. An increase in interest rates could result in financial income on the cash.

#### Price risk

The company has no investments that could give rise to price risk.

#### Credit risk

The company has no accounts receivable and thus no credit risk

#### Financing and liquidity risk

Financing risk is defined as the risk that costs will increase and financing opportunities will be limited, and that payment obligations cannot be met due to insufficient liquidity or difficulties in obtaining funding.

The company works continuously to address liquidity and supply of capital. The supply of capital could come from private placements and rights issue, various grants and, in the future, through income.



## Note 5

### Other operating income (grants)

	2021	2020
Recognition of EU grant	13,663	7,813
Other support	252	300
<b>Total</b>	<b>13,915</b>	<b>8,113</b>

Total EU research funding of EUR 2,868,734. Of this total, EUR 1,290,930 (MSEK 12.7) was received on January 3, 2018, another EUR 295,075 (MSEK 0.3) on December 18, 2018 and EUR 550,455 (MSEK 6.0) on March 31, 2020. EUR 301,964 (MSEK 3.1) was received in 2021. EUR 430,310 (MSEK 4.5) remains, which is expected to be paid out during 2022. The funding will be recognized as revenue over time, as project reports are submitted. As of the closing of the 2021 annual accounts, the entire grant has been recognized in profit or loss.

## Note 6

### Operating leases

	2021	2020
Future minimum lease fees, which are to be paid in respect of non-cancellable leases:		
Fall due for payment within one year	504	1,081
Fall due for payment within one to two years	-	450
Fall due for payment within two to three years	-	-
Fall due for payment within four years	-	-
<b>Total</b>	<b>504</b>	<b>1,531</b>
Lease fees expensed during the period	1,184	990

Leases pertain to rental agreements for office premises at Medicon Village as well as previous car leases.

The leases are classified as operating leases, whereby lease fees are distributed straight line over the lease term.

## Note 7

### Remuneration of auditor

	2021	2020
Deloitte AB		
Audit	207	230
Other assignments	-	-
<b>Total</b>	<b>207</b>	<b>230</b>

Fees and compensation for expenses are divided into four components: Audit work (refers to examination of the annual accounts and accounting records and of the Board of Directors and Chief Executive Officer's administration), other audit work, taxation and other assignments.

## Note 8

### Remuneration of the Board of Directors

2021	Fees	Other remuneration	Pension	Other benefits	Total
Chairman of the Board	300	77	-	-	377
Other Board members	525	27	-	-	553
<b>Total</b>	<b>825</b>	<b>105</b>	<b>-</b>	<b>-</b>	<b>930</b>

The fees resolved are KSEK 300 for the Chairman of the Board and KSEK 150 per Director. Fees are paid in the various years they are earned. The Chairman of the Board received remuneration for contributions to Vinnova's initiative for ATMP development in Sweden, in which Idogen is participating (other remuneration). Board member Sharon Longhurst performed assignments concerning CMC in 2021. Board member Karin Hoogendoorn performed assignments concerning CMC in 2020. Refer otherwise to Note 15.

2020	Fees	Other remuneration	Pension	Other benefits	Total
Chairman of the Board	300	167	-	-	467
Other Board members	450	59	-	-	509
<b>Total</b>	<b>750</b>	<b>226</b>	<b>-</b>	<b>-</b>	<b>976</b>

#### Guidelines for the remuneration of senior executives

The General Shareholder Meeting on November 4, 2020 established guidelines for individuals who are part of Idogen AB's ("Idogen" or the "Company") management team. The management team currently comprises the CEO, CFO, CSO, CTO, CBO and Patent Manager, CMO and CRO. The guidelines also cover any remuneration of Board members for work in addition to Board fees. The guidelines can be found in full in the Corporate Governance Report.

## Note 9

### Salaries, other remuneration and social security expenses

	2021	2020
<b>Average number of employees</b>		
Women	9	9
Men	2	2
<b>Total</b>	<b>11</b>	<b>11</b>

#### Salaries, remuneration, social security contributions and pension expenses

Salaries and remuneration of other employees	6,189	5,499
Social security contributions according to law and agreement	1,869	2,090
Pension expenses for other employees	587	492
<b>Total</b>	<b>8,637</b>	<b>8,080</b>

2021	Salary/Fees	Other remuneration	Pension	Other benefits	Total
CEO Anders Karlsson	1,885	269	551	10	2,715
Other members of Management (7 persons)	9,461	102	263	-	9,827
<b>Total</b>	<b>11,346</b>	<b>371</b>	<b>814</b>	<b>10</b>	<b>12,542</b>

2020	Salary/Fees	Other remuneration	Pension	Other benefits	Total
VD Anders Karlsson	1,874	262	550	26	2,712
Övrig ledningsgrupp (7 personer)	8,714	-	217	67	8,998
<b>Totalt</b>	<b>10,588</b>	<b>262</b>	<b>707</b>	<b>93</b>	<b>11,710</b>

The current CEO Anders Karlsson has been employed since August 20, 2019.

Two of the senior executives are employees with a period of notice of three to six months.

Employees have a normal pension expense according to ITP1. In 2021, there were 7 senior executives (7).

The senior executives who have consultancy agreements receive fixed remuneration per hour or day. Apart from that, they have no benefits. The various consultancy agreements are subject to a period of notice of three months.

## Note 10

### Profit/loss from financial items

	2021	2020
Exchange-rate gains	296	7
Interest expenses	-2	-1
Exchange-rate losses	-184	-676
<b>Total</b>	<b>110</b>	<b>-670</b>

## Note 11

### Tax on profit/loss for the year

	2021	2020
Recognized loss before tax	-38,854	-26,822
Tax calculated at current tax rate (20.6%)	8,004	5,740
Tax effect of non-taxable income	-	-
Tax effect of non-deductible expenses	-113	-120
Tax effect of capital-raising expenses entered against equity	188	2,325
Loss carry forwards not assigned a value	-8,079	-7,945
<b>Recognized tax expense</b>	<b>0</b>	<b>0</b>

Unused tax loss carry forwards amounted to approximately MSEK 204 (166).

