



# Annual Report 2023



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# **MODUS AT A GLANCE**



# **2023 IN SUMMARY**

### Milestones 2023

### Development

- Positive topline and final respiratory and immune cell data from the LPS-challenge study paves the way for further patient studies. Presented at ISICIP (International Symposium on Infections in the Critically III Patient) in October.
- The suppressive effect of sevuparin on the hepcidin hormone is demonstrated in mice and human cells, providing an indication of the potential for anemia in chronic inflammation/kidney disease. Presented at the EHA (European Hematology Association Congress) in May.
- Sevuparin, alone as well as in combination with erythropoietin (standard treatment), counteracts both anemia and kidney deterioration in a preclinical chronic kidney disease mouse model. The study was presented at ASH (American Society of Hematology) in December.

#### **Patents**

- The successful clinical results have enabled 2 new patent applications - based on anemia in kidney disease, as well as on the the LPS study in humans.

### Pipeline

- Long-term research has enabled a broadened pipeline for Modus, which now includes 2 projects in planning phase for Phase IIa (sepsis and anemia in chronic kidney disease), as well as a project with an ongoing study in Phase Ia in severe malaria (in collaboration with Imperial College London and funding from Wellcome).

### Financing

- During December, Modus carried out a rights issue of approximately SEK 19.4 million to finance a first phase IIa study of anemia in chronic kidney disease. The company is now deemed to have sufficient resources to implement its strategy for 2024.

# Key financial figures

TSEK	2023	2022
Net sales	-	-
Operating profit	-16 401	-18 006
Cash equivalents	19 060	10 424
Cash flow from operating activities	-16 684	-21 724
Equity ratio	88%	Neg
Earnings per share*	-1,01	-1,14
Average number of employees	2	2

With positive top-line data for our main candidate sevuparin against serious systemic inflammations such as sepsis and endotoxemia, new research from cell to human that shows sevuparin's potential in additional therapeutic areas as well as secured financing, we have laid the foundation for a new phase in the company's development."

- John Öhd, CEO







<sup>\*</sup> average number of shares during 2023

# A WORD FROM OUR CEO



### 2023 - a year that lays the foundation for a new phase in the company's development

2023 has been a very important and exciting year for Modus Therapeutics. With positive top-line data for our main candidate sevuparin against serious systemic inflammation disorders such as sepsis and endotoxemia. new research from cell to human that shows sevuparin's potential in additional therapeutic areas as well as secured financing, we have laid the foundation for a new phase in the company's development.

During the year, Modus has continued to deliver on the stated goal of a broadened clinical project portfolio which at the same time enables improved intellectual

property protection. Sevuparin's mechanisms of action are now being evaluated in three clinical tracks; anemia (lack of red blood cells) in kidney disease and other conditions with chronic inflammation, sepsis, and severe malaria.

### New data enables expanded pipeline

In line with our ambition to broaden the project portfolio, we were able to present positive preclinical and clinical data regarding sevuparin's potential to treat anemia in chronic kidney disease during the months of June and November/December.

The research, presented at the annual European Hematology Association (EHA) and American Society of Hematology Meeting and Exposition 2023 (ASH), showed consistent results regarding sevuparin's ability to potently suppress the iron-regulating hormone hepcidin in cultured cells, mice and humans. In our research sevuparin was also able to counteract anemia and improve kidney status in mice that developed chronic kidney disease. These data reinforce the potential for a new clinical program for patients with anemia in chronic kidney disease starting with a tailored, two-part phase IIa study. We expect to be able to initiate such a study in the first half of 2024, with estimated reporting of its first part in the first guarter of 2025 and in the beginning of 2026 for its second part.

### Continued way forward for sevuparin in sepsis

At the beginning of the year, positive top-line data from our study regarding sevuparin for the treatment of sepsis were published. The full results were also presented as part of the "best poster presentation" at the annual ISICIP Congress in Barcelona in October.

In this phase Ib LPS challenge study, which was performed on healthy volunteers, both the safety profile and promising effects of sevuparin in induced inflammatory conditions could be confirmed. In addition, sevuparin was judged to be safe and tolerable in combination with the standard blood-thinning

treatment given to patients with acute inflammatory conditions, such as sepsis.

The results are a major milestone for Modus and will form the basis for continued business discussions and for designing the Phase II study planned for sepsis patients - a study expected to begin in 2025, depending on future funding options.

An important step in the future management of sepsis is that new, more effective treatments become available as a complement to today's standard treatments. Modus' hope is that in the future sevuparin will be able to make a difference for patients with sepsis, but there is still need for further awareness in society at large about this serious disease.

This awareness is a prerequisite for the right focus and early care of sepsis, which is "....as common as cancer and as deadly as a heart attack", according to Adam Linder who is a sepsis researcher at Lund University (https://www.medicin. lu.se/artikel/sepsis-lika-vanligt-som-cancer-lika-dodligt-somhjartinfarkt). Therefore, we think that it is a particularly promising development to see the numerous features about sepsis in broad Swedish media during the past six months. Among other things, representatives from the healthcare system and patients spoke on TV4 Nyhetsmorgon and Dagens Nyheter.

### Severe malaria

In parallel with the fact that we were able to advance the projects in sepsis and anemia, the ongoing phase Ib study evaluating sevuparin for the treatment of severe malaria in young children continues. The study is carried out together with Imperial College London and is funded by grants from Wellcome. Today, Modus is unique in developing an additional treatment (adjuvant) that is used early against the acute systemic inflammation in severe malaria, before standard malaria treatments work optimally.

# Successful rights issue ensures the potential of the development work

During the year, Modus successfully carried out a rights issue with pre-emptive rights for existing shareholders as well as a directed issue to our main owner Karolinska Development. Modus is thus provided with financial resources that ensure that the company can proceed on a debt-free basis with an adapted clinical development plan where the primary focus in 2024 will be the first part of the anemia study in patients with chronic kidney disease.

We consider creating a broader clinical pipeline to be a priority as it limits the risks in the business while at the same time opening up opportunities in new markets and strengthening us in dialogues with potential partners. Modus' stated strategy is still to take underlying projects further to market via, for example, partnerships and out-licensing.

As we make clinical progress, we increase the value of the project portfolio and strengthen our position as an interesting partner. In 2023, we delivered on our long-term strategy and I look forward to being able to report on new successes in 2024 where we maximize the value of our project portfolio in various ways.

I would like to take this opportunity to express a special thank you to our existing and new shareholders who have chosen to participate in the issue. Your continued support is invaluable in our endeavor to develop new, effective and safe treatments for high-need diseases with multi-billion dollar market potentials.

John Öhd, CEO Modus



# **SEVUPARIN**

### Multimodal mechanism of action

Modus' vision is to be able to offer effective drug treatment for conditions requiring advanced medical care. By building on sevuparin's unique abilities to neutralize harmful inflammation components, protect the inside of the blood vessels and influence blood formation during inflammation, we make use of its advantageous multimodal mechanism of action to maximize the value of the portfolio and explore the effects in a number of diseases with high unmet medical need.

### The drug candidate sevuparin

Modus' drug candidate sevuparin is based on the well-known drug heparin, which has been marketed for clinical use as an anticoagulant since the 1930s. Thanks to an innovative chemical modification, sevuparin differs from heparin in that it has a greatly reduced blood thinning ability and can therefore be dosed in higher doses compared to standard heparins without the risk of unwanted bleeding. This allows sevuparin to be used in a way that maximizes the potential benefits of heparinoids beyond anticoagulation in critically ill patients. The drug candidate has a confirmed safety profile in humans based on clinical phase II studies in sickle cell anemia and malaria. The patient populations targeted by sevuparin are all those affected by sepsis, severe malaria or anemia in kidney disease and chronic inflammation. By helping these patients, Modus expects to reduce the number of deaths and serious complications as a result of the diseases, increase the patients' quality of life, and through a more efficient clinical course of care, be able to reduce the time spent on costintensive treatment methods for these indications.

### Innovative modification of well-known heparin

Sevuparin is a heparinoid, a hormone that usually has an anticoagulant or blood-thinning effect, a useful property in treating sepsis with blood clots. The fact that heparinoids could be used as part of specific treatment for sepsis is not unknown in preclinical research, but a challenge has been the anticoagulant effects of heparinoids, as the dosage needs to be adjusted to avoid unnecessary risk of bleeding. The same applies to indications such as severe malaria and anemia in chronic inflammation/kidney disease. These are conditions where bloodthinning heparins have already shown beneficial effects, however due to the blood thinning and the risk of bleeding, ordinary heparins cannot be used. Modus has solved this problem by inventing a heparin molecule with a significantly reduced bloodthinning effect, while maintaining the other benefits of the drug. The result is a unique molecule that is based on heparin but that has been chemically modified by changing 3 sugar groups, which also alters the molecule from a typical heparinoid - with anticoagulant properties - to sevuparin, which has a substantially lower anticoagulant effect. The chemically modified sevuparin molecule allows significantly higher doses to be given compared to regular mainstream anticoagulants, without the associated risk of unwanted bleeding - but with retained immunomodulation properties.

#### Multimodal mechanism of action

Effectively, the body's own heparin-like molecules (heparins) have many different roles in healthy and diseased conditions, which forms the basis for sevuparin having the potential to be beneficial in several important and mutually different disease states. Thanks to the confirmed safety profile, sevuparin has

the potential to be used for the treatment of several conditions such as sepsis/septic shock and other conditions with systemic inflammation, e.g. those caused by severe trauma, burns, major surgery and severe forms of malaria. Furthermore, the properties of sevuparin can address anemia conditions in chronic inflammatory diseases such as kidney disease.



