

# Annual Report

# 2022

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# MODUS AT A GLANCE

Modus Therapeutics is advancing its clinical-stage, proprietary drug: sevuparin in the sepsis indication.

Sevuparin is Phase 2 ready; toxicology and safety package + extensive clinical safety data significantly de-risk the program.

Preclinical data indicate a protective role for sevuparin on the vasculature of the lung during septic inflammation.

Positive top line data from the Phase 1b LPS challenge study shows clinically relevant and differentiated effects.

Fast to market approach. Billion \$ commercial potential in sepsis indication alone – no approved specific products available.

Patent protection and further IP expansion explored in preclinical academic collaborations. Patent applications filed recently to further strengthen the IP portfolio.

Modus is actively exploring opportunities to partner/license the clinical program with relevant external parties

Modus is considering options for financing of the future Phase 2a study in sepsis patients following finalization and data disclosure of the Phase 1b study.

## Key Financial Figures

TSEK	2022	2021
Net sales	-	-
Operating profit	-18 006	-20 690
Cash equivalents	10 424	20 648
Cash flow from operating activities	-21 724	-16 078
Equity ratio	Neg	74%
Earnings per share	-1,14	-1,67
Average number of employees	2	2

### Modus

Modus Therapeutics is a Swedish biotechnology company with its roots in innovation from Karolinska Institutet. Founded in 2011, Modus is developing its proprietary drug candidate sevuparin, a compound that has the potential to revolutionize the treatment of sepsis/septic shock and systemic inflammation, also known as "blood poisoning". Sepsis and septic shock are one of the leading causes of death in intensive care units globally.

### Drug candidate sevuparin

Modus' candidate drug sevuparin is based on the well-known drug heparin, which has been marketed for clinical use as a blood-thinning agent since the 1930s. Thanks to innovative chemical modification, sevuparin differs from heparins in that it has a much-reduced anti-coagulant activity and therefore can be dosed without concern for the bleeding risk. This enhances the potential of sevuparin to deliver the non-anticoagulant benefits of heparinoids to patients across multiple serious conditions. Sevuparin, has a multimodal mechanism of action that is typical of heparinoids allowing it to target and neutralize the processes that underlie serious inflammatory conditions.

# IMPORTANT EVENTS

## Important Events during 2022

### **Modus Therapeutics secures access to bridge financing from Karolinska Development**

On May 12, 2022, Modus Therapeutics announced the completion of bridge financing of up to SEK 11.5 million from its largest shareholder, Karolinska Development. Access to this funding ensures that momentum of clinical development of the company's lead asset, sevuparin, for the treatment of sepsis is sustained and includes the planning for the forthcoming Phase 2a study in patients with sepsis.

### **First patient enrolled in the Phase I SEVUSMART clinical trial evaluating sevuparin in paediatric patients with severe malaria**

On September 1st, 2022, Modus Therapeutics announced the inclusion of the first patient and the start of SEVUSMART, an Imperial College London/Wellcome sponsored phase I clinical trial evaluating the Company's proprietary drug sevuparin in paediatric patients with severe malaria. The SEVUSMART phase I trial will evaluate the safety and tolerability of escalating doses of sevuparin in up to 20 paediatric patients aged 3 months to 12 years presenting with severe malaria at the Kilifi County Hospital, Kilifi, Kenya. The study is designed to identify the appropriate dose of sevuparin together with standard of care in severe malaria to be taken forward in future clinical studies. Sevuparin has already shown promising effects on the malaria parasite in patients with uncomplicated malaria and in human samples (Leitgeb et al 2017, Saiwaew et al 2017). The trial is the result of a collaboration between Modus and a team led by Professor Kathryn Maitland from Imperial College London, UK. The project is funded by a collaborator grant in science from Wellcome (209265/Z/17/Z) to Professor Maitland's research group at KEMRI-Wellcome Trust Programme, Kilifi Kenya and to the international consortium "Severe Malaria Africa – a consortium for Research and Trials" (SMAART), the goal of which is to identify and research new treatments for severe malaria.

### **Recruitment for Phase 1b LPS provocation study completed**

On September 27, 2022, Modus Therapeutics announced that recruitment was completed into the company's clinical Phase 1b LPS provocation study evaluating the potential of its lead asset, sevuparin, for the treatment of sepsis and septic shock.

## Important Events after year-end 2022

### **Modus Therapeutics submits patent application for sevuparin in kidney disease**

On January 23, 2022, Modus Therapeutics announced the submission of 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. New avenues for development and commercialization of Modus' key asset are actively being evaluated, in parallel to the continuous development of the patent portfolio. While the patent application for sevuparin in kidney disease is a tangible result of these efforts, it also demonstrates Modus' ability to successfully collaborate internationally with leading academic institutions.

### **Modus Therapeutics announces positive topline data from its Phase 1b LPS provocation study**

On 21 February, 2023 Modus announced positive top-line data from its Phase 1b lipopolysaccharide (LPS) provocation study, a key step in evaluating the potential of its lead asset, sevuparin, as a treatment for sepsis and other conditions with systemic inflammation. All three doses of sevuparin were found to be safe and tolerable throughout the study period, confirming the candidate drug's favorable safety profile under induced inflammatory conditions. Furthermore, sevuparin treatment caused statistically significant and dose-dependent increases in the levels of certain white blood cells as well as a dose-dependent inhibition of the LPS induced increase in respiratory rate. In a separate study part, sevuparin was also found to be safe and tolerable when combined with a blood thinning heparin (enoxaparin) - a thrombosis prophylactic standard of care for patients that are critically ill such as patients with sepsis.

The encouraging results from the LPS-challenge study mark a very important milestone in Modus' mission to develop sevuparin as a fundamental change in the treatment for sepsis and other conditions with systemic inflammation. The results enhance the understanding of the immunomodulatory action of sevuparin and reinforce its potential in this area of extremely high unmet need. These data will also allow Modus to develop an optimized trial protocol for the planned Phase 2a trial in sepsis patients.

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

On March 29, 2023, Modus Therapeutics announced that it has secured access to bridge financing of up to SEK 7.0 million from its largest shareholder, Karolinska Development. The bridge financing facility will be submitted to the annual general meeting, to be held on 11 May 2023, for approval. 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, expected to commence at the end of 2023. The funding will also allow Modus to continue exploring the development of new indications for sevuparin with promising potential such as chronic kidney disease.