In accordance with the accounting policies, the company's tax loss carry forwards are not recognized as assets.

## Note 12

### Tangible assets

	2021	2020
<b>Leasehold improvements</b>		
Opening cost	2,255	2,255
Capitalized expenditure for the year	-	-
<b>Closing accumulated cost</b>	<b>2,255</b>	<b>2,255</b>
Opening depreciation according to plan	-1,595	-986
Depreciation according to plan for the year	-609	-609
<b>Accumulated depreciation according to plan for the year</b>	<b>-2,204</b>	<b>-1,595</b>
<b>Closing residual value according to plan</b>	<b>51</b>	<b>660</b>

## Note 13

### Equipment, tools, fixtures and fittings

	2021	2020
Opening cost	3,577	3,577
Capitalized expenditure for the year	510	-
<b>Closing accumulated cost</b>	<b>4,087</b>	<b>3,577</b>
Opening accumulated depreciation	-2,117	-1,402
Depreciation according to plan for the year	-809	-715
<b>Depreciation according to plan for the year</b>	<b>-2,927</b>	<b>-2,117</b>
<b>Closing residual value according to plan</b>	<b>1,161</b>	<b>1,459</b>

## Note 14

### Shareholders' equity

One Idogen AB share has a quotient value of SEK 0.7.

At the end of the financial year, the number of shares was 23 070 475 (18 243 308) and share capital amounted to KSEK 16,149 (12,770).

## Note 15

### Related-party transactions

In addition to Board duties, the Chair of the Board, Agneta Edberg, was paid KSEK 77 (167) for her contributions to Vinnova's Swelife and CAMP projects. Board member Sharon Longhurst performed consultancy assignments in 2021 totaling KSEK 28 (0).

## Note 16

### Significant events after year-end

The Extraordinary General Shareholders Meeting in January approved the rights issue that was completed in February and generated proceed of MSEK 50.4.

Application to the Swedish MPA was submitted in December and answers to the reply was submitted in January. The application was approved in March. Corresponding process is on-going for Norway.

The war in Ukraine has no influence on Idogen as the Company has no business with Ukraine or Russia/Belarus.

The company's income statement and balance sheets will be presented to the AGM on May 4, 2022 for adoption and are thereby approved for publication.

The Board of Directors and the CEO affirm that the annual accounts have been prepared in accordance with generally accepted accounting standards and RFR 2 (Swedish Financial Reporting Board), and provide a true and fair view of the company's earnings financial position.

The Directors' Report for the company provides a fair review of the development of the company's operations, earnings and financial position, and describes material risks and uncertainties facing the company.

**Lund, March 31, 2022**

**Agneta Edberg**

Chairman of the Board

**Christina Herder**

Board member

**Sharon Longhurst**

Board member

**Leif G Salford**

Board member

**Lennart Svensson**

Board member

**Anders Karlsson**

Chief Executive Officer

Our audit report was issued on March 31, 2022

**Deloitte AB**

**Maria Ekelund**

Authorized Public Accountant

# Auditor's Report

## To the general meeting of the shareholders of Idogen AB corporate identity number 556756-8521

### *Opinions*

We have audited the annual accounts of Idogen AB for the financial year 2021-01-01 - 2021-12-31. The annual accounts of the company are included on pages 46-55 in 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 Idogen AB as of 31 December 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 Idogen AB in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

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

### *Other Information than the annual accounts*

This document also contains other information than the annual accounts and is found on 1-45. The Board of Directors and the Managing Director are responsible for this other information.

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

In connection with our audit of the annual accounts, our responsibility is to read the information identified above and consider whether the information is materially

inconsistent with the annual accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

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

### *Responsibilities of the Board of Directors and the Managing Director*

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and 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 the 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 Idogen AB for the financial year 2021-01-01 – 2021-12-31 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit to 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 Idogen AB 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.

Malmö March 31<sup>st</sup> 2022

**Deloitte AB**

Signature on Swedish original

Maria Ekelund  
Public Authorized Auditor

# Corporate Governance Report

Idogen AB (publ), "Idogen" or "the company" is a Swedish public limited company listed on Nasdaq First North Growth Market in Stockholm. Idogen's corporate governance is based on Swedish laws, the Articles of Association, Nasdaq Stockholm's Rule Book for Issuers, and internal regulations and provisions. The company is applying the Swedish Corporate Governance Code ("the Code") for the second time. The complete Code is available at [www.bolagsstyrning.se](http://www.bolagsstyrning.se).

## Corporate governance

The trust of the company's markets, owners and the public are paramount to Idogen's continued success. It assumes that the Board of Directors and management act in a responsible, dedicated and transparent manner. Therefore, it is reassuring that the company has had a well-functioning Board during the year that has constructively analysed and decided on key issues regarding the company's long-term financing and the progress of its development projects.

Equally important for Idogen's credibility is openness to the market and that the company provides information regularly regarding initiatives and the outcome of these in the operations. This is the basis of a value-creating relationship with all stakeholders where both existing and new shareholders should feel confident that they receive the correct information at the right time.

## Application of the Code

The Code applies to all Swedish companies whose shares are listed on a regulated market in Sweden. The company is not required to comply with all the rules in the Code since the Code provides that companies may deviate from the rules providing that they report each deviation, describe their own solution and explain why in the corporate governance report (in accordance with the "comply or explain" mechanism).

To date, Idogen has chosen not to appoint any Board committees, but instead, the entire Board of Directors has served as the audit and remuneration committees. This is justified by the fact that the Board of Directors is comprised of only five members, and considering the size of the company in terms of employees and consultants. One period during the year was not audited due to a heavy workload in the company, with clinical trials and a new share issue.