# **INDICATIONS**

# Anemia in chronic inflammation / kidney disease (CKD)

### Anemia in chronic inflammation/kidney disease

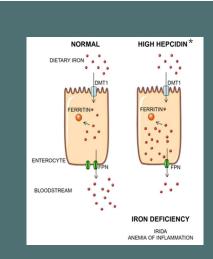
Anemia is defined as a lack of red blood cells or low levels of hemoglobin, the protein in blood cells that binds and transports oxygen. The most common type of anemia is iron-deficiency anemia, as iron is an indispensable component of hemoglobin to be able to bind oxygen molecules. Iron deficiency anemia is often caused by conditions where extra supplementation of iron is sufficient as a treatment, but there is also a large subgroup of diseases where the problem is more severe and where optimal treatment is still lacking. However, in conditions with chronic inflammation, the ability to absorb iron can be significantly impaired. In these conditions, due to the chronic inflammation, a misregulation arises in the hepcidin hormone which should normally protect us from excessively high iron levels. When hepcidin is high, the body cannot absorb iron from the diet nor access iron from the body's stores, which thus leads to a paradoxical iron deficiency despite the fact that iron is available both in the diet and in the body. Anemias that



develop due to high hepcidin are also more resistant to standard treatments such as iron supplementation and bone marrow stimulating treatment called erythropoietin (EPO). A large and specific patient group in this category are those with chronic kidney disease (CKD), which is one of the most common chronic diseases with a global prevalence of 10% in stage 3-5. Studies have shown that anemia is an important aggravating component in CKD, with increased frequency of morbidity and death as well as significantly reduced quality of life. This is also further emphasized by the large amount of resources spent on treating anemia in this group, mainly with EPO. It is well known that the response to such EPO treatment tends to worsen as the disease progresses with increasing levels of the iron-regulating hormone hepcidin. There are currently no registered treatments capable of lowering hepcidin in order to address this severe form of anemia and restore sensitivity to other treatments such as EPO. There is thus a pronounced need for a treatment alternative in the event of failed response to standard treatment.

### Support for sevuparin in kidney disease with anemia

A collaboration ongoing since 2018 with the University of Brescia has provided new preclinical and clinical data highlighting the potential of sevuparin in the treatment of specific anemias. This data was also the basis for the patent application filed by Modus in December 2022. At the European Hematology Association (EHA) 2023 congress, data showing how sevuparin lowers the iron-regulating hormone hepcidin was presented. In particular, high levels of hepcidin are suspected of causing and exacerbating the anemia that often leads to complications in chronic kidney disease and other chronic inflammations. High hepcidin levels also cause resistance to current standard treatments of anemia in non-responsive patients. The data showed how sevuparin, through a specific signaling mechanism,



- The hepcidin hormone is the key player controlling the availability of iron in the body.
- Hepcidin inhibits the mobilization of iron from the body's own cells, resulting in "internal" iron deficiency.
- High hepcidin levels are often associated with anemia in chronic inflammatory diseases such as chronic kidney disease (CKD).
- Resistance and lack of response to standard therapy of anemia is often attributed to increased hepcidin levels.
- Currently there are no approved hepcidin-lowering drugs.
- Anemia in chronic disease/kidney disease constitutes a significant medical need.



suppressed the expression of hepcidin in cell cultures, mice and healthy volunteers. In early November and December, a second part of the results from the collaboration was also made public as the summaries from the American Society of Hematology Meeting and Exposition 2023 (ASH) were published and then presented. The work includes trials in an established kidney disease model with anemia in mice. Similar to humans with kidney disease, mice in the model develop chronic kidney disease with concomitant moderate to severe blood deficiency (anemia). This makes it possible to study the effect of new treatments to see if disease progression can be reduced. The work shows that sevuparin was able to counteract both the increase in hepcidin and anemia in the mice as well as provide some protection to kidney function (by measuring the filtration capacity with the blood test creatinine) and tissue (by looking at the degree of scarring, or fibrosis under a microscope). In addition, the effect of sevuparin in

combination with the standard treatment EPO was evaluated, where sevuparin significantly increased and maintained the positive effect on the anemia, even with a significant dose reduction of EPO to simulate a situation with a lack of treatment response to the standard treatment. Overall, the study results regarding hepcidin, chronic kidney disease and anemia form a very good basis for further clinical development of sevuparin in kidney disease with anemia. With the support of these data, Modus is now preparing a phase 2a study in patients with anemia and CKD including high hepcidin.

Sevuparin forcefully inhibits hepcidin in cell lines, in mice and in healthy voluntary individuals.

In a chronic kidney disease mouse model, sevuparin counteracted anemia, decreased kidney function and fibrosis both alone and in combination with erythropoietin (presented at ASH in December).

Sevuparin demonstrates these effects at safe and tolerable dose levels, supporting its use in chronic inflammation with anemia such as chronic kidney disease (CKD).

# **INDICATIONS**

# Sepsis

### Sepsis in summary

Sepsis, previously known as blood poisoning, is a common, severe and acute disease with high morbidity and mortality. Sepsis and its most progressed and severe form, septic shock, occur when a bacterial infection causes an exaggerated immune response, resulting in strong inflammation that can lead to harmful substances being secreted into the blood by activated white blood cells. These substances risk damaging the inside of the blood vessels, eventually causing leakage of plasma into the tissue. The consequence of this course of events is an increased risk of hampered organ function, and if the condition is not treated, it may lead to acute organ failure and severe tissue damage. In sepsis, it is common to have several symptoms that develop rapidly as a result of the violent inflammation: respiratory collapse, circulatory failure, altered coagulation with blood clots and bleeding, kidney failure and decreased mental awareness that can develop into unconsciousness.

There is currently no drug available specifically intended to treat patients with sepsis and septic shock, although most patients are already being treated with antibiotics against the infection that caused the condition. Instead, the healthcare system uses supportive and broad treatment methods typically used in intensive care, such as fluid therapy, antihypertensive drugs, oxygen, steroids, and respiratory care. The lack of effective treatment for sepsis contributes to its high healthcare costs. In fact, sepsis is currently one of the most expensive conditions to treat in global healthcare. Thus, there are significant benefits to be gained from treatment with drugs that target the specific aspects of sepsis – both in terms of reduced mortality, improved outcomes for patients and reduced treatment costs. Sevuparin has the potential to be such a drug.

### Sevuparin and sepsis

Preclinical research suggests that sevuparin can counteract the harmful effects of systemic inflammation by binding and neutralizing harmful substances secreted by white blood cells and also influencing the behavior of these cells during sepsis and septic shock as well as providing robust vascular protection. These effects were particularly evident on lung tissue in mice where fluid swelling was counteracted by sevuparin. Sevuparin could thus break the molecular chain of events that leads to impaired blood vessel integrity, plasma leakage and ultimately organ failure. In 2023, data was announced from the Modus phase 1b lipopolysaccharide (LPS) challenge study evaluating the efficacy of sevuparin in conditions with induced systemic inflammation similar to that seen in sepsis. Positive data from the study showed effects that correlated well with preclinical data. Treatment with sevuparin contributed to a statistically significant and dose-dependent increase in certain populations of white blood cells that would otherwise decrease in systemic inflammation, as well as a dose-dependent inhibition of increased respiratory rate induced by LPS.

These observations demonstrate clinically relevant and immunomodulatory effects exerted by sevuparin in conditions of systemic inflammation. In a separate part of the Phase 1b study, sevuparin was shown to be safe and tolerable in combination with the blood-thinning heparin treatment enoxaparin. which constitutes a standard treatment for patients in critical conditions, such as sepsis. The positive data from this placebocontrolled Phase-1b clinical trial will be used to design a Phase 2a trial to be performed in sepsis patients.

### **SEPSIS**

Estimated 50 million cases globally/year of which approx. 11 million with fatal outcome

Corresponds to approx. 2 million cases/year in the US and in Sweden exceeds the 4 most common types of cancer

Septic shock, the most severe form, has a mortality of about 30%

No approved treatments specifically intended for sepsis

One of the most costly conditions in hospital care



# **INDICATIONS**

### SEVERE MALARIA

A phase 1b study in severe malaria with sevuparin is ongoing

Sevuparin is the only drug under development as

Severe malaria is caused by infected blood cells that accumulate in the blood vessels of vital organs, causing systemic inflammation and rapid organ failure

Preclinical and clinical evidence shows that sevuparin can enhance accumulation of infected cells and prevent reinfection of new host cells

Current anti-malarial treatments have a lag effect that limits acute usability. Death usually occurs in the first 24 hours

The anti-malarial effect of sevuparin is already observed during the first hour, providing a unique opportunity for benefit in the critical care setting



### Severe malaria in summary

Infection caused by malaria parasites can result in a variety of symptoms, ranging from unnoticeable or very mild symptoms to severe illness and even death. Malaria disease is therefore classified as either uncomplicated or severe. All clinical symptoms associated with malaria are caused by parasites in the blood. When the parasite develops in blood, many known and unknown waste substances are formed, which in turn cause the inflammation giving rise to symptoms. The uncomplicated form causes attacks and transient episodes with symptoms that can be difficult to distinguish from influenza.