## A WORD FROM OUR CEO

2022 was an encouraging year for Modus Therapeutics with our efforts directed in two main areas – the completion of our Phase 1b study for sevuparin in sepsis and, in parallel, the investigation of the drug’s potential to address other conditions both within and outside the field of systemic inflammation



### Positive topline data from our Phase 1b provocation study

Throughout 2022, the effects of the Covid pandemic continued to pose challenges in the recruitment of study patients to our Phase 1b provocation study. After putting much effort into overcoming those challenges we are delighted to have now reported positive topline data from the study which evaluated sevuparin’s safety and tolerability as well as its ability to mitigate relevant effects in healthy volunteers who have been injected with the bacterial toxin lipopolysaccharide (LPS). This LPS challenge study is a well-established model used to induce a state of systemic inflammation in healthy volunteers. The outcomes showed that all three doses of sevuparin were found to be safe and tolerable throughout the study period, confirming the candidate drug’s favorable safety profile under induced inflammatory conditions. Furthermore, sevuparin treatment caused statistically significant and dose-dependent increases in the levels of certain white blood cells as well as a dose-dependent inhibition of the LPS induced increase in respiratory rate. In a separate study part, sevuparin was also found to be safe and tolerable when combined with a blood thinning heparin (enoxaparin).

The study outcome strengthens the potential of sevuparin as a treatment for sepsis, septic shock and other conditions with systemic inflammation. This is an area of high unmet medical need as current treatment options fail to address the high disease burden of these critically ill patients.

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The estimated 49 million patients affected by sepsis globally each year are in great need of new, effective treatment options for this often-fatal condition. The impact of sepsis on society is a key driver behind our goal of advancing sevuparin through clinical development and we are proud to be part of the growing global effort to tackle these challenges.”

The results will also assist in the design of our next planned clinical study, a Phase 2a trial evaluating sevuparin in sepsis patients—including support for dose selection as well as providing a possibility to further refine patient selection and monitoring of treatment responses.

### Advances in the evaluation of sevuparin’s potential to address other conditions

In parallel with sevuparin’s encouraging progress in sepsis, we have also spent time this past year investigating the drug’s potential to address other conditions with systemic inflammation as well as indications outside of that field.

In September we announced that the first patient was enrolled in the Phase 1 SEVUSMART clinical trial evaluating sevuparin in paediatric patients with severe malaria. The trial is a collaboration between Modus and a team led by Professor Kathryn Maitland from Imperial College London, UK. It will evaluate the safety and tolerability of sevuparin and its potential to support the treatment of severe malaria in children, where the disease causes a systemic inflammation syndrome that shares similarities with sepsis.

Outside of the systemic inflammation area, we recently submitted a patent application claiming the use of sevuparin 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. From a future scientific and development angle, with the establishment of potentially new and patent protected indications for sevuparin, we judge that the prospect of value generation by research and development has increased significantly. An initial assessment of the commercial potential for the use of sevuparin in kidney disease indicated a

>\$1 billion market potential. Going forward we will be looking at the possibilities to address this new indication clinically in parallel with the sepsis program.

### Additional financing efforts

Through the access to a bridging loan of up to SEK 7 million from Karolinska Development, we can secure our strategy by maintaining speed and direction in the development projects and in the business development towards potential future partners. We are delighted that our largest owner continues to show confidence in this opportunity. In the future, greater research efforts such as the planned Phase 2a study in sepsis patients, will require us to secure additional financing and Modus’ management and board are in the process of considering how best to finance sevuparin’s continued development. It is our assessment that with the enhanced pipeline and long-term supportive major shareholders, Modus is in a strong position to attract investors in future financing endeavors.

Last, but not least, I would like to thank our CRO partners at the Centre for Human Drug Research (CHDR) in the Netherlands, whose team effort has allowed the Phase 1 trial of sevuparin to proceed as smoothly as possible given the challenges posed by the Covid pandemic. I would also like to thank our investors and shareholders whose continued support over the last 12 months, has been vital to helping us reach this key milestone.

We are confident that 2023 will be another key year in Modus’ development as a company, and we look forward to providing more updates as the year progresses.

John Öhd  
CEO Modus

## WHY SEPSIS?

### A long-standing unmet medical need

Unknown to many, Sepsis may be the leading cause of death in the world according to the WHO. An estimated 50 million people globally develop Sepsis every year, of which about 11 million cases lead to death, with more people dying annually from sepsis/septic shock than from cancer. In addition, there is currently no specifically approved treatment for patients suffering from sepsis/septic shock.

#### Sepsis in summary

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. As a result, sepsis can develop in a short time from a common infection to becoming life-threatening affecting the lungs, heart, kidneys, and brain.

#### A common infection with high mortality and severe side effects

In the single largest market, the US, about 2.1 million patients develop Sepsis each year and in Sweden approximately 40,000 cases are reported each year – more cases than for the 4 most common cancers. Not only is Sepsis a very common disorder but also very serious, with a mortality of 30% in its most severe form, septic shock, the stage when the sepsis reaction has progressed the furthest. Even in its earlier stages the mortality is still high, in the range of 15-20%. Additionally, survivors are often subject to severe side effects of the infection. It is not uncommon with side effects such as loss of limb, long-term mental confusion, kidney failure and blindness.



#### Currently no specifically approved drug that treats sepsis or septic shock

There is no approved pharmaceutical product available that is specifically developed to treat the actual sepsis reaction. Treatment today consists of standard intensive care treatment and drugs to counteract the effects on vital functions such as fluid therapy, blood pressure-raising drugs and respiratory aid. Today, sepsis / septic shock is one of the costliest conditions to treat in global health care and a new effective drug specifically intended for the treatment of sepsis is considered to be able to make a big difference in this regard. In the United States, it is estimated that sepsis costs U.S. health care about \$ 22 billion annually in direct costs and health care, a figure that could increase by a multiple of 10 if indirect costs are added.

There are thus substantial benefits to be gained from treatment with drugs that target the specific aspects of sepsis – both in terms of reduced mortality, improved patient outcomes and the reduction of treatment costs. Sevuparin is developed to be such a drug. Further, there is also the added potential to help other patients with other types of systemic inflammation of severe character as there are several overlapping mechanisms between sepsis and other types of systemic inflammation.