Due to the coronavirus pandemic, various meetings were held in 2021 without physical attendance by the Board of Directors and auditor.

At present, the company has not identified any other deviations from the Code.

## Shareholders

As of June 4, 2020, Idogen's shares have been traded on Nasdaq First North Growth Market in Stockholm. On December 31, 2021, the total number of shares and votes in the company was 23,070,475, distributed among approximately 4,000 shareholders. For more information about the company's ownership structure and major shareholders, refer to page 45 in the Annual Report.

## Articles of Association

Idogen's Articles of Association stipulate that the company's business is to operate within various disease fields including, but not limited to, autoimmune diseases and transplantation; conduct research and development in order to identify future drugs; patent and commercialize new drugs from research; and reposition currently existing drugs as well as any such related activities. The Articles of Association otherwise contain provisions regarding the number of shares, the number of Board members and auditors as well as the Annual General Meeting. The Articles of Association contain no separate provisions pertaining to the appointment or removal of Board members or the amendment of the Articles of Association. The Articles of Association can be downloaded at [www.idogen.com](http://www.idogen.com)

## General meeting

Shareholders exercise their influence over Idogen at the general meeting, which is the company's highest governing body. The general meeting convenes at least once per year and decides on such matters as the adoption of the company's balance sheets and income statements, including the appropriation of the company's profit, discharge from liability for the Board of Directors and CEO, election of the Board of Directors and auditors, fees to the Board of Directors and auditors and procedures for appointment of the Nomination Committee. Amendments to the Articles of Association also require a resolution at the general meeting. Shareholders who wish to participate in the general meeting are required to be registered in the register of shareholders under their own name no later than five days before the meeting, and to notify the

company of their intention to participate no later than the date stipulated in the notice. Shareholders are to attend the meeting in person or via a representative.

The Annual General Meeting is held in Lund, Sweden, during the first half of each year. In conjunction with the third interim report, Idogen's shareholders will be notified of the time and place of the Annual General Meeting as well as their right to have matters addressed at the meeting. Notice of the Annual General Meeting will be published no earlier than six weeks and no later than four weeks before the meeting. Extraordinary General Meetings can be held if the Board of Directors feels there is a need or if requested by the company's auditors or shareholders who hold at least ten percent of the shares.

## Annual General Meeting 2021

Idogen's Annual General Meeting (AGM) was held on May 11, 2021 in Lund. The meeting was fully adapted to the coronavirus restrictions and held solely through postal voting. A total of 5 shareholders voted, corresponding to 7.0% of the total number of votes.

The company's Board of Directors, management, the Nomination Committee and auditors did not attend the Meeting due to coronavirus restrictions.

The following resolutions were made:

Idogen's income statements and balance sheets were adopted. Furthermore, it was decided that dividends for the 2020 financial year would be SEK 0.00 per share.

The Board of Directors and the CEO were granted discharge from liability.

Board members Agneta Edberg, Leif G. Salford, Sharon Longhurst and Christina Herder were re-elected. The Board was expanded by one member, and Lennart Svensson was elected as new Board member. Agneta Edberg was re-elected Chairman of the Board. Re-election of Deloitte AB as the company's auditors, with Maria Ekelund as principal.

Fees to the Board of Directors were unchanged and are presented in the table on page 63 and in Note 8 of the Annual Report.

The principles for the Nomination Committee were approved. Furthermore, an incentive program for company management was approved.

The minutes of the Annual General Meeting were published on the website within one week of the Meeting. Material from the Meeting, such as the notice, minutes

and information about the Nomination Committee is available on Idogen's website under the heading "Investera/Bolagsstämmor" (available in Swedish only). The complete resolutions of the Meeting as listed above are available at the company at the address: Medicom Village, Scheelevägen 2, SE-223 81 Lund, Sweden, and will be sent to shareholders who request a copy.

## Nomination Committee

The Nomination Committee's primary duty is to submit proposals for the composition of the Board of Directors to be decided at the Annual General Meeting. The work of the Nomination Committee begins with reviewing the Board's evaluation of the work performed by the Board of Directors. A presentation of the operations is made by the CEO.

The work of the Nomination Committee is distinguished by transparency and discussion with the ambition of creating a well-balanced Board of Directors in relation to the needs of the company. The Nomination Committee then nominates members to the Board of Directors for the next term, submits proposals for Board and auditor fees, and provides proposals regarding the election of audit firm when applicable.

## Nomination Committee ahead of the 2022 Annual General Meeting

In accordance with the 2021 Annual General Meeting's decision, Idogen's Nomination Committee will, ahead of the 2022 Annual General Meeting, comprise one representative for the three largest shareholders at the end of August 2021. Should a shareholder decline, the invitation passes to the next largest shareholder/group of shareholders.

The first meeting of the Nomination Committee will be convened by the Chairman of the Board who is co-opted at Committee meetings. The composition of the Nomination Committee was announced on November 3 in a press release. Tobias Ekman (Chairman) (representing Tobias Ekman), Per Eliasson (representing Per Eliasson) and Leif G Salford (representing Leif G. Salford and Hans-Olov Sjögren) were appointed to the Nomination Committee.

During the 2021/22 period, in addition to maintaining contact via email and over the phone, the Nomination Committee held one meeting. The Nomination Committee's proposals were presented in a press release in November, and in the notice of the 2022 Annual General Meeting, which is also available on the company's website together with a reasoned statement regarding the proposed Board of Directors.

## Board of Directors

The Board of Directors and, by extension, the CEO, administer the company's affairs on behalf of the owners. The Board appoints the CEO who is responsible for the day-to-day management of the company. How the work and responsibility is divided between the Board and the CEO is described in the Rules of procedure for the Board and the Instructions for the Chief Executive Officer.