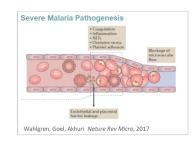
Red blood cells infected with malaria can under certain circumstances become trapped in groups on the inside of blood vessels, so-called sequestration, which is believed to be an important reason for the development of severe malaria. Severe malaria primarily affects children under the age of 5 (other risk groups include pregnant women, tourists and people with immunodeficiency from e.g. HIV/AIDS) and occurs when the infection is worsened early by severe organ failure and major deteriorations in the patient's blood count and metabolism. In addition to the presence of severe anemia, several of the symptoms are similar to those of sepsis/septic shock such as; respiratory collapse, circulatory failure, altered coagulation with blood clots and bleeding, kidney failure and decreased mental awareness that can progress to unconsciousness. As with sepsis, severe malaria is a medical emergency with a mortality rate of 10-20% and should therefore be treated urgently and aggressively. Because severe malaria develops quickly, antimalarial medicines are unable to begin to give effect within the time window that could avert the worst course of severe complications and death. There is thus a lack of treatment that can be administered and respond in time during the acute phase.

### Support for sevuparin as add-on treatment in severe malaria

During the 60s and 70s, it was discovered that ordinary heparin worked as a treatment for severe malaria, and researchers were able to show that it was not due to heparin's blood-thinning properties. However, the form of treatment with heparin in severe

malaria was discontinued after it was found that the occurrence of bleeding was too great a risk. Today, the use of standard heparins in severe malaria is discouraged. Sevuparin was created with the aim of retaining all the properties that heparin has but without blood thinning. Beneficial effects of sevuparin have already been seen in proof-of-mechanism studies on patients with sevuparin without risk of bleeding, and preclinical studies have also shown that sevuparin affects the malaria parasite in the same way as heparin. Sevuparin acts partly by counteracting the sequestration, partly by preventing free parasites in the blood from infecting new blood cells. A problem is also the increasingly widespread development of resistance to the available treatments, where sevuparin has an additional advantage because the mechanism of action is not affected by this type of resistance.

Modus is undertaking a promising clinical development program in collaboration with Imperial College London for the treatment of patients with severe malaria. As with sepsis, there is no specific treatment for severe malaria, and through the collaboration, Modus wants to evaluate the benefits of sevuparin as an early response treatment in intensive care. Imperial College London is conducting the first clinical trial at its facility in Kilifi, Kenya, as well as at a clinic in Zambia. WHO estimated in 2021 that there were 247 million cases of malaria in the world, 619,000 cases were fatal and 80% of these were children. As much as 95% of all cases of malaria as well as the majority of deaths occurred in Africa, emphasizing the importance of focusing on the development of new treatments in this region.





# MARKET OVERVIEW

With sevuparin Modus has its sights set on three challenging indications, each of which has significant potential.

### Anemia in chronic kidney disease

Anemia is a global health challenge affecting approximately 2.3 billion people - 25% of the world's population. The most common type of anemia is iron deficiency anemia, which affects almost a billion people. Chronic kidney disease is also very common with a global prevalence of 10% if you count the more serious forms (CKD stage 3-5). The global mortality rate for chronic kidney disease was estimated in 2017 at 1.4 million, making it the 12th leading cause of death globally. Anemia is one of the most serious complications of chronic kidney disease where approximately 25% of all patients with with chronic kidney disease (CKD stage 3-5) are estimated to have anemia, which corresponds to 4.5 million patients on the US market. It is well known that these patients have worse prognosis without adequate standard treatment.

The course of CKD is chronic with long treatment times, which is reflected in the market potential even if it is based on a conservative assumption that sevuparin would be used only in those who do not respond or who lose response to the standard treatment EPO (hyporesponders). Modus and the external valuation company XPLICO identify the addressable market for sevuparin in CKD/Anemia as anemia in CKD for level 3-5. It is estimated that this will include more than 7 million patients for 7MM in 2038, which represents a billion-dollar market. The potential in this area can be exemplified by previous deals in the billion-dollar class (Otsuka Holdings-Akeba 2016/17, https:// www.genengnews.com/news/otsuka-akebia-expand-vadadustatdevelopment-deal-to-europe- and-beyond/), as well as reflected in the market capitalization of a company like Disc Medicine (NASDAQ: IRON, \$784 M, at market close on April 8, 2024).

### Sepsis

According to the WHO, sepsis may be the leading cause of death in the world. In 2017, sepsis accounted for 11 million deaths, which corresponds to 19.7 percent of all deaths globally. In the USA it corresponds to approximately 2 million cases/ vear and in Sweden it exceeds the four most common types of cancer. Septic shock, the most serious type of sepsis, is one of the leading causes of death in intensive care around the world, with a mortality rate of around 30%. There are no drugs available specifically for the treatment of sepsis and septic shock, although many are already treated with antibiotics for the infection that caused the condition. In the absence of effective treatment, the diagnosis and treatment of sepsis and septic shock remain extremely cost-intensive. In the United States, it is estimated that sepsis costs the healthcare system about \$22 billion each year, an increase of \$5 billion since 2012.

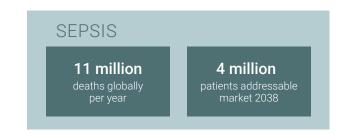
Sepsis is a vital indication and places itself in the high price segment for medicines. Modus and the external valuation company XPLICO identify the target market for sevuparin in sepsis as patients treated for septic shock, which includes approximately 700 thousand patients for 7MM and a total sales potential of approximately USD 6 billion in 2038, or as patients diagnosed with sepsis in which case the market is about 5 times as large.

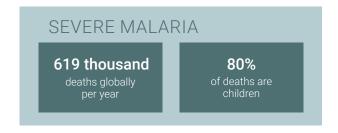
### Severe malaria

Severe malaria develops rapidly and is a serious sepsis-like condition caused by the malaria parasite, mainly in young children and with a mortality rate of 10-20%. Available standard treatments are effective in disease manifestations if administered in time, but there is a lack of an adjuvant treatment that can be given immediately and that counter effects the mechanism causing the severe symptoms. Another problem is the increasingly widespread development of resistance to the available treatments, where sevuparin has an additional advantage because the mechanism of action is not affected by this type of resistance.

The WHO estimated in 2021 that there were 247 million cases of malaria in the world, whereof 619,000 cases with a fatal outcome and 80% of these were children of which 475,000 were under the age of 5. As much as 95% of all cases of malaria, including deaths, occur in Africa, which underlines the importance of focusing on the development of new treatments in this region.







# **CLINICAL PROGRAM**

### MODUS PIPELINE

- Maximizing the potential of sevuparin in acute and advanced care settings
- Enables risk diversity through increased flexibility of product and business development

Indication	Collaboration	Preclinical	Phase la	Phase Ib	Phase IIa	Phase IIb	Phase III
Sepsis	Internal	Sepsis	/septic chock		Planning Phase	lla	
CKD/Anemia	Internal	CKI	D/Anemia		Planning Phase		
Malaria	Collaboration*	Severe malaria (ong	joing study No	v -23)			

CKD: Chronic Kidney Disease

### Successful early research as the base for continued development of sevuparin

Sevuparin has undergone preclinical toxicology testing, the results of which enable dosage for up to 14 days in clinical studies. Preclinical in vivo effectiveness studies on mice have also shown beneficial effects on various disease models for. among other things, sickle cell anemia and malaria. Studies have also been carried out on experimental models in mice and in vitro human cells for sepsis. Clinical trials in healthy volunteers in a phase I study have shown that sevuparin is safe and tolerable for single and multiple intravenous administration within clinically relevant dose ranges. Two patient studies (phase Ib and II) further showed that sevuparin has inhibitory effects on the malaria parasite's ability to bind to blood cells and the vessel wall. In a larger phase II study in the treatment of acute sickle cell anemia, sevuparin was shown to have a favorable safety profile, although no improvement in disease status could be observed compared to placebo.

#### Sepsis

In 2023, Modus reported positive data from the Phase Ib lipopolysaccharide (LPS) challenge study for the evaluation of sevuparin in the treatment of sepsis and other conditions with systemic inflammation. In this study, healthy subjects received LPS to induce a transient endotoxemic and systemic inflammatory response together with one of three dosage levels of sevuparin or placebo for 6 hours. These were then followed up 24 hours after the treatment. LPS challenge is a well-established model for the study of endotoxemia and septic inflammation through the induction of a number of measurable symptoms.

All three dosage levels of sevuparin were found to be safe and tolerable during the study period, confirming a favorable safety profile for the drug candidate in induced inflammatory conditions. Furthermore, treatment with sevuparin showed a statistically significant and dose-dependent increase in certain populations of white blood cells as well as dose-dependent inhibition of increased respiratory rate induced by LPS. These results indicate clinically relevant and immuno-modulatory effects caused by sevuparin in systemic inflammation.



<sup>\*</sup> In collaboration with Imperial College London and financed by Wellcome



### Anemia and chronic kidney disease

Together with the University of Brescia, Modus is also evaluating sevuparin's potential as a treatment option for disease conditions with high levels of the iron-regulating hormone hepcidin, such as anemia in chronic inflammation and kidney disease as well as certain other chronic inflammatory diseases.