**It's most severe form, septic shock,  
has a mortality rate of 30%**  
- Survivors have a high degree of complications

**There are no approved treatments  
specific for sepsis**

**It is estimated that 50 million sepsis cases/year  
causes up to 11 million deaths/year world-wide**  
- Approx. 2 million cases/year in the US  
- Approx. 40 000 cases/year in Sweden  
(>4 most common types of cancer)

**One of the costliest conditions for health care**  
- Estimated annual cost in the US: 22 BUSD

**Potential to help patients with other  
types of severe systemic inflammation**

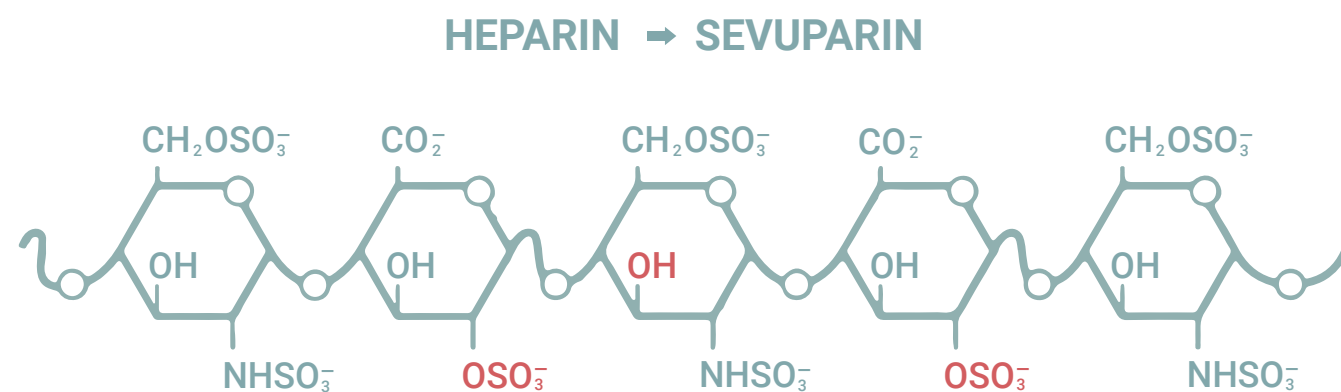


## SEVURPARIN & SEPSIS

Modus Therapeutics ambition is to initiate a paradigm shift in sepsis care and potentially for other systemic inflammatory conditions. Their drug candidate – Sevuparin – has the potential to do this.

### Modification of a proven technology

Heparin – a well-known anticoagulant drug based on a subgroup of polysaccharides – has been observed by researchers using pre-clinical models to have potentially beneficial properties in sepsis and systemic inflammation. Heparin has many qualities; however, the problem is that it is a blood thinning medicine which limits dosage due to the risk of bleeding. Modus has solved this problem by inventing a heparin molecule with substantially decreased blood thinning, all while keeping the other benefits of the drug.



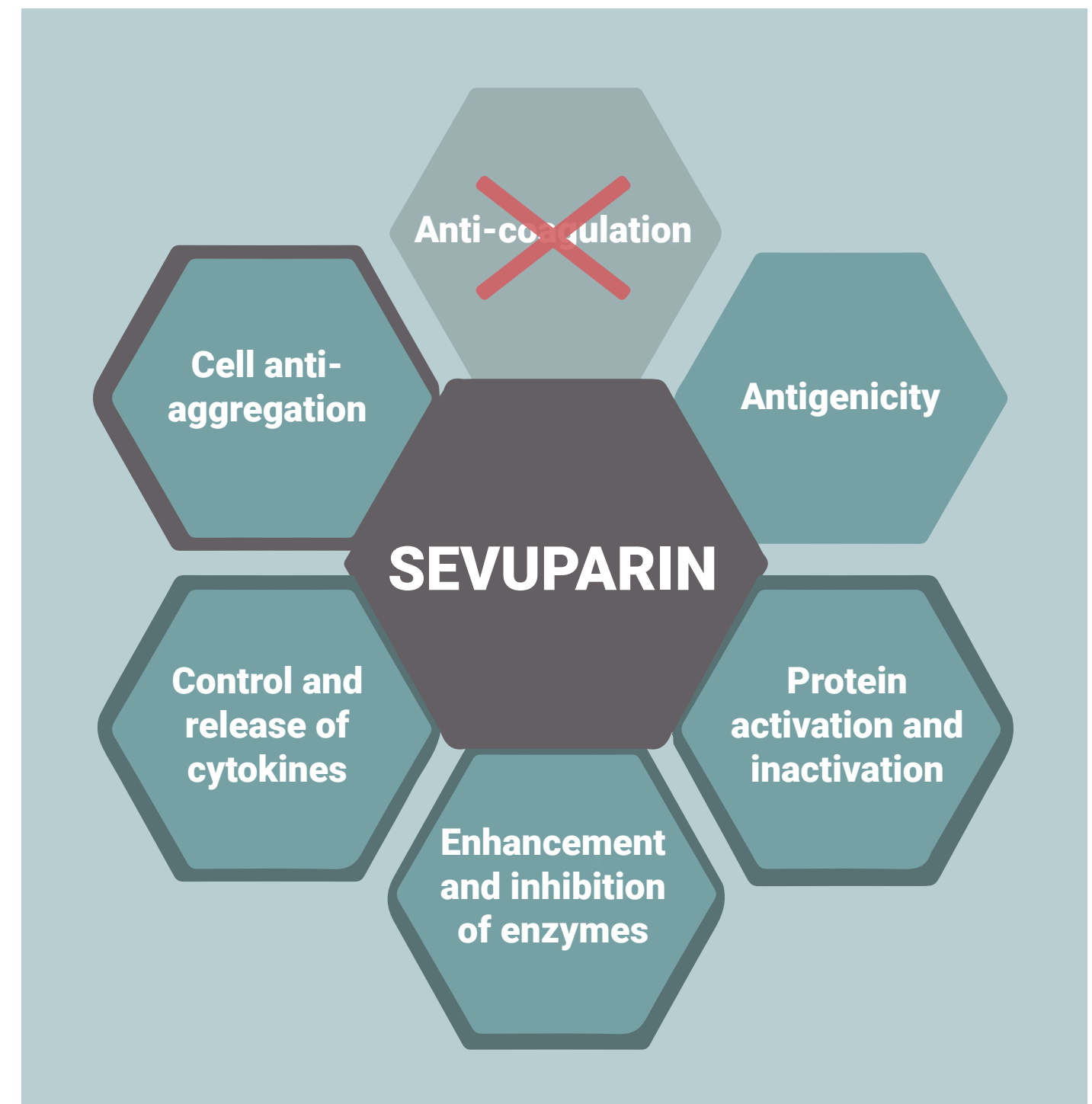
### Possibilities without the bleeding risk

Sevuparin is a unique molecule that is based on Heparin but that has been targeted for modification chemically by modifying 3 residues - altering the pentasaccharide motif that is

responsible for the anti-coagulation properties of Heparin to a disaccharide repeat. The sevuparin molecule - is thereby designed to have markedly reduced anti-coagulant activity. 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 immuno-modulation properties.