The Board is elected by the shareholders at the Annual General Meeting for a term lasting from one annual general meeting through to the end of the next annual general meeting. On behalf of the owners, the Board of Directors is responsible for the administration of the company by setting targets and strategies, assessing operating management and securing follow-up and control systems for the evaluation of set targets. It is also the responsibility of the Board to secure a communication channel and ensure that the company's communication is correct, relevant and reliable.

If more than half of the members are present, the Board constitutes a quorum. According to Idogen's Articles of Association, the Board shall consist of a minimum of three and a maximum of eight ordinary Board members with no deputies. The Board is constituted at the inaugural meeting held immediately after the Annual General Meeting.

## Chairman of the Board

Since 2016, Idogen's Board of Directors has been led by Chairman of the Board Agneta Edberg. The Chairman of the Board is elected by the Annual General Meeting. The Chairman of the Board organizes and leads the work of the Board, ensures that the Board constantly improves its knowledge of the company, conveys the owners' opinions and provides support to the CEO. The Chairman of the Board and the CEO prepare proposals for Board meeting agendas. It is the responsibility of the Chairman to monitor that the Board's decisions are effectively carried out, that the work of the Board is evaluated every year and that the Nomination Committee is informed of the outcome of the evaluation.

## The Board's Rules of Procedure

The work of the Board of Directors is governed by Rules of procedure approved annually. The current Rules of procedure were adopted on May 11, 2021. The Rules of procedure are reviewed annually and establish the duties of the Board and the Chairman of the Board, audit matters, and which reports and financial information the Board will receive ahead of each regular Board meeting.

Decisions regarding Board committees will be made at the inaugural meeting when the Rules of procedure are adopted. An annual review of various policies is performed, in particular, of the information policy.

## Evaluation of the work of the Board

Under the leadership of the Chairman of the Board, the Board will evaluate its work once a year. The evaluation reviews the structure, the flow of information between management and the Board, and the work atmosphere. Furthermore, the focus of the Board's work will be evaluated as well as access to and need for special expertise on the Board. The evaluation is used as an aid to improve the Board's work and communication with company management. In accordance with the Swedish Corporate Governance Code, relevant segments of the outcome will be presented to the Nomination Committee.

## Composition of the Board of Directors, 2021

In 2021, the Board of Directors consisted of five ordinary Board members, with no deputies.

Board members Agneta Edberg, Leif G. Salford, Sharon Longhurst and Christina Herder were re-elected. The Board was expanded by one member, Lennart Svensson. Agneta Edberg was re-elected Chairman of the Board. The Board members possess extensive experience and expertise in research, clinical trials and medical regulations such as finance as well as business and international operations. The composition of the Board complies with the Code's requirement concerning independent members. Information concerning Board members required in accordance with item 10.2 of the Code can be found on page 38-39.

## The work of the Board in 2021

In 2021, Idogen's Board held a total of 14 (18) recorded meetings, of which four per capsulam. Four of the meetings were held in conjunction with the approval of the year-end report and the interim reports. Attendance has been excellent and facilitated by the fact that all meetings have been digital. This has enabled all members to attend all meetings.

The company's CEO and CFO participate regularly in the Board meetings. Members of the Management Team are invited to account for the status of the IDO 8 project within their particular spheres of responsibility. The company's auditor participated in the January Board meeting when the year-end report was approved.

## Board meetings and main issues

Month	No. of meetings	Main items
Feb	1	Research & projects and year-end report Prospectus
Mar	1	Annual General Meeting and Annual Report
Apr	1	Research & projects
May	3	Q1, research & projects, inaugural meeting and policies
Jun	1	Research & projects and allotment of warrants
Aug	2	Q2, research & projects and financing
Sep	1	Research & projects
Oct	2	Q3, allotment of shares (T04), research & projects, evaluation of the Board
Dec	2	Prospectus, new issue, research & projects, budget, evaluation of the CEO

## Attendance of the Board

Name	Independent to company	Independent to shareholders	Remuneration (KSEK)	Attendance Board meetings
Agneta Edberg	Yes	Yes	300	14/14
Leif G. Salford	Yes	Yes	150	14/14
Christina Herder	Yes	Yes	150	14/14
Sharon Longhurst	Yes	Yes	150	13/14
Lennart Svensson	Yes	Yes	75	7/7 (after election)

## CEO and Company management

The CEO is appointed by and receives instructions from the Board. Idogen's CEO for 2021, Anders Karlsson, was responsible for the company's day-to-day management as well as strategic and operating issues in accordance with the Board's guidelines and instructions. The current Instructions for the CEO were adopted by the Board on May 12, 2020. The CEO prepares information and decision-making material in collaboration with the Chairman ahead of Board meetings and presents information at the meetings. The Board regularly evaluates the work of the CEO by following up set targets. A formal evaluation is performed annually that is then discussed with the CEO.

### *Composition of management, 2021*

The CEO has appointed a Management Team that is responsible for various aspects of Idogen's operations. In 2021, in addition to the CEO, the Management Team consisted of seven members:

CFO

CSO

CTO

CBO

CMO

CRO

Projects and information

Most of the company's staff and management work at the company's office in Lund, Sweden. The Management Team

has minuted meetings during which operations-related issues are discussed, measures decided on or referred to the Board, and minuted. Assignments from the Board are followed up and reported back to the Board. Every year, management drafts a business plan and targets for the year ahead that are adopted by the Board during the first quarter. A presentation of the CEO and the Management Team is available on page 40-43, along with information concerning the CEO required in accordance with item 10.2 of the Code.

## Auditors

The external auditors elected by the Annual General Meeting review the administration of the Board and CEO and examine the financial reporting. The auditors are nominated by the Nomination Committee and elected by the Annual General Meeting for a term of one year. The 2021 Annual General Meeting re-elected Deloitte as auditors for the period up until the 2022 Annual General Meeting, with authorized public accountant Maria Ekelund as the auditor in charge. The auditor is tasked with auditing Idogen's annual report and annual accounts, as well as the administration of the Board and the CEO on behalf of the shareholders. In addition to the annual audit, the auditor also audits at least one of the company's annual interim reports (generally Q3). The auditor's fee will be paid in accordance with approved account. Refer to Note 7 for the amount.