Compelling data presented at the European Hematology Association (EHA) in June 2023 demonstrate sevuparin's potential as a treatment for anemia in chronic diseases. The dataset demonstrates sevuparin's ability to reduce the level of the hormone hepcidin as well as reduce the signals that play an important role in blocking the body's access to iron for vital physiological processes, including the formation of hemoglobin and red blood cells. These robust results from preclinical cell and animal models as well as clinical observations in human subjects demonstrate the ability of sevuparin to suppress hepcidin levels at clinically safe dosing levels, thus providing clear evidence for its ability to modulate the effects of hepcidin. In addition, data from a disease model in mice with chronic kidney disease, which was presented at the annual meeting of the American Society for Hematology (ASH) in December 2023, showed that sevuparin alone and together with the standard treatment erythropoietin had a positive effect on both anemia and kidney status in the mice. The results make sevuparin a promising candidate for the treatment of diseases with high hepcidin and anemia, eg in chronic kidney disease, and reinforce Modus' intention to plan for a new Phase IIa clinical program with sevuparin in such patients.

Conducted studies support Phase II development of sevuparin in sepsis and anemia in chronic kidney disease. The combined data from these studies provide a strong incentive for Modus to continue the clinical development of sevuparin both for sepsis/septic shock and chronic kidney disease with anemia and other chronic inflammatory diseases.

#### Severe malaria

Another promising clinical development program with sevuparin is underway in collaboration with Imperial College London for treatment of patients with severe malaria. Similar to sepsis, there is no specific treatment for severe malaria, and in our collaboration we want to evaluate the benefits of sevuparin as an early response treatment in

intensive care. Imperial College London is conducting the first clinical trial at its facility in Kilifi, Kenya, as well as at a clinic in Zambia. The phase Ib study SEVUSMART evaluates dose level and tolerability/ safety in combination with the standard treatment in severe malaria in up to 20 pediatric patients between the ages of 3 months and 12 years. The study investigates the potential of sevuparin as supportive treatment (adjuvant treatment) in children affected by severe malaria, which means that the disease causes a type of systemic systemic inflammation similar to sepsis. The SEVUSMART study is a collaboration between Modus, Imperial College London in Great Britain, who run the study, and Wellcome, who finance the study.

# **BUSINESS MODEL & COLLABORATIONS**

### **Business model**

As sevuparin has the potential to be the only drug for the specific treatment of sepsis and is the only adjuvant treatment in development for severe malaria as well as for anemias associated with chronic inflammation, Modus expects that market interest in sevuparin will be significant pending favorable clinical trial outcomes. Modus' business model is to independently drive the development of sevuparin through phase IIa proof-of-concept studies both in the anemia indication for kidney disease patients and in the sepsis indication. With data from these studies, it is Modus' intention to initiate a sale of the company, alternatively to out-license sevuparin in order to eventually establish sevuparin on the market. If the market's interest is not strong enough based on the phase IIa studies, acquisitions/license purchases can become relevant at different time points, for example at the end of phase IIb studies. A future major acquirer with an interest in takeovers/license purchases would then have the opportunity to drive the development of phase III studies in a way that maximizes the acquiring party's individual operational and strategic conditions. Based on the current development plan, a market introduction/NDA (New Drug Application) could be implemented in 2028.

In order to obtain market support for a registration, two large Phase III studies over 1,000 patients over a more extended period are typically required. Given that there is no approved drug for sepsis, the bar is likely to be somewhat lower for sevuparin than for other drugs. Several FDA and EMA programs potentially facilitating development may be available. Modus may have the opportunity for Accelerated Approval upon successful Phase IIb/ early Phase III results if, for example, improved symptoms for sepsis or severe malaria can be demonstrated., which could allow for earlier marketing of the sevuparin while additional confirmatory Phase III studies are conducted. There is also the potential to obtain Breakthrough Therapy designation, which could facilitate studies and approvals through lower endpoint requirements (objectives of the study).

A final option is for Modus to run the business until the end of phase III studies, when acquisition/licensing would become relevant again. There is also readiness for Modus to bring sevuparin to the market on its own, based on geographic market licenses to sales partners.

#### Collaborations

Modus has an ongoing research collaboration with Professor Maura Poli and her group at the University of Brescia which has been important for the establishment of the therapy area within anemia and kidney disease in the Modus pipeline. Another collaboration agreement was signed in 2021 with Imperial College London for the investigation of sevuparin's effects in severe malaria. During the collaboration, Modus contributes with sevuparin to the various phases of clinical studies in patients with severe malaria. The program is fully funded through research grants as well as the program's sponsor Imperial College from Wellcome.

### Timeline in traditional drug development



### Accelerated approval

### Breakthrough Therapy

A process designed to accelerate the development and review of drugs intended to treat a serious condition where preliminary clinical evidence suggests that the therapeutic agent may show significant improvement over available therapy at one or more clinically

# **KEY REASONS TO INVEST**

Experienced team, enabling Modus to effectively target indications that represent large unmet medical needs.

Risk-diversified clinical portfolio with indications in sepsis and anemia/chronic kidney disease (Phase IIa) and severe malaria (Phase Ia).

Sevuparin is Phase 2 ready; toxicology and safety package, comprehensive clinical safety data reduces scope moving forward.

Positive final data from the phase 1b LPS challenge study shows clinically relevant effects (biomarkers and symptoms).

Support for development as a treatment for CKD/anemia with strong inhibition of and kidney status in a preclinical kidney

Strong upside with commercial potential for billion-dollar markets and multiple

Extensive patent portfolio, continuously

- Sevuparin substance patent until 2032 plus up to 5 years, based on regulatory approval.
- New patent applications filed; December 2022 in chronic inflammation, kidney disease (CKD) and anemia and February 2023





# **SHARE PRICE DEVELOPMENT IN 2023**

Modus Therapeutics share was listed on Nasdaq First North Growth Market in Stockholm on 22 juli 2021. At the end of 2023, the total number of Modus shares amounted to 35 938 899 and the number of shareholders was 1 014.

### Share capital and ownership

At the end of 2023, Modus share capital amounted to SEK 2 156 334 distributed between 35 938 899 shares. All shares have equal voting rights and rights to dividend. The company's principal owners are Karolinska Development AB (66,1%), KDev Investment AB (7,7%), Hans Wigzell (5,8%) and John Öhd (4,8%).

### Dividend policy

In view of the Modus financial position and negative earnings, the company's Board of Directors does not intend to propose any dividend before the company generates long-term sustainable profit and positive cash flow.

Financial Calendar	
Interim Report Q1 2024	May 14, 2024
Annual General Meeting 2024	May 17, 2024
Interim Report Q2 2024	August 23, 2024
Interim Report Q3 2024	November 20, 2024

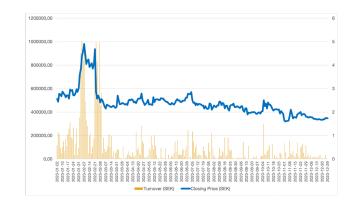


### **Certified Advisor**

Svensk Kapitalmarknadsgranskning AB is appointed as the company's certified adviser.

Contact information: www.skmg.se Phone: +46 11 32 30 732 e-mail: ca@skmg.se

### Share price development in 2023



### Largest shareholders on December 31, 2023

Owner	No. of shares	Share capital %
Karolinska Development AB	23,761,390	66.1%
KDev Investments AB	2,752,516	7.7%
Hans Wigzell	2,076,283	5.8%
Öhd, John	1,730,591	4.8%
Bladh, Anders	531,550	1.5%
Nordnet Pensionsförsäkring AB	315,792	0.9%
Aktiebolaget Wigzellproduktion	280,162	0.8%
Kinson Donnelly, Ellen	195,073	0.5%
Försäkringsbolaget Avanza Pension	164,732	0.5%
Lindqvist, Per	145,000	0.4%
Hederstedt, Bo	100,000	0.3%
Others	3,885,810	10.8%
Total registred shares	35,938,899	100%

# **LEADERSHIP TEAM AND BOARD**



John Öhd, M.D., PhD
CEO since 2020 and previously CMO since 2018

**Born:** 1971

**Education and experience:** MD, PhD. John Öhd has extensive experience in drug development and has previously worked in several different indication areas, including CNS, cancer and blood diseases. His previous qualifications include leadership positions within the research organizations of AstraZeneca and Shire and as Chief Medical Officer at the biotechnology company Medivir.

Other current roles: Chief Scientific Officer at Karolinska Development AB. Board member at Umecrine Cognition and SVF Vaccines AB.

Holdings: 1 730 591 shares and 86 000 warrants of series 2021/2024.



Claes Lindblad CFO since 2021

**Born:** 1967

Education and experience: Master of Sciences in Chemical and administrative sciences from university of Karlstad. Claes Lindblad has over 25 years of broad experience from leading positions in life science. He has previously been CFO of the Medtech company OssDsign, where he led the company's financial and administrative functions and played a key role in the company's listing on Nasdaq First North Growth Market 2019. Before that, he has held several senior positions, including Country manager for the global and market leading Medtec company ConvaTec, and in the role of Sales director for the OTC and generic portfolio at Nycomed / Takeda.

Holdings: 24 327 shares and 86 000 warrants of series 2021/2024.



Viktor Drvota, M.D, PhD Chairman since 2016

\* Viktor Drvota is independent in relation to the Company and company management but dependent in relation to the Company's major shareholders.

**Born:** 1965

**Education and experience:** MD, PhD, Assoc Prof in Cardiology at Karolinska Institute. Viktor Drvota has over 18 years' experience from venture capital in life sciences. He was responsible for life science at SEB Venture Capital 2002–2016 and has many years of experience of board duties in biotech and medtech companies.