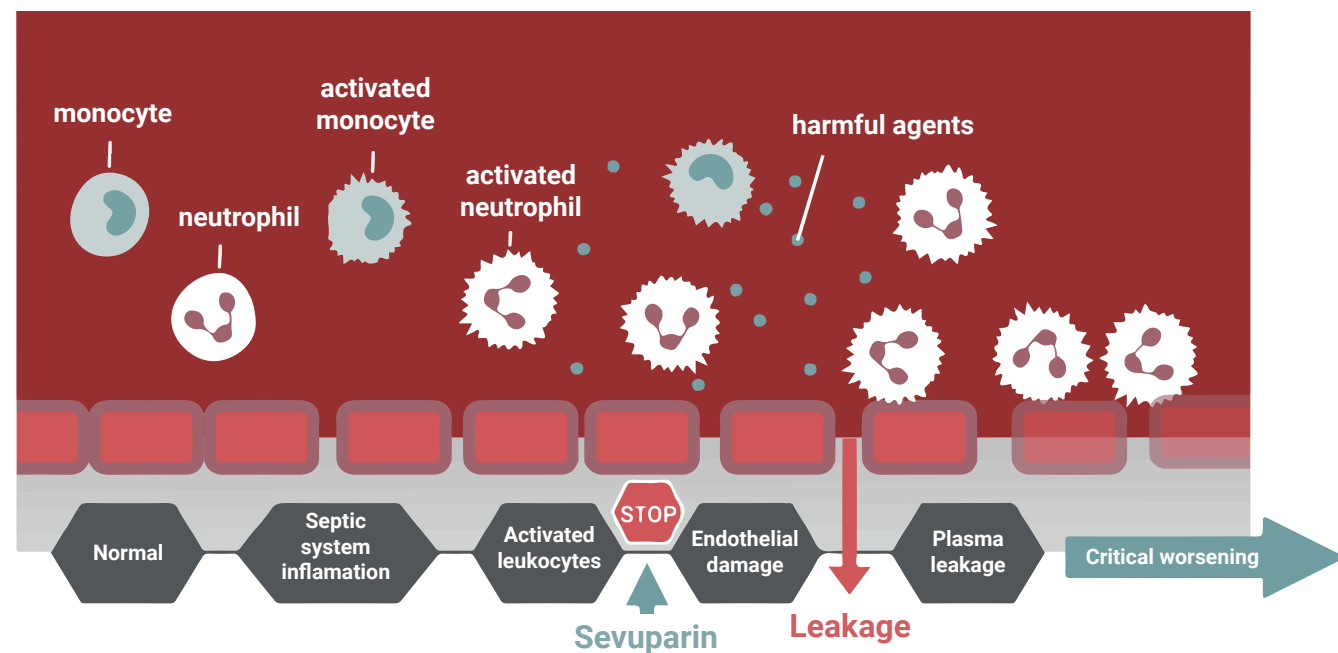
### A broad set of mechanisms

Sevuparin is an innovative proprietary polysaccharide drug with a multimodal mechanism of action, including immuno-modulation, anti-adhesive and anti-aggregate effects. Sevuparin therefore affects a number of mechanisms that can be targeted with relevance for other kinds of disorders than anti-coagulation such as sepsis and septic shock. A number of different targets that are potentially affected by a heparinoid have been identified and for these, sevuparin has the advantage of being dosed without the associated bleeding risk.



### Mode of action

Based on preclinical research, sevuparin is believed to counteract systemic inflammation by binding and neutralizing harmful substances secreted by activated white blood cells in sepsis and septic shock, providing robust vascular protection including the vasculature of the lung that is particularly sensitive to septic insult. Sevuparin could thereby break the molecular chain of events that lead to loss of blood vessel integrity, plasma leakage, and ultimately failing organ function.



The effects of sevuparin help protect the endothelial lining of the blood vessels during septic inflammation and systemic inflammation. In a normal situation white blood cells and the endothelium monitor each other and manage immune threats through careful regulation. However, certain situations when the blood stream is infiltrated by bacteria can lead to over-activation of the white blood cells at the same time as the endothelium loses its protective coating. The white blood cells react by degranulating and releasing active agents that not only threaten bacteria but also risk to harm the exposed endothelial lining of the blood vessels. This leads to a destructive chain of events with continued endothelial damage and white blood cells getting activated and caught up in the vessel walls as the patient progresses to organ failure, which in the case of the lung may lead to ventilator care.

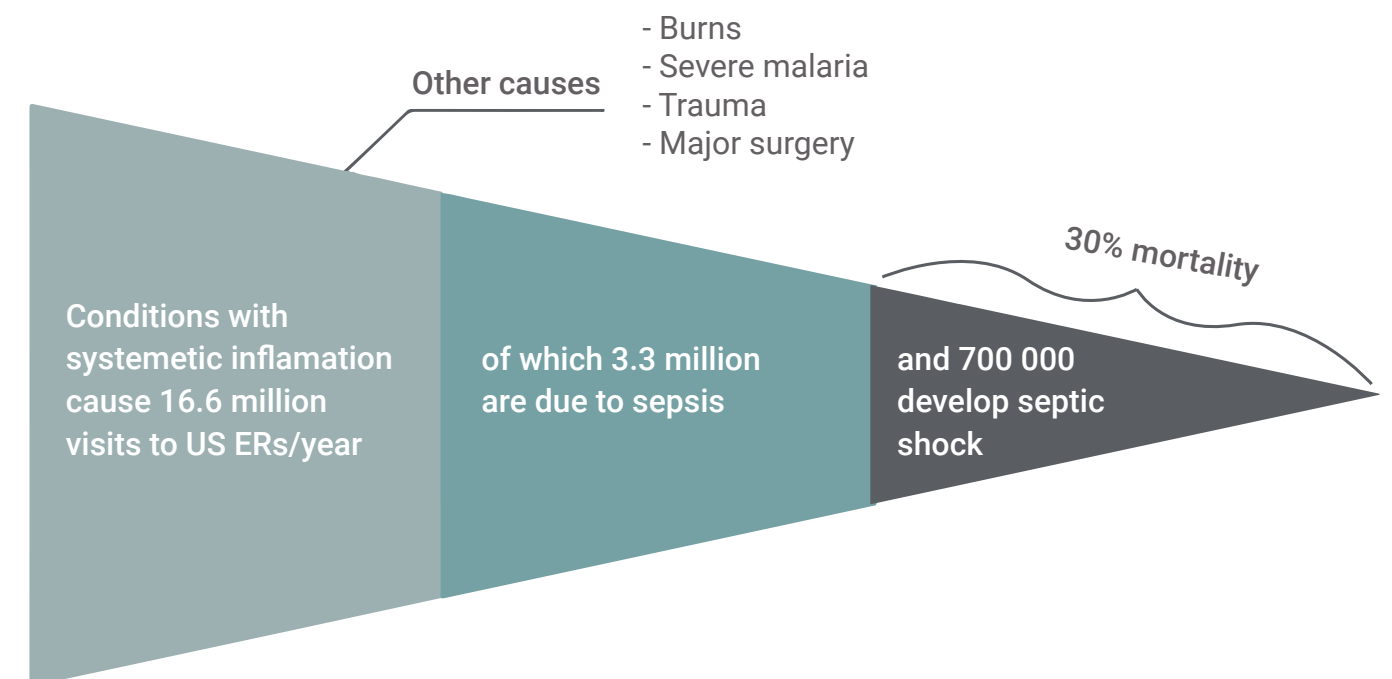
Sevuparin has been shown to bind and neutralize the potentially harmful agents generated by white blood cells that are known to threaten vascular integrity during systemic inflammation. This can break the destructive molecular chain of events that lead to vascular damage, depletion of white blood cells and plasma leakage in patients with sepsis/septic shock and other conditions where systemic inflammation is involved. This activity has been shown in pre-clinical animal models, where sevuparin has been effective in protecting the blood vessels and the lungs of mice and in human cell cultures. Recently, the top-line data from a Phase Ib LPS challenge study showed that sevuparin could modulate the levels of certain types of white blood cells as well as alleviating the increased respiratory rate seen in human subjects challenged by this bacterial endotoxin.