## Remuneration

Salaries, remuneration and other benefits to the Board of Directors, the CEO and other senior executives is presented in the Annual Report in Note 9. Remuneration of the Board of Directors can also be viewed in the table on page 63.

### *Guidelines for Remuneration to Senior Executives, 2021*

These guidelines refer to the members of Idogen AB's ("Idogen" or "the company") Management Team. The Management Team currently comprises the CEO, CFO, CSO, CTO, CBO and Patent Officer, CMO and CRO. The guidelines also cover any remuneration of Board members for work in addition to Board fees.

The guidelines are applicable to remuneration agreed, and changes made to remuneration already agreed after adoption of the guidelines at the Extraordinary General Meeting on November 4, 2020 and approved by the Annual General Meeting on May 11, 2021. For senior executives who perform their duties as consultants, relevant segments of the guidelines apply. The guidelines do not cover remuneration decided by the General Meeting, such as fees to Board members and share-related incentive programs.

## **The guideline's promotion of the company's business strategy, long-term interests and sustainability**

Idogen is a biotech company that develops tolerogenic cell therapies to prevent the patient's immune system from attacking biological agents, transplanted organs or the body's own cells or tissues. The term 'tolerogenic' refers to the immune system's selective tolerance of a specific pathogenic or immunostimulatory antigen following treatment with Idogen's therapy. In brief, Idogen's business strategy involves revolutionizing the treatment of several disorders in which the body's immune system does not function as it should, and for which there is a major unmet medical need – such as in autoimmune diseases, organ rejection after transplantation (primary indication: kidneys) and in patients who have developed anti-biologic antibodies. A prerequisite for the successful implementation of Idogen's business strategy and safeguarding of its long-term interests, including its sustainability, is that Idogen is able to recruit and retain senior executives who have the qualification and capacity to achieve set goals. To do so, Idogen must offer competitive remuneration that reflects the market, which these guidelines facilitate.

Idogen has established a rolling share-related incentive program. For a description of the share-related incentive

program, refer to page 75. The Annual General Meeting resolved to implement the share-related incentive program, which is therefore not included in these guidelines.

### **Types of remuneration, etc.**

Remuneration will be in line with market conditions and competitive, and consist of fixed salary, variable cash remuneration, pension benefits and other benefits. The level of remuneration for each individual senior executive will be based on such factors as duties, expertise, experience, position and performance. In addition, the general meeting may – irrespective of these guidelines – decide on share-related and share-price-related remuneration.

Concerning terms of employment that adhere to regulations other than Swedish regulations in terms of pension benefits and other benefits, appropriate adaptations will be made to comply with such statutory regulations or fixed local practice so that the overall intention of these guidelines is met as well as possible.

#### *Fixed salary*

The CEO and other senior executives will be offered a fixed annual cash salary. The fixed salary will reflect the senior executive's competence, sphere of responsibility and performance. A review of the fixed salary should be made annually. For senior executives who perform their duties as consultants, consultant fees will be settled in accordance with agreed invoicing principles.

#### *Variable cash remuneration*

In addition to a fixed salary, the CEO and other senior executives may receive variable cash remuneration in accordance with separate agreements. Variable cash remuneration covered in these guidelines is intended to award achieved targets that promote Idogen's business strategy and long-term interests, including its sustainability. The size of the company and financial position will be taken into account.

The qualification period for the criteria for awarding variable cash remuneration shall be measured over a one-year period and largely based on the Board-set targets. The annual variable cash remuneration may not exceed 35 percent of the fixed annual salary for the CEO and 25 percent of the fixed annual salary for other senior executives, at which point the individual maximum levels will be set based on the individual's position, among other factors. Variable cash remuneration shall not qualify for pension benefits.

In other words, the variable cash remuneration shall be linked to predetermined and measurable criteria set by the Board that may be financial, such as meeting budget, or non-financial, such as delivery in line with project deadlines or significant progress in collaborations with external partners. More than 50 percent of the variable cash remuneration should be based on non-financial criteria. Because the targets link Idogen's financial and operational progress to senior executive's remuneration in a clear and measurable manner, they promote the implementation of the company's business strategy, long-term interests and sustainability.

When the qualification period for the criteria for awarding variable cash remuneration has ended, the outcome will be assessed and determined to what extent the criteria have been met. Idogen's Board, or remuneration committee if such is established by Idogen's Board to carry out these duties, is responsible for said assessment. Fulfilment of financial criteria will be determined based on the company's most recent published financial information. The Board will have the opportunity to, either in whole or in part reclaim variable cash remuneration that subsequently proves to be incorrect.

Additional variable cash remuneration may be awarded in the event of extraordinary circumstances, on the condition that such extraordinary arrangements only be made on an individual level, either with the intent to recruit or retain executives, or as remuneration for extraordinary performance of duties above and beyond the individual's ordinary duties. Such remuneration may not exceed an amount corresponding to 50 percent of the fixed annual salary and may not be awarded more than once a year per individual. Decisions regarding such remuneration will be made by the Board. If Idogen's Board has established a remuneration committee, the Remuneration Committee will be responsible for the preparation of such a decision by the Board.

#### *Pensions benefits*

Pensions, including health insurance, are a defined contribution plan (ITP1). The premiums for defined contribution plans, including medical insurance, may not exceed 35 percent of the fixed annual salary for the CEO or the terms of ITP1 for other senior executives. Extraordinary provisions may be made when these are based on terms of employment or salary renunciation

#### *Other benefits*

Other benefits may consist of life insurance, medical insurance and company cars. Premiums and other associated

costs that refer to such benefits may not collectively exceed 10 percent of the fixed annual salary.