Other current roles: CEO of Karolinska Development AB. Chairman of the board at Modus Therapeutics AB, Modus Therapeutics Holding AB, Umecrine Cognition AB and KDev Investments AB. Board member at UC Research AB, Dilafor AB and Dilafor Incentive AB. Deputy board member at Promimic AB and Svenska Vaccinfabriken Produktion AB.

Holdings: 0



Torsten
Goesch,
M.D, PhD
Board Member
since 2014

\* Torsten Goesch is independent in relation to the Company, the Company management and the Company's major shareholders.

**Born**: 1959

**Education and experience:** Licensed physician, Doctor of Medicine and holds an MBA from the Kellogg School of Management in Chicago. Torsten Goesch has more than 25 years of experience from the Life Science sector, including as senior executive within Biogen and Merck KGaA. He also has experience from successful divestments, such as Cytochroma, Enobia and STI Technologies.

**Other current roles:** Chairman of the Board of Dilafor. Board member of Biosergen, EyeSense, Forward Pharma and ProMore and partner for Rosetta Capital.

Holdings: 0



Ellen K.

Donnelly, PhD

Board Member
since 2020

\* Ellen Donnelly is independent in relation to the Company, the Company management and the Company's major shareholders.

**Born:** 1974

Education and experience: PhD in Neuroscience from the Yale School of Medicine. Ellen Donnelly has extensive experience from leadership positions within Life Science, including as former CEO of Modus and senior positions within Pfizer and Combinato Rx. She was previously CEO of Epigenetics Division and Juvenescence and management consultant for MEDACorp / Leerink and Swann Strategic Advisors.

**Other current roles:** CEO Abliva AB. Board member of Alzecure Pharma AB.

Holdings: 195 073 shares.

# **MANAGEMENT REPORT**

The board and managment of Modus Therapeutics Holding AB (publ) hereby present the annual report for fiscal year 2023-01-01 to 2023-12-31. Unless otherwise specified all amounts are stated in SEK thousand.

### **Management Report**

Modus is a Swedish biotechnology company that is developing its proprietary polysaccharide sevuparin as a potential treatment for several major healthcare needs including sepsis, endotoxemia, severe malaria and other disorders with severe systemic inflammation as well as for anemia in chronic inflammation such as kidney disease. There is a great need for new treatments that can effectively treat these conditions. Modus' ambition is to create a paradigm shift in the care of these diseases, where sevuparin could provide therapeutic benefits. The company is listed on Nasdaq First North Growth Market since July 22, 2021 and the Company's Certified Advisor is Svensk Kapitalmarknadsgranskning AB.

Sevuparin is an innovative proprietary polysaccharide drug in clinical phase with a multimodal mode of action including immunomodulating, anti-inflammatory, anti-adhesive and antiaggregating effects. Sevuparin is a heparinoid with significantly reduced anti-coagulant activities which allows much higher doses to be given compared to standard heparinoids without the associated risk of unwanted bleeding. Sevuparin is currently being developed as two formulations – one for intravenous administration and one subcutaneous formulation that can be given in outpatient care or in a home environment. Read more at www. modustx.com.

### Ownership structure

At the end of the fourth quarter of 2023 there was a total of 1,014 shareholders in Modus Therapeutics Holding AB (publ). The three largest shareholders owned 80% of the capital and votes. The total number of shares was 35,938,899. The main shareholders were, per December 31 2023, Karolinska Development AB 66,1%, KDev Investment AB 7,7% and Hans Wigzell 5,8%.

### Important events during the fiscal year

# Modus Therapeutics submits patent application for sevuparin in kidney disease

On January 23, 2023 Modus announced that it has submitted a patent application claiming the use of sevuparin, its lead asset, for the treatment of kidney disease. The patent application is based on novel preclinical work that was undertaken in an established kidney disease animal model during an academic collaboration project. A granted patent would provide patent protection until at least 2043. Sevuparin is a proprietary compound of Modus Therapeutics, currently being evaluated in Phase 1 clinical trials as a potential treatment for sepsis and septic shock, as well as for severe malaria in children.

### Modus Therapeutics announces positive topline data from its Phase 1b LPS provocation study evaluating the potential of sevuparin for treatment of sepsis

On February 21, 2023 Modus announced positive topline data from its Phase 1b LPS provocation study. The study is a key step in evaluating the potential of its lead asset, sevuparin, as a treatment for sepsis and other conditions with systemic inflammation.

In this study, healthy volunteers received LPS to induce a transient systemic inflammation reaction together with one of three dose levels of sevuparin, or placebo for 6 hours. They were then followed up at 24 hours post treatment. Provocation with LPS is a well-established model used to characterize the early stages of septic inflammation by provoking a range of measurable symptoms.

All three dose levels of sevuparin were found to be safe and well tolerated throughout the study period, confirming a favorable safety profile of the candidate drug under induced inflammatory conditions.

Furthermore, sevuparin treatment induced statistically significant and dose-dependent increases in the levels of certain white blood cell populations as well as a dose-dependent inhibition of

the increase in respiratory rate induced by LPS. These findings are indicative of clinically relevant and immunomodulatory effects exerted by sevuparin in a state of systemic inflammation. Sevuparin also demonstrated a favorable safety and tolerability profile when combined with the blood thinning heparin (enoxaparin), which is an important standard of care in severely ill patient populations that need thrombosis prophylaxis.

The positive top-line data from this trial will be used to design the Modus Phase 2a study of sevuparin in patients with sepsis. For example, this data will inform the dose of sevuparin to be assessed, the dosing schedule and the patient population for the planned patient study.

The Phase 1b study was conducted in collaboration with The Centre for Human Drug Research in Leiden, The Netherlands, an independent Contract Research Organisation (CRO), which specializes in advanced early clinical drug research based on its leading expertise in inflammation models.

# Modus Therapeutics secures access to bridge financing from longstanding investor Karolinska Development

On March 29, 2023 Modus announced that it has secured access to bridge financing of up to SEK 7.0 million from its largest shareholder, Karolinska Development. Access to this funding ensures that momentum of clinical development of Modus' lead asset, sevuparin, will be enhanced while the company continues to explore licensing and partnership opportunities. These future development plans include preparation for a Phase 2a study evaluating sevuparin for the treatment of sepsis. The funding will also allow Modus to continue exploring the development of new indications for sevuparin with promising potential such as chronic kidney disease.

### The annual general meeting was held on May 11, 2023

The annual general meeting resolved on the determination of the income statement and balance sheet, the group income statement and the group balance sheet, determination of profit allocation and discharge of liability for the board and CEO. Furthermore, the annual general meeting resolved:

- That no dividend would be paid.
- That the board of directors shall comprise three board members without any deputies.
- To re-elect the board members Viktor Drovta, Ellen Donnelly and Torsten Goesch and to re-elect Viktor Drovta as the chairman of the board.
- To re-elect Ernst & Young Aktiebolag as auditor.
- To adopt principles for the Nomination Committee, in accordance with the Nomination Committee's proposal.
- To authorize the board, for a period that does not extend past the date of the next annual general meeting, on one or several occasions, with or without pre-emptive rights for the shareholders, to resolve on the issue of new shares, convertibles and/or warrants.
- To approve a bridge financing facility of up to SEK 7 million from Karolinska Development.

### Modus Therapeutics presented new data on sevuparin demonstrating its potential to treat anemia related to chronic diseases at the annual European Hematology Association Congress

On June 10 2023 Modus presented new data at the annual meeting of the European Hematology Association (EHA) showing that its proprietary clinical candidate drug sevuparin was able to potently suppress the iron regulating hormone hepcidin. The hormone plays a key role in controlling the body's access to iron for vital physiological processes such as the formation of hemoglobin and red blood cells.

The data presented at EHA shows that sevuparin could represent a major advance in the treatment of anemia, a condition in which the number of red blood cells in the body or the hemoglobin concentration within them is lower than normal. In particular, high levels of hepcidin have been implicated in causing and aggravating the anemias that often complicate chronic kidney

disease and chronic inflammation disorders. High hepcidin is also responsible for conferring resistance to the current standard of care therapies to anemia in non-responding patients.

The presentation, titled "Sevuparin potently reduces hepcidin expression in cells, mice and human volunteers" was presented by Dr Michaela Asperti, co-author and a senior member of Professor Maura Poli's research group at the University of Brescia. Professor Poli and her team at the University of Brescia are renowned for their world-leading research on hepcidin and its role in anemia.

# Modus Therapeutics presents final data from its Phase 1b LPS-provocation study with sevuparin at the annual ISICIP symposium in Barcelona

On October 5, 2023 Modus announced the presentation of results from the final data analysis of their Phase 1b LPS challenge study in healthy volunteers. In this study, the effect of Modus' proprietary substance sevuparin was studied against the background of an acutely provoked systemic inflammation. The study will be presented as part of the "Best poster presentation" session at the 27th International Symposium on Infections in the Critically III Patient (ISICIP), October 5-6 in Barcelona, Spain.

The poster entitled "The effects of sevuparin in induced systemic inflammation- A randomized, placebo-controlled LPS-challenge study" will be presented orally by Modus' CEO, John Öhd on behalf of all co-authors. The presentation includes final analyses of the effects of sevuparin on certain types of white blood cells and clinical signs following LPS challenge (induced endotoxemia) in healthy volunteers. In accordance with the preliminary Topline analysis communicated in a press release earlier this year, the efficacy data from this study together with the favorable safety profile of sevuparin support the continued development of the substance as a treatment for acute systemic inflammation disorders such as sepsis and endotoxemia.