### Sepsis – part of a bigger problem

Sepsis is part of an even bigger problem – systemic inflammation disorders. Just as with sepsis these disorders are characterized by an inflammatory reaction that becomes over-determined, often threatening the patient's well-being beyond what is clinically manageable. It can be caused not only by bacteria but also by other situations where the patient's immune system overreacts.

Thanks to sevuparin's unique profile with greatly reduced blood-thinning properties and a confirmed safety profile, sevuparin has the potential to harness these potential properties not only for sepsis and septic shock but also other conditions with systemic inflammation. Examples of other such conditions are severe trauma, burns, major surgery, autoimmunity, viral infections and severe malaria to name a few.

Modus continuously evaluates possible research collaborations that can increase the understanding of sevuparin's mode of action. An excellent example of this is the collaboration with Imperial College London around severe malaria. Such collaborations with academic institutions can sometimes lead to so-called investigator-initiated clinical studies as exemplified by the Imperial College collaboration. Furthermore, Modus also collaborates externally to enable new patentable uses of sevuparin, as exemplified by the recently submitted patent application covering the use of sevuparin in chronic kidney disease and kidney disease with anemia.





## CLINICAL PROGRAM

In 2021 we made a significant decision to launch a new strategy for sevuparin, focusing on the clinical development of our drug candidate as a potential treatment for sepsis/septic shock and other severe inflammatory complications. We are now rapidly moving from concept to clinical development with positive results just released from a Phase Ib study to be followed by a Phase IIa study to be initiated year-end 2023.

**Successful early research formed the basis for a new strategy for sevuparin as a potential treatment for sepsis/septic shock and other severe conditions with systemic inflammation**

As part of early research, sevuparin has undergone preclinical toxicological testing enabling dosing for up to 14 days in clinical trials. Furthermore, preclinical in vivo efficacy studies have been performed previously in mice indicating beneficial effects on several disease models for, among others, sickle cell disease and malaria, as well as in mouse and in vitro human experimental systems for sepsis. In clinical trials with healthy phase I volunteers, sevuparin has been shown to be safe and tolerable with single and multiple intravenous dosing within clinically relevant dose ranges. Two patient studies (phase Ib and II) also showed the inhibitory effects of sevuparin on the ability of the malaria parasite in its binding to blood cells and the vessel wall. In a sizeable phase II patient study for the treatment of acute sickle cell disease, sevuparin was shown to have a favorable safety profile, although no improvement in disease status was observed compared with placebo.

Based on these encouraging results, we made a significant decision in 2021 to launch a new strategy for sevuparin, focusing on the clinical development of our drug candidate as

a potential treatment for sepsis/septic shock and other severe conditions with systemic inflammation. Our new strategy is paying off, with Modus rapidly moving from concept to clinical development.

**Phase Ib provocation study (LPS Challenge Study) – Positive top line results**

Rather than going directly into Phase 2, Modus opted to test the effect of sevuparin in systemic inflammation triggered by bacterial endotoxin in healthy volunteers (LPS provocation study). There are several advantages to this approach – besides being more cost effective than doing a larger dose optimization study in sick patients it also provides a very controlled system where different doses can be evaluated in parallel through the different stages of the inflammatory reaction. In this study healthy volunteers received an injection with lipopolysaccharides (LPS), an endotoxin which provokes a strong immune response. This causes systemic inflammation in healthy volunteers that is milder and less dangerous than the true clinical conditions. The LPS provocation approach thereby provides valuable information from a controlled environment that can guide decision making on fundamental aspects such as dosing, patient selection and biomarkers when designing the subsequent Phase II study in patients.





In the study the dosage of sevuparin was addressed in 3 areas:

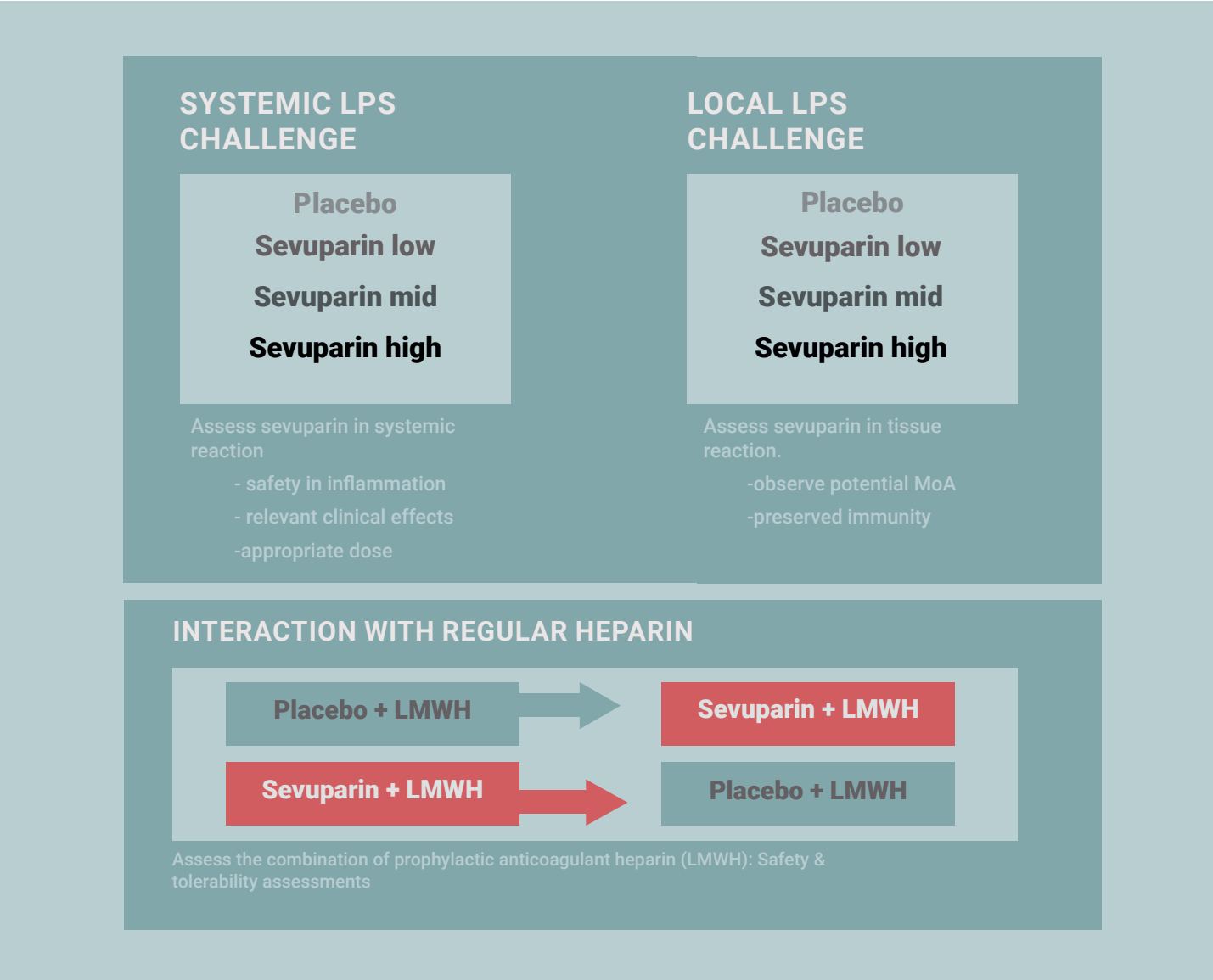
- Systemic LPC challenge: injecting the endotoxin directly into the bloodstream. This gives the possibility to study three main objectives using three different doses of sevuparin vs. placebo: the safety during induced systemic inflammation, any relevant effects on the clinical symptoms, and the relevance of the selected sevuparin doses vis a vis of the preclinical model.
- Local LPS challenge: In this part of the study, the effects of three different sevuparin doses on the reaction following LPS challenge in the skin are studied. Since the skin LPS challenge is a model

for the normal, local peripeheral immune defense, it can for example be used to test whether a treatment interferes with this important function that needs to be retained also in severe disease states such as sepsis.

- Interaction with regular heparin (enoxaparin): All severely ill patients may have an increased risk of blood clots and are therefore often given a low prophylactic dose of heparin, an important standard of care in patient populations that need thrombosis prophylaxis. The third part of the study therefore evaluates the potential interaction between enoxaparin and sevuparin.



We are delighted by the encouraging results from our LPS-challenge study, a very important milestone in our mission to develop sevuparin as a fundamental change in the treatment for sepsis and other conditions with systemic inflammation.”

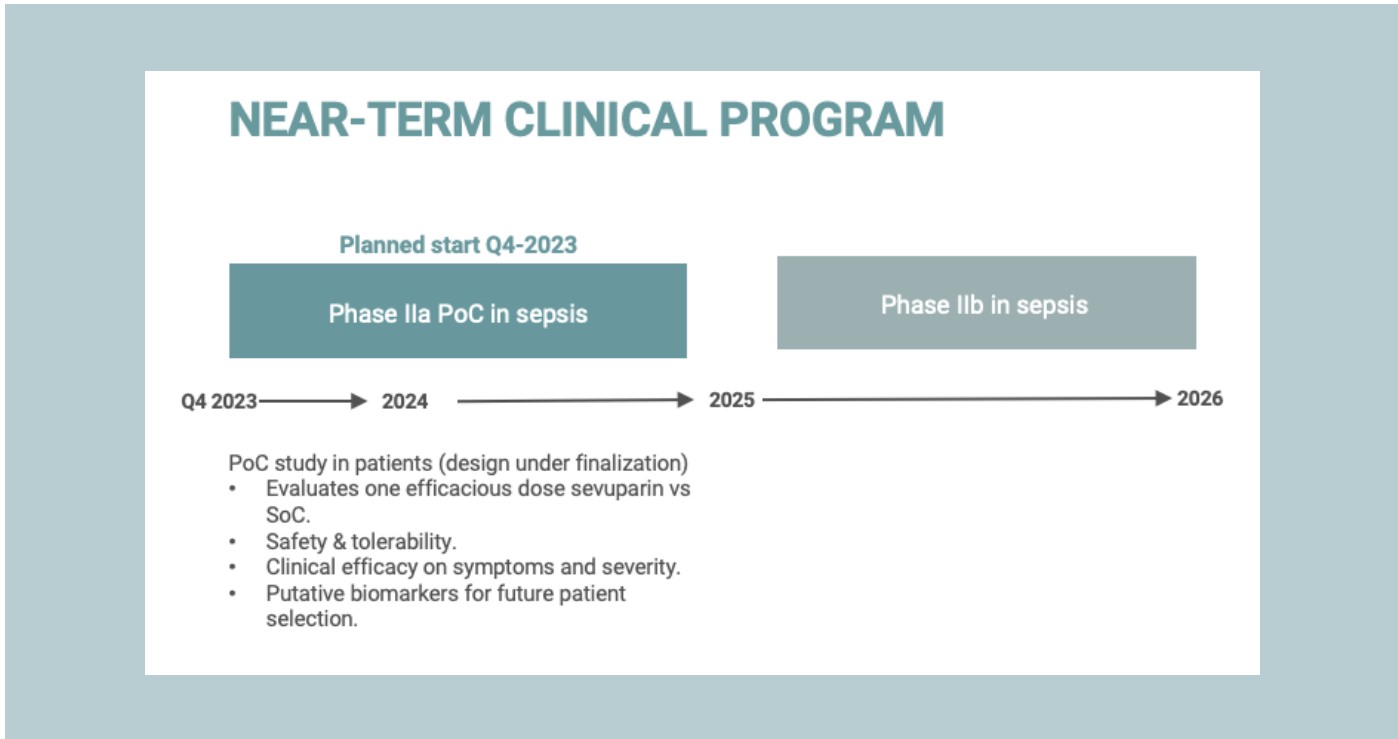


The phase Ib study was conducted during 2022 and top-line results were presented in February 2023.