## Termination of employment and severance pay

A maximum six-month period of notice applies for employees terminated at Idogen's initiative. Severance pay, in addition to salary and other remuneration during the period of notice may not exceed an amount that corresponds to six times the cash monthly salary. A maximum six-month period of notice applies when termination is made by the senior executive.

Compensation for commitments to non-compete clauses may be awarded to compensate for any possible loss of income. Such compensation will only be awarded if the former senior executive is not entitled to severance pay. Compensation will be based on the fixed salary at the time of termination, not exceed 60 percent of the fixed salary at the time of termination, and be paid during the period for which the non-compete clause is valid, which will not exceed twelve months after employment is terminated. This will be set off against other forms of income from employment.

## Employee salaries and terms of employment

In the preparation of the Board's proposal for these remuneration guidelines, salary and terms of employment for Idogen's employees have been considered by including data on the employees' total income, the components of remuneration, and increase and growth rate over time, in the Board's basis of decision when evaluating whether the guidelines and the limitations stipulated are reasonable.

## Consultant fees to Board members

To the extent a Board member performs services for the company, in addition to the board assignment, the company will pay market-based consultant fees for such services to the board member or to a board member-controlled company provided that such services promote the implementation of Idogen's business strategy and safeguard Idogen's long-term interests, including its sustainability.

## Preparation and decision-making procedure

Idogen's Board, or remuneration committee if such is established by Idogen's Board to carry out these duties, is tasked with preparing the decision on the proposed guidelines for senior executive remuneration. The Board

shall prepare a proposal for new guidelines at least every fourth year and submit it to the Annual General Meeting. Adopted guidelines shall be in force until new guidelines are adopted by the Annual General Meeting. Idogen's Board, or remuneration committee if such is established by Idogen's Board to carry out these duties, will also monitor and evaluate the program for variable remuneration to Company Management, the application of the guidelines for senior executive remuneration, and the remuneration structures and levels in the company. Neither the CEO nor other members of company management participate in the Board's processing of and decisions regarding remuneration-related matters in so far as they are affected by such matters.

## Derogation from the guidelines

The Board may temporarily resolve to derogate from the guidelines, in whole or in part, if in a specific case there is special cause for the derogation and a derogation is necessary to serve the company's long-term interests, including its sustainability, or to ensure the company's financial viability. As set out above, the duties of any remuneration committee include preparing the Board's resolutions in remuneration-related matters, including any resolution to derogate from the guidelines.

## Information regarding resolved remuneration not yet due for payment

In addition to the obligation to pay regular remuneration such as salary, pension and other benefits, no previous resolved remuneration amounts to any senior executive are outstanding. For further information regarding senior executive remuneration, refer to Note 9 of Idogen's Annual Report.

### *Employee incentive program*

The 2020 Annual General Meeting resolved to introduce a long-term incentive program for senior executives and other key employees (employees and consultants) in the company based on an issue of warrants and the payment of a stay-on bonus ("Warrant Program 2020/2023"). A total of 250,000 subscription warrants were issued to eight different people, at a maximum cost of approximately SEK 320,000.

The 2021 Annual General Meeting resolved to introduce a long-term incentive program for senior executives and other key employees (employees and consultants) in the company based on an issue of warrants and the payment of a stay-on bonus ("Warrant Program 2021/2024").

A total of 445,000 warrants were issued to eight different people, at a maximum cost of approximately SEK 463,000.

After the right issue 2022 a recalculation has taken place of both warrant programs. For 2020/2023 the signing price is 8.69 and the number of warrants is 256,000. For 2021/2024 the signing price is 5.65 and the number of warrants is 456,920. The long-term incentive program is planned to be annually recurring. Subsequently, after evaluating the program, the Board intends to revert with a proposal for a comparable or modified program ahead of future annual general meetings.

## The Board of Directors' Report on Internal Control and Risk Management Concerning Financial Reporting

This internal control report regarding financial reporting is submitted by Idogen's Board of Directors and is prepared in accordance with the Swedish Corporate Governance Code.

### *Background*

According to the Swedish Companies Act and the Code, the Board is responsible for internal controls.

### *Control environment*

The basis for internal controls is the overall control environment. A good control environment is rooted in an organization that has clear decision-making procedures in which responsibility, authority and the flow of communication and resolutions are clearly defined. Idogen has policies, guidelines and process descriptions for the various stages of running the business, from processing transactions to accounting and the preparation of external reporting. Fortnox is used for accounting, storage and backup in the cloud.

### *Risk assessment*

The Board is responsible for identifying and managing material financial risks and the risk of misstatements in external reporting. Every year the Board reviews the need for risk management and drafts written policies for both overall risk management and for specific areas such as exchange rate risks, interest rate risks, etc.

### *Control activities*

Control activities are primarily designed to prevent and detect errors as early as possible so that corrections can be made and shortcomings can be remedied. Procedures and activities have been designed to detect and manage the most material risks related to the financial reporting. The Board receives monthly reports in which the CEO

and CFO account for the most recent period in terms of the company's results and financial position. Routines for monthly financial statements and the annual report are well defined and reporting follows standardized reporting templates, including comments for all material income and balance sheet items. A significant aspect of internal controls is the division of responsibility for procurement, authorization of invoices and payments between different people. This ensures more controls of the company's financial statements, thereby reducing the risk of misstatement.

For the moment, the review indicates that the company's size and risk exposure mitigate an internal audit. It is the Board's assessment that given the existing monitoring and control procedures, there is at this time no need for this.

#### *Information and communication*

Idogen's procedures and systems for communicating information aim to provide the market with relevant, reliable, correct and pertinent information about the company's progress and financial position. The Board has adopted an information policy that stipulates what should be communicated, by whom and in what manner the information shall be released to ensure that the external information is accurate and complete. Financial information is made available regularly in the form of interim reports, annual reports and press releases about news that is share-price sensitive. The material is published in Swedish and English on the company's website.