The study was a randomized, double-blind and placebocontrolled study in healthy volunteers. The data to be presented at this year's ISICIP includes both a systemic and a local (skin) LPS challenge and study endpoints that capture the clinical and biomarker-related effects of three different doses of sevuparin compared to placebo under induced systemic and local inflammatory conditions. At the same time, the safety and tolerability profile of sevuparin was observed under these conditions.

In the design and delivery of this Phase 1b study, Modus collaborated with The Centre for Human Drug Research (CHDR) in Leiden, The Netherlands, an independent Contract Research Organisation (CRO), which specializes in advanced early clinical drug research based on its leading expertise in inflammation models.

# Modus Therapeutics Holding AB conducts a rights issue of 40.3 MSEK and an offset Issue of 20.3 MSEK

On November 8th 2023, the Board of Directors of Modus Therapeutics Holding AB resolved, based on the authorization from the Annual General Meeting on May 11, 2023, to carry out a new issue of up to 20,125,060 shares with pre-emptive rights for the Company's shareholders, as well as a directed issue of 10,156,569 shares through the offsetting of loans from Karolinska Development AB amounting to approximately 20.3 MSEK. The Rights Issue is primarily intended to finance general working capital, a clinical phase Ila study in anemia of chronic kidney disease, preparation for other clinical activities, as well as the storage of sevuparin and its distribution to the malaria study. The Rights Issue is covered by subscription commitments of approximately 43.8 percent, corresponding to approximately 17.6 MSEK.

Through targeted scientific efforts, Modus has been able to secure applications for new intellectual property, which in turn has enabled an expansion of the clinical project portfolio. The portfolio now includes an indication for anemia in chronic inflammation/kidney disease. The aim of the expansion is to achieve diversification of indication-specific risks in the portfolio and to provide increased flexibility for future business development and financing.

# Modus Therapeutics Holding AB announces final outcome in rights issue

On December 5 2023, Modus Therapeutics Holding AB announced the conclusion of its new share issue with preemptive rights for the Company's shareholders that was announced on November 8, 2023. The rights issue was covered by subscription commitments of approximately 43.8 percent. In total, 9,682,280 shares were subscribed for, corresponding to approximately 48.1 percent of the rights Issue, of which approximately 47.8 percent of the shares were subscribed for with the support of subscription rights, and approximately 0.3 percent without the support of subscription rights.

The subscription price in the rights Issue was SEK 2.00 per share. Modus thus receives approximately MSEK 19.4 before issue costs through the rights Issue, primarily financing general working capital, a clinical phase IIa study in anemia of chronic kidney disease, preparation for other clinical activities, as well as the storage of sevuparin and its distribution to the malaria study.

Through the rights issue, Modus' share capital increases by SEK 580,936.80, through the issue of 9,682,280 shares, amounting thereafter to SEK 2,156,333.94 distributed over 35,938,899 shares.

Modus Therapeutics presented data on sevuparin demonstrating its potential to treat anemia in chronic kidney disease at the annual American Society of Hematology (ASH) On December 11, 2023 Modus announces announces data on its proprietary clinical candidate drug sevuparin and its ability to treat anemia and improve kidney status in a chronic kidney disease mouse model. The results were presented at the annual meeting of the American Society of Hematology (ASH), on December 10 in San Diego, USA.

The data from a preclinical disease model in mice presented at ASH, shows that sevuparin could represent a major advance in the treatment of anemia in chronic kidney disease and other disorders with chronic inflammation. About 10% of the general

population is assumed to have Chronic Kidney Disease (CKD) at stages 3-5 and in approximately ¼ of these, the condition is aggravated by anemia. In anemia, the number of red blood cells in the body or the hemoglobin concentration within them is lower than normal and when present in CKD, it significantly contributes to the overall disease. In addition to the effects on anemia, sevuparin also ameliorated kidney function and fibrosis in the treated animals.

The poster, entitled "The Heparinoid Sevuparin Improves Anemia and Kidney Status in a Mouse Model of Chronic Kidney Disease" were presented as a poster by Dr Michela Asperti, co-author and a senior member of Professor Maura Poli's research group at the University of Brescia who is collaborating with Modus on this research.

### Important events after year-end 2023

No event to report.

# Expected future development and significant risks and uncertainties

The development of pharmaceutical agents for the treatment of disease is a historically risky endeavour with the estimated likelihood of a specific therapeutic making it through all stages of development to the market of 11.9%, with Phase II products having the lowest likelihood of success of all phases (estimated at 30.7%; BIO, June 2016). The factors that contribute to this high level of risk include many things that are outside of the control of the Company, including lack of drug efficacy, patient safety, the competitive landscape, changes in legislation, lack of access to manufacturing material etc.

As a result of the completion of share issues during the fourth quarter 2023 Modus is debt-free. The rights issue will primarily finance general working capital, a clinical phase IIa study in anemia with kidney disease, preparation of other clinical activities and storage of sevuparin and distribution of the same to the study in malaria. The board and management make the assessment that, after fulfilment of financing, the company has sufficient resources to implement the decided strategy in

2024, and the annual report has therefore been prepared with assumptions of continued operation for at least twelve months.

Russia's invasion of Ukraine affects the economy and society as a whole, including Modus. Delays in clinical trials may occur and the opportunities for refinancing can be hampered. The Board monitors the evolvement of the crises closely and Modus is working intensively to minimize the impact of these crises. The ability to raise capital to support research and development activities is critical for development companies such as Modus.

Modus is investigating future possibilities for the funding required in order to complete the clinical research plan for its drug candidate sevuparin. There are no guarantees that the required capital can be raised to finance the development on favorable terms, or that the capital can be procured at all. The Board and the CEO make the assessment that these projects will be able to be completed and put into use, and they also make the assessment that the prospects for future capital raising are good provided that the development projects deliver according to plan.

Should capital raising activities according to the above not be fulfilled, there is significant uncertainty regarding the group's ability to continue operations.

# Financial overview (TSEK)

Group Company	2023	2022	2021	2020	2019
Net sales	-	-	-	-	-
Profit/Loss after financial items	-17 897	-18 320	-20 691	-6 020	-43 575
Balance sheet total	20 041	11 271	21 191	7 491	2 051
Quick asset ratio, % 1)	88,2	Neg	74,3	93,4	Neg
Average number of employees	2	2	2	1	4

Parent Company	2023	2022	2021	2020	2019
Net sales	740	740	505	609	1 491
Profit/Loss after financial items	-8 763	-6 646	-6 525	63 115	-233 478
Balance sheet total	89 194	79 824	89 871	77 314	2 414
Quick asset ratio, % 1)	80,9	61,6	82,0	98,5	Neg
Average number of employees	2	2	2	1	2

### Definitions

# **Proposed distribution of earnings**

SEK	69 981 958
loss be carried forward as retained earnings	69 981 958
The Board of Directors proposes that the accumulated	
SEK	69 981 958
Net loss for the year	-15 186 844
Accumulated loss	-247 603 969
Share premium reserve	332 772 771

Regarding the company's results and financial position in other respects, please refer to income statements, balance sheets and accompanying, supplementary disclosures set out below.

<sup>1)</sup> Equity in relation to balance sheet total.

# **FINANCIAL STATEMENTS**

### **Consolidated income statement**

TSEK	Note	2023-01-01 - 2023-12-31	2022-01-01 - 2022-12-31
Net sales		_	-
Research and development costs	3	-8 482	-10 898
Administration costs	3	-7 831	-6 988
Other operating income		-	-
Other operating expenses		-87	-120
Operating profit/loss		-16 401	-18 006
Other interest received and similar items		3	-
Interest expenses and similiar profit/loss items		-1 499	-314
Total results from financial investments		-1 496	-314
Profit/loss after financial items		-17 897	-18 320
Income tax		-	-
Profit/loss for the period		-17 897	-18 320
Profit/loss attributable to			
Parent Company shareholders		-17 897	-18 320
Earnings per share before and after dilution (SEK)		-1,01	-1,14
Average number of shares, thousands		17 745	16 100

### **Consolidated balance sheet**

TSEK	Note	2023-12-31	2022-12-31
Assets			
Accounts payable			
Financial assets	5		
Other long-term receivables		50	50
Total financial assets		50	50
Current assets			
Accounts payable			
Current tax claim		314	-
Other receivables		357	230
Prepaid expenses and accrued income	7	260	567
Total accounts payable		931	797
Cash and bank		19 060	10 424
Total current assets		19 991	11 221
Total assets		20 041	11 271

TSEK	Note	2023-12-31	2022-12-31
Equity and liabilities			
Share capital		2 156	966
Additional paid-in capital		332 899	295 926
Retained earnings including net loss for the year		-317 373	-299 477
Total equity attributed to equity holders of the Parent Company		17 682	-2 585
Total equity		17 682	-2 585
Current liabilities			
Convertible loan		-	11 500
Accounts payable - trade		1 312	1 361
Current tax liabilities		.=	36
Other liabilities		521	101
Accrued expenses and deferred income	8	527	858
Total current liabilities		2 359	13 856
Total equity and liabilities		20 041	11 271

# Group account changes in the equity

TSEK	Share capital	Additional paid-in capital	Received earnings incl net loss for the year	Equity to main shareholder	Total equity
Equity at 2022-01-01	966	295 926	-281 157	15 735	15 735
Profit/loss for the year	-	-	-18 320	-18 320	-18 320
Equity at 2022-12-31	966	295 926	-299 477	-2 585	-2 585
Equity at 2023-01-01	966	295 926	-299 477	-2 585	-2 585
Profit/loss for the year	-	-	-17 896	-17 896	-17 896
Transaction with the shareholders:					
New share issue	1 190	38 487	-	39 677	39 677
Cost attributed to new share issue	-	-1 515	-	-1 515	-1 515
Equity at 2023-12-31	2 156	332 898	-317 373	17 681	17 681

The equity is assignable to the shareholders of the parent company.