- 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 as well as when combined with blood thinning heparin.
- 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.

During an ongoing systemic inflammation, the level of lymphocytes may decrease which can be serious. For example, lymphocyte depletion in sepsis patients is associated with a particularly unfavorable progression. Increased respiratory rate is one of the symptom hallmarks of systemic inflammation and sepsis, as it increases while the oxygen level in the blood drops. Most scales used to evaluate systemic inflammation conditions and sepsis have respiratory rate measurement as a main component. It is therefore particularly encouraging that the study shows that the effects on white blood cells are seen in parallel with a notable improvement of the respiratory rate and that these follow the same dose response.





The phase Ib study outcomes provide support for the assumption that the broad and potent mechanisms of sevuparin shown in earlier animal models are also relevant in humans.

Furthermore, the study data enhances the understanding of the immunomodulatory action of sevuparin and reinforces its potential for further development. This data will inform and help optimize future studies with sevuparin in sepsis and systemic inflammation.

**Preliminary Phase IIa Proof of Concept study in sepsis – planned start Q4 2023**

In phase IIa, a sevuparin dose supported by the findings in the phase Ib study will be used on top of standard of care (SoC), using SoC as control. It is expected to comprise 30-60 patients with sepsis in a multicenter setting. The aim of this proof-of-concept study would be to confirm the safety profile of sevuparin in septic patients along with the assessment of relevant clinically beneficial effects.

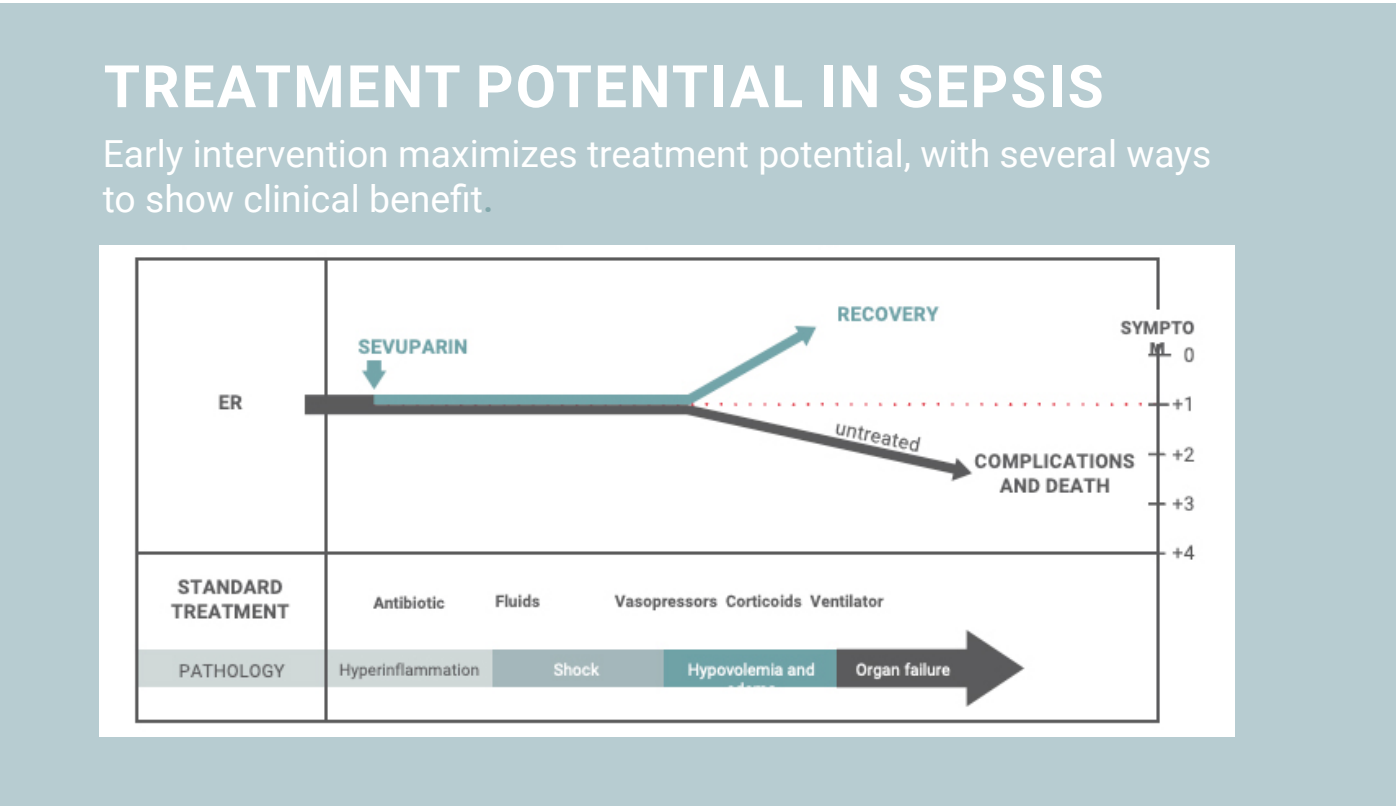
Safety and tolerability can potentially vary depending on the populations studied, whether in different patient types or in LPS-provoked

healthy volunteers. It is therefore important to ensure observations that correlate to previous safety and tolerability data before expanding the study further to a larger phase 2 study population with sepsis.

Data from the phase Ib study demonstrate clinical effects early in the course of a condition. Already during the first hours of the systemic inflammation, the effect of sevuparin is evident. These insights are valuable when considering the measurement of relevant clinical effects in the upcoming phase 2b study.

Early prevention of development towards a very serious condition, with complications and death, is crucial in the treatment of sepsis and other systemic inflammations. Complications and death are very closely linked with a worsening level of symptoms. As sevuparin shows an effect already at an early stage, there is an opportunity to improve the course of disease before the situation becomes even more difficult to reverse.

Another important aspect of high relevance considering what we now know of sevuparin, is how long a patient is in need of intensive care including respiratory support with a ventilator. In the US, a patient who needs ventilator care costs about 45 KUSD compared to 15 KUSD for a patient without a ventilator, i.e. 3 times as much – costs which can be avoided if sevuparin can intervene early in the progress of the reaction.