#### *Follow-up*

The compliance and efficiency of the internal controls is followed up regularly. The company's financial situation and strategy in regard to the financial position is addressed at every Board meeting where the Board receives detailed monthly reports on the financial position and progress of the operations. Every interim report is analysed by the Board, feedback is given and discussed with the CEO and CFO after which it is approved by the Board ahead of publication.

#### *Activities 2021*

Idogen works continuously to minimize risks by eliminating unnecessary manual stages in the company's processes. The company uses Fortnox and digitally authorizes all invoices. The routine for commencing and terminating employment has been improved.

# Auditors report corporate governance

To the general meeting of the shareholders  
in Idogen AB corporate identity number  
556756-8521

## Engagement and responsibility

It is the board of directors who is responsible for the corporate governance statement for the financial year 2021-01-01 - 2021-12-31 and that it has been prepared in accordance with the Annual Accounts Act.

## The scope of the audit

Our examination has been conducted in accordance with FAR's standard RevU 16. The auditor's examination of the corporate governance statement. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

## Opinions

A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2-6 the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the annual accounts and the consolidated accounts and are in accordance with the Annual Accounts Act.

Malmö March 31<sup>st</sup> 2022

Deloitte AB

Maria Ekelund  
Authorized public accountant

# Financial Calendar

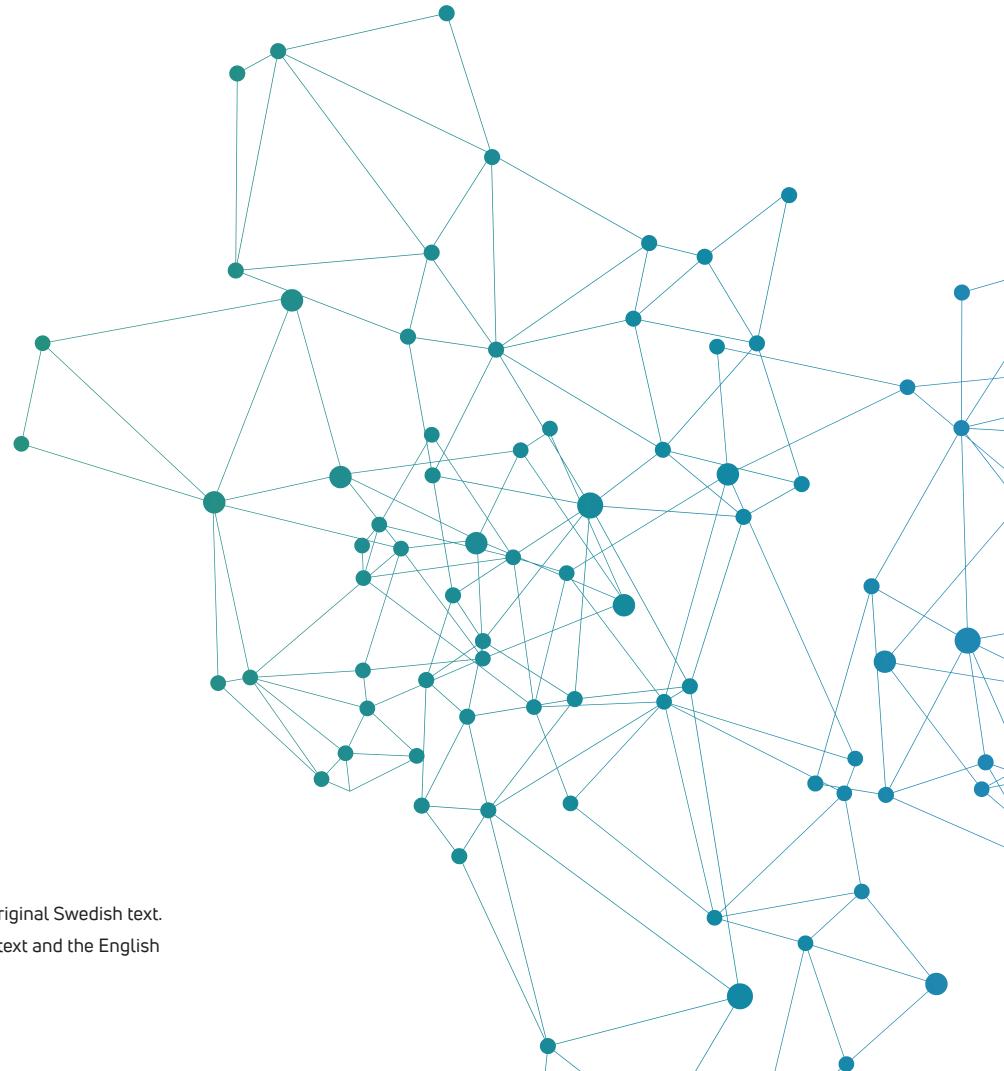
Annual General Meeting .....	May 4, 2022
Interim report January–March 2022 .....	May 4, 2022
Interim report January–June 2022 .....	August 25, 2022
Interim report January–September 2022 .....	October 26, 2022
Year-end report 2022 .....	February 8, 2023

If you have any questions, please contact:

Anders Karlsson, Chief Executive Officer  
Phone: +46 (0) 709 18 00 10  
E-mail: anders.karlsson@idogen.com