### Share capital and share classes

The share capital consists of 35 938 899 ordinary shares.

### **Consolidated cash flow statement**

TSEK	Note	2023-01-01 -	2022-01-01 -
		2023-12-31	2022-12-31
Operating activities			
Operating profit/loss		-16 401	-18 006
Interest received		3	-
Interest paid		-	-
Cash flow from operating activities before changes in working capital		-16 398	-18 006
Increase (-) Decrease (+) in current receivables		-133	-304
Increase (+) Decrease (-) in current liabilities		-153	-3 414
Cash flow from operating activities		-16 684	-21 724
Acquisition of financial assets		-	-
Cash flow from investment activities		-	-
New issue of shares		19 365	-
Cost attributed to new share issue		-1 045	-
Convertible loans*		7 000	11 500
Cash flow from financing activities		25 320	11 500
Cash flow from the period		8 636	-10 224
Cash and equivalents at the beginning of the year		10 424	20 648
Casg and cash equivalents at year-end		19 060	10 424

<sup>\*</sup> The loan has been offset during year as part of the completed offset issue.

# Parent company income statement

TSEK	Note	2023-01-01 - 2023-12-31	2022-01-01 - 2022-12-31
Net sales		740	740
		740	740
Research and development costs	3	-1 419	-1 210
Administration costs	3	-6 588	-5 862
Other operating expenses		-	-
Total operating expenses		-8 007	-7 072
Operating profit/loss		-7 267	-6 332
Results from financial investments			
Interest expenses and similiar proft/loss items		-1 496	-314
Total results from financial investments		-1 496	-314
Profit/loss after financial investments		-8 763	-6 646
Year-end appropriations	4	-6 424	-17 900
Income tax expense		-	-
Net profit/loss for the year		-15 187	-24 546

# Parent company balance sheet

TSEK	Note	2023-12-31	2022-12-31
Assets			
Fixed assets			
Financial asstes	5		
Participation in Group companies		70 000	70 000
Other long-term assets		50	50
Total financial assets		70 050	70 050
Current assets			
Short-term receivables			
Current tax claim		283	-
Other receivables		242	78
Prepaid expenses and accrued income	7	238	515
Total short-term receivables		763	593
Cash and bank		18 381	9 181
Total current assets		19 144	9 774
Total assets		89 194	79 824

TSEK	Note	2023-12-31	2022-12-31
Equity and liabilities			
Share capital		2 156	966
Total restricted equity		2 156	966
Non-restricted equity:			
Share premium reserve		332 773	295 800
Retained earnings		-247 604	-223 058
Profit/loss for the year		-15 187	-24 546
Total non-restricted equity		69 982	48 196
Total equity		72 138	49 162
Current liabilities			
Convertible loan		-	11 500
Accounts payable		845	274
Liabilities to Group companies		15 201	17 999
Current tax liabilities		-	36
Other liabilities		521	101
Accrued expenses and deferred income	8	488	752
Total current liabilities		17 055	30 662
Total equity and liabilities		89 194	79 824

# Parent company changes in equity

TSEK	Share capital	Premium share	Retained earnings	Profit/loss for the year	Total equity
Equity at 2022-01-01	966	295 800	-191 332	-31 725	73 709
Disposition of previous years' result	-	-	-31 725	31 725	-
Profit/loss of the year	-	-	-	-24 546	-24 546
Equity at 2022-12-31	966	295 800	-223 057	-24 546	49 163
Equity at 2023-01-01	966	295 800	-223 057	-24 546	49 163
Disposition of previous years' result	-	-	-24 546	24 546	-
Reduction of share capital	-	-	-	-	-
Profit/loss of the year	-	-	-	-15 187	-15 187
Transactions with shareholders:					
New issue of shares	1 190	38 487	-	-	39 677
Cost attributable to new share issue	-	-1 515	-	-	-1 515
Equity at 2023-12-31	2 156	332 772	-247 603	-15 187	72 138

# Parent company cash flow statements

TSEK	Note	2023-01-01 - 2023-12-31	2022-01-01 - 2022-12-31
Operating activities			
Operating profit/loss		-7 267	-6 332
Interest paid		2	-
Cash flow from operating activities before changes in working capital		-7 265	-6 332
Cash flow from changes in working capital			
Increase (-) Decrease (+) in current receivables		-125	-258
Increase (+) Decrese (-) in current liabilities		-2 306	-475
Cash flow from operating liabilities		-9 696	-7 065
Investment activities			
Made Group contribution		-6 424	-14 740
Cash flow from investment activities		-6 424	-14 740
Financing activities			
New issue of shares		19 365	-
Cost attributable to new share issue		-1 045	-
Convertible loans*		7 000	11 500
Cash flow from financing activities		25 320	11 500
Cash flow for the year		9 200	-10 305
Cash and cash equivalents at the beginning of the year		9 181	19 486
Cash and cash equivalents at year-end		18 381	9 181

<sup>\*</sup> The loan has been offset during year as part of the completed offset issue.

# **NOTES**

### General information

This consolidated report includes the parent company Modus Therapeutics Holding AB (publ), company registration number 556851-9523 and the subsidiary Modus Therapeutics AB, company registration number 556669-2199. The parent company is a limited company with its registered office in Stockholm. The address of the head office is Olof Palmes gata IV, 111 22 Stockholm. The group's main activity is the development of pharmaceuticals.

Major owners of Modus Therapeutics Holding AB (publ) are Karolinska Development AB (66.1%), company registration number 556707-5048. located in Solna.

# Note 1 Accounting principles and valuation principles

Modus Therapeutics Holding ABs consolidated accounts have been prepared in accordance with the Annual Accounts Act and the Swedish Accounting Standards Board's general advice BFNAR 2012:1 Annual accounts and consolidated accounts (K3).

### Accounting currency

The company's accounting currency is Swedish kronor (SEK thousand). At each balance sheet date, monetary items denominated in foreign currencies are translated at the exchange rate on the balance sheet date. Exchange rate differences are reported in operating profit or as a financial item based on the underlying business event, in the period in which they arise.

### Consolidated financial statements

The consolidated financial statements include subsidiaries in which Modus Therapeutics Holding AB holds the majority of the votes at the Annual General Meeting and companies in which, by agreement, have a controlling influence are classified as subsidiaries and consolidated in the consolidated financial statements. The subsidiaries are included in the consolidated financial statements from the date on which the controlling influence is transferred to the Group. They are excluded from the consolidated financial statements from the date on which the

controlling influence ceases. The consolidated financial statements have been prepared in accordance with the acquisition method. The time of acquisition is the time when the controlling influence is obtained. Identifiable assets and liabilities are initially valued at fair values at the time of acquisition. The minority's share of the acquired net assets is valued at fair value. Goodwill consists of the difference between the acquired identifiable net assets at the time of acquisition and the acquisition value, including the value of the minority interest, and is initially valued at acquisition value.

Intercompany balances between group companies are eliminated in their entirety.

### Revenue recognition

Revenue is reported at the fair value of the compensation received or will be received, less VAT, discounts, returns and similar deductions.

#### Leasing

Leasing agreements where the lessor essentially retains all risks and rewards of ownership are classified as operational agreements. Leasing fees are expensed on a straight-line basis in the income statement during the leasing period. In the Group, there are only leasing agreements that are classified as operational agreements.

### Remuneration to employees

Remuneration to employees in the form of salaries, bonuses, paid holidays, paid sick leave, etc. and pensions are recorded as costs in accordance with earnings. Pension costs and other post-employment benefits, these are classified as defined-contribution or defined-benefit pension plans. In the Group, there are only defined contribution pension plans. There are no other long-term benefits for employees.

#### Income tax

The tax cost consists of the sum of current tax and deferred tax.

#### Current tax

Current tax is calculated on the taxable profit for the period. Taxable profit differs from the reported profit in the income statement as it has been adjusted for non-taxable income and non-deductible expenses and for income and expenses that are taxable or deductible in other periods. Current tax liability is calculated according to the tax rates that apply on the balance sheet date.

### Deferred tax

Deferred tax is reported on temporary differences between the carrying amount of assets and liabilities in the financial statements and the tax value used in calculating taxable income. Deferred tax liabilities are reported for in principle all taxable temporary differences, and deferred tax assets are reported in principle for all deductible temporary differences to the extent that it is probable that the amounts can be utilized against future taxable surpluses.

### Intangible assets

Acquisition through separate acquisitions

Intangible assets acquired separately are reported at acquisition value less accumulated depreciation and any accumulated writedowns. Depreciation takes place on a straight-line basis over the asset's estimated useful life, which is estimated at 5 years. Estimated useful lives and depreciation methods are reassessed if there is an indication that these have changed compared with the estimate at the previous balance sheet date. The effect of any changes in estimates and assessments is reported in the future. Depreciation begins after the acquisition date or when the asset can be used.

#### Expenditure on development activities

Development expenses are capitalized when they meet the criteria according to K3 chap. 18.

In other respects, development expenses are expensed as normal operating expenses. The most important criteria for activation are that the product of the development work has a demonstrable future earnings or cost savings and that

there are technical and financial conditions for completing the development work. The development work for Modus Therapeutics AB does not meet all the criteria for activation, thus no expenses have been capitalized. After the first reporting occasion, internally generated intangible fixed assets are reported at acquisition value after deductions for accumulated depreciation and any accumulated write-downs. Depreciation begins in connection with the asset being capitalized and amortized on a straight-line basis over an estimated useful life of 5 years. An intangible fixed asset is removed from the balance sheet upon disposal or disposal or when no future economic benefits are expected from the use or disposal / disposal of the asset. The gain or loss that arises when an intangible fixed asset is removed from the balance sheet is the difference between what may be received, after deduction of direct sales costs, and the asset's carrying amount. This is reported in the income statement as other operating income or other operating expenses.

### Impairment of non-financial fixed assets

When there is an indication that the value of an asset has decreased, an impairment test is performed. If the asset has a recoverable amount that is lower than the carrying amount, it is written down to the recoverable amount. When assessing impairment, assets are grouped at the lowest levels where there are separate identifiable cash flows (cash-generating units). For assets, other than goodwill, that have previously been written down, an examination is made on each balance sheet date as to whether reversal should be made. Impairment losses and reversals of impairments within the business are reported in the income statement.

#### Financial instruments

Financial instruments are reported in accordance with the rules in Chapter 3, Chapter 11, which means that valuation is based on acquisition value. Financial instruments reported in the balance sheet include securities, accounts receivable and other receivables, short-term investments, accounts payable and loan liabilities. Financial assets are removed from the balance sheet when the right to receive cash flows from the instrument has expired or been transferred and the Group has transferred virtually all risks and benefits associated with ownership. Financial liabilities are removed from the balance sheet when the obligations have been settled or otherwise ceased.

### Impairment testing of financial fixed assets

At each balance sheet date, Modus Therapeutics Holding assesses whether there is any indication of impairment in any of the financial fixed assets. Impairment occurs if the decline in value is deemed to be permanent. Impairment is reported in the income statement item Profit from other securities and receivables that are fixed assets. The need for impairment is tested individually for shares and participations and other individual financial fixed assets that are significant.

#### Cash and bank balances

Cash and bank include cash and available balances with banks and other credit institutions as well as other short-term liquid investments that can easily be converted into cash and are subject to an insignificant risk of value fluctuations. To be classified as cash and cash equivalents, the term may not exceed three months from the time of acquisition.

#### Equity

Ordinary shares, other contributed capital and retained earnings are classified as equity. Financial instruments that are judged to meet the criteria for classification as equity are reported as equity even if the financialinstrument is legally designed as a liability.

#### Warrants

The Group has only issued warrants that have been transferred at fair value. Premiums received for issued options to acquire shares in companies are reported as a supplement to equity, based on the option premium, at the date when the option was transferred to the counterparty.

### Cash flow analysis

The cash flow analysis shows the company's changes in the company's cash and cash equivalents during the financial year. The cash flow analysis has been prepared according to the indirect method. The reported cash flow only includes transactions that resulted in inflows and outflows.

# The parent company's accounting and valuation principles

The same accounting and valuation principles are applied in the

Parent Company as in the Group, except for the cases listed below.

### Shares in subsidiaries

Shares and participations in subsidiaries are reported at acquisition value after deductions for any write-downs. The acquisition value includes the purchase price paid for the shares. Any capital injections are added to the acquisition value when they are provided. Both received and paid group contributions are reported as appropriations in accordance with the alternative principal, as income or cost. Dividends from subsidiaries are reported as income when the right to receive dividends is deemed secure and can be calculated in a reliable manner.

### Note 2 Important estimates and assessments

Some important accounting assessments made in the application of the Group's accounting principles are described below:

### Assumption of going concern

The company's continued operations remain uncertain and are dependent on the required resources to complete the development. This leads to estimates concerning the prerequisites for drug development and the potential to generate future financial gain. The Board and management assess that these projects can be completed and put into use. The company's development project will require additional capital injections from investors for the values to be realized. This need arises primarily in connection with the execution of new clinical studies. There are no guarantees that the required capital can be raised to finance the development on favorable terms, or that such capital can be raised at all. The Board and management assess that the company has sufficient resources to deliver on the agreed strategy for 2024 and the annual report has therefore been prepared with assumptions of continued operations for a period of at least twelve months..

# Note 3 Employee salaries and benefits

	Gı	Group		company
Average number of employees	2023	2022	2023	2022
Male	2	2	2	2
Female	_	-	-	-
Total	2	2	2	2

	Group		Parent company	
Gender distribution of senior executives	2023	2022	2023	2022
Board members:				
Female	1	1	1	1
Male	2	2	2	2
CEO and senior executives:				
Female	-	-	-	-
Male	2	2	2	2

		Group	Pare	nt company
Salaries, other benefits and social contribution	2023	2022	2023	2022
Board, CEO and business management	2 779	2 789	2 779	2 789
Total	2 779	2 789	2 779	2 789
Social contribution	771	731	771	731
Pension cost to board and CEO	825	708	825	708
Total salaries, social contributions and pension costs	4 375	4 228	4 375	4 228

Alloted warrants	202	23-12-31	2022-12-31		
	Number of outstanding warrants	Average exercise price, SEK per warrant	Number of outstanding warrants	Average exercise price, SEK per warrant	
Opening balance	172 000	8,32	172 000	8,32	
Exercised during the period	-	-	-	-	
Total	172 000	8,32	172 000	8,32	

# Note 4 Year-end appropriations

	Parent company		
TSEK	2023	2022	
Group contribution paid	-6 424	-17 900	
Total	-6 424	-17 900	

### **Note 5 Financial assets**

Participation in Group companies	Parent compan	
TSEK	2023	2022
Cost of acquisition at opening balance	233 156	233 156
Shareholders contribution paid	-	-
Total accumulated cost of acquisition	233 156	233 156
Impairment at opening balance	-163 156	-163 156
Reversal of impairment	-	-
Impairment at closing year	-163 156	-163 156
Net book value	70 000	70 000

				Carrying amouunt
Subsidary / Corp. reg. no / Domicile	Equity %	Shares of votes %	Number of shares	2023
Modus Therapeutics AB	100%	100%	100 000	70 000
556669-2199, Stockholm				
				70 000

Other long-term receivables		Group		Parent company	
TSEK	2023	2022	2023	2022	
Opening balance	50	50	50	50	
Additional receivables	-	-	-	-	
Outgoing accumulated acquisition	50	50	50	50	
Net book value	50	50	50	50	

Long-term receivables are deposits for rent.

# Note 6 Transactions with related parties

	Gro	Parent company		
Total	2023	2022	2023	2023
Sales to Group companies	-	-	740	740

For remuneration to senior executives and the Board, see Note 3.

# Note 7 Accrued expenses and deferred income

	Gro	ир	Parent c	ompany
TSEK	2023	2022	2023	2022
Prepaid rent	7	7	-	0
Prepaid cost for share issue	-	470	-	470
Prepaid insurance cost	71	90	71	-
Other prepaid cost	182	-	167	45
Total	260	567	238	515

# Note 8 Prepaid expenses and accrued income

	Gro	Group		Parent company		
TSEK	2023	2022	2023	2022		
Accrued personnel cost	318	250	318	250		
Accrued interest	0	314	0	314		
Other items	209	293	170	187		
Total	527	858	488	752		

# Note 9 Important events at the end of the financial year

No event to report.

# **CERTIFICATION**

This report has been prepared in both Swedish and English. In the event of discrepancies between the versions, the Swedish version applies.				
Stockholm 10/4 2024				
Viktor Drvota, Chairman of the board	Torsten Goesch, Board member	John Öhd, CEO	Ellen K. Donnelly, Board member	
Our audit report was given on 10/4 2024 Ernst & Young AB				
Linn Haslum Lindgren, Authorized auditor				

# **AUDITOR'S REPORT**



To the general meeting of the shareholders of Modus Therapeutics Holding AB, corporate identity number 556851-9523

### Report on the annual accounts and consolidated accounts

### Opinions

We have audited the annual accounts and consolidated accounts of Modus Therapeutics Holding AB for the year 2023-01-01 -2023-12-31. The annual accounts and consolidated accounts of the company are included on pages 20-38 in this document.

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

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

### **Basis for Opinions**

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

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

### Other Information than the annual accounts and consolidated accounts

This document also contains information other than the annual report and consolidated accounts found on pages 1-19. The Board of Directors and the Managing Director are responsible for the other information. Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

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

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

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

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

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

### Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

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

- · Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and

related disclosures made by the Board of Directors and the Managing Director.

- · Conclude on the appropriateness of the Board of Directors' and the Managing Director's use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions.

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

# Report on other legal and regulatory requirements

### **Opinions**

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Director of Modus Therapeutics

Holding AB for the year 2023-01-01 – 2023-12-31 and the proposed appropriations of the company's profit or loss.

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

### **Basis for Opinions**

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

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

# Responsibilities of the Board of Directors and the Managing Director

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

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

### Auditor's responsibility

Our objective concerning the audit of the administration, and

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

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

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

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

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

Stockholm, 10/04-2023, as stated in our digital signature

Ernst & Young AB

Linn Haslum Lindgren Authorized Public Accountant





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