## Address

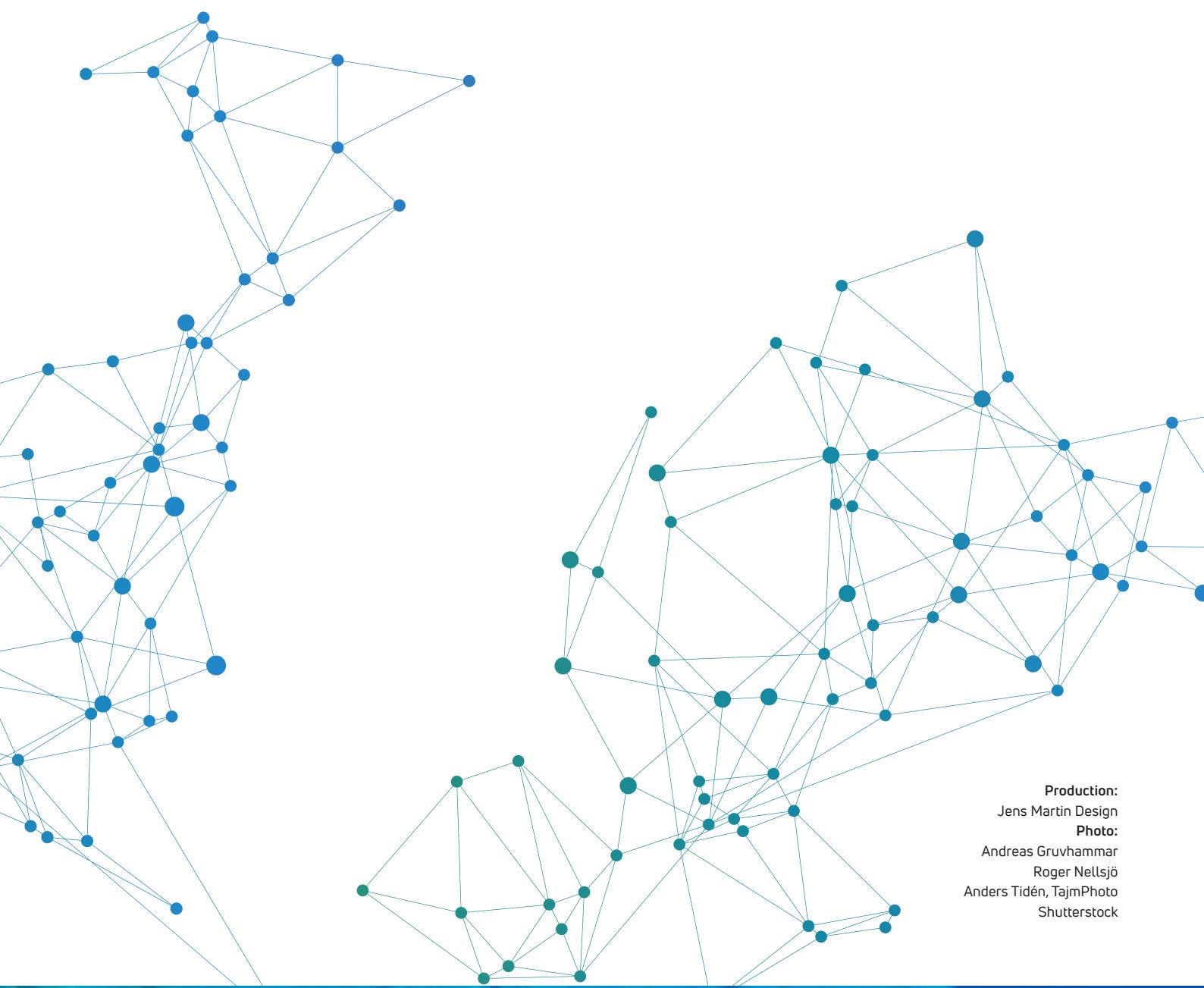
Idogen AB  
Medicon Village  
Scheelevägen 2  
SE-223 81 Lund  
Sweden



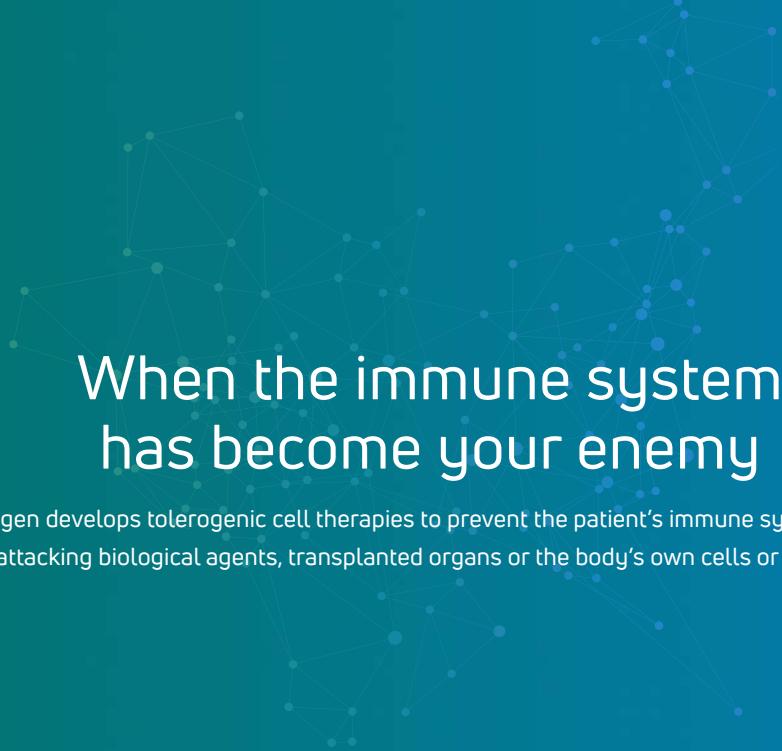
This information is also available in English.

The English text is an unofficial translation of the original Swedish text.

In case of any discrepancies between the Swedish text and the English translation, the Swedish text shall prevail.



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Jens Martin Design  
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## When the immune system has become your enemy

Idogen develops tolerogenic cell therapies to prevent the patient's immune system from attacking biological agents, transplanted organs or the body's own cells or tissues.