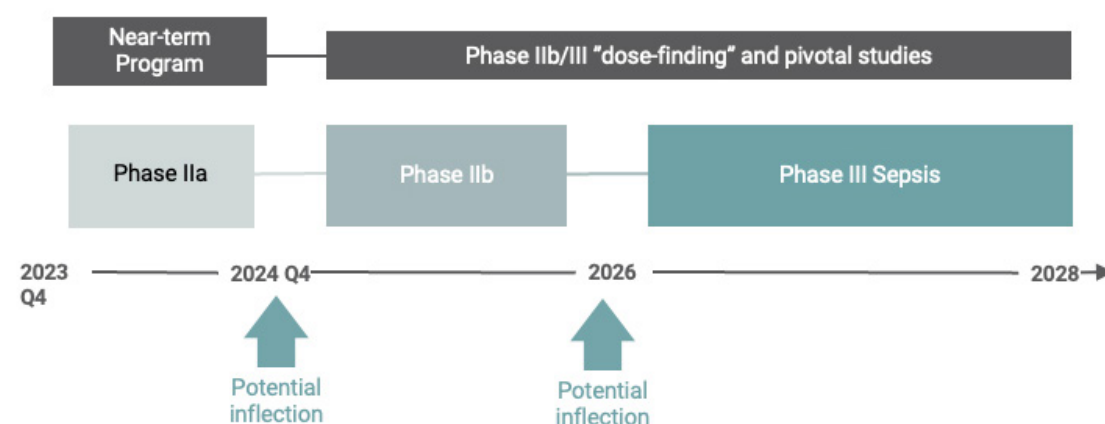
## BUSINESS MODEL

### Creating value for partnering

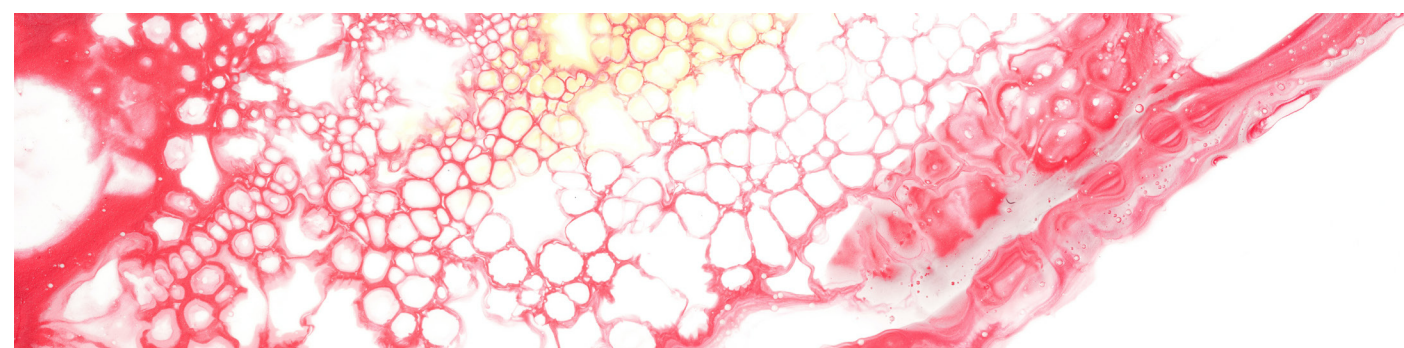
#### Modus business model - a clear strategy for value creation

An important part of Modus' strategy is to attract partnerships and buyers for sevuparin by creating product value in our clinical research. We believe that product value is best created through robust clinical data with value-building milestones as a natural part of the development with the possibility to build that value further with a strategic partnership that has presence in the area. A significant such milestone has just been reached with the positive outcome from the Phase Ib study, the next will be reached after the completion of the phase IIa patient study by the end of 2024. Modus definitely has the ability to drive development all the way to registration thanks to the combined experience of our team, supported by consultants who followed Modus for the past 10 years, and our scientific advisors. However, Modus believes that there is more benefit to the value development for a project like this to come under the attention of partner who can drive market entry through an established market structure and/or via co-development. Our business model is therefore based primarily on partnership. In the current development plan, a market introduction/ NDA (New Drug Application) can be implemented around the end of 2028.

**Market potential \$6 billion based on septic shock<sup>1</sup>, and \$27 billion based on sepsis<sup>2</sup>.**



<sup>1</sup> evaluation commissioned March 2021 from Xplico, <sup>2</sup> Base analysis by Carlsquare Oct 2021, both assessments valid for 7 MM.



### Timeline in traditional drug development



#### Faster route to market than traditional drug development

To obtain market support for a registration, two large Phase III studies with a total of more than 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 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, improvement in symptomatic measures of sepsis 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).

#### Accelerated approval

Issued by both EMA and FDA to accept a drug faster than the traditional process. The FDA intends to review the application and provide a decision within 60 days of receipt of the application for the candidate. Issued for indications with high unmet medical need.

#### 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 important endpoints.

#### Patent and market protection

Modus patent extends to 2032 in the US and 2033 in Europe, with the possibility of a patent extension of up to five years in each market. In addition, Modus has recently submitted patent applications with a potential to broaden and further extend the IP portfolio of sevuparin if granted.



## BUSINESS DEVELOPMENT OPPORTUNITIES

Sevuparin – one single molecule with a broad mechanism of action providing potential beneficial effects on several disease models. We are rapidly expanding our understanding of sevuparin's impact on systemic inflammation mechanisms due to different causes, as a key part of Modus' strategy to maximize the development potential of sevuparin.

### Sevuparin in paediatric patients with severe malaria

Malaria is one of the world's most notorious diseases where severe malaria remains an unaddressed medical problem in the parts of the world with endemic malaria. The condition primarily affects young children infected with the parasites. In severe malaria, the parasitic infection causes a systemic inflammation syndrome that shares similarities with sepsis and other severe conditions which uncontrolled may then progress into shock and multi-organ failure. The devastating impact of severe malaria cannot be overstated, and the need for transformative treatments is as great as it has ever been.

In September 2022, the first patient was enrolled in SEVUSMART, an Imperial College London/Wellcome sponsored phase I clinical trial evaluating sevuparin in paediatric patients with severe malaria. The trial will evaluate the safety and tolerability of escalating doses of sevuparin in up to 20 paediatric patients aged 3 months to 12 years presenting with severe malaria at the Kilifi County Hospital, Kilifi, Kenya. The study is designed to identify the appropriate dose of sevuparin together with standard of care in severe malaria to be taken forward in future clinical studies. Sevuparin has already shown promising effects on the malaria parasite in patients with uncomplicated malaria and in human samples (Leitgeb et al 2017, Saiwaew et al 2017). The trial is the result of a collaboration between Modus and a team

from Imperial College London, UK. The project is funded by a collaborator grant in science from Wellcome to a research group at KEMRI-Wellcome Trust Programme, Kilifi Kenya and to the international consortium "Severe Malaria Africa – a consortium for Research and Trials" (SMAART), the goal of which is to identify and research new treatments for severe malaria. Modus believe that sevuparin has the potential to support the treatment of severe malaria in children. With this study we hope to grow our understanding of how to improve patient outcomes in what remains a very challenging disease area.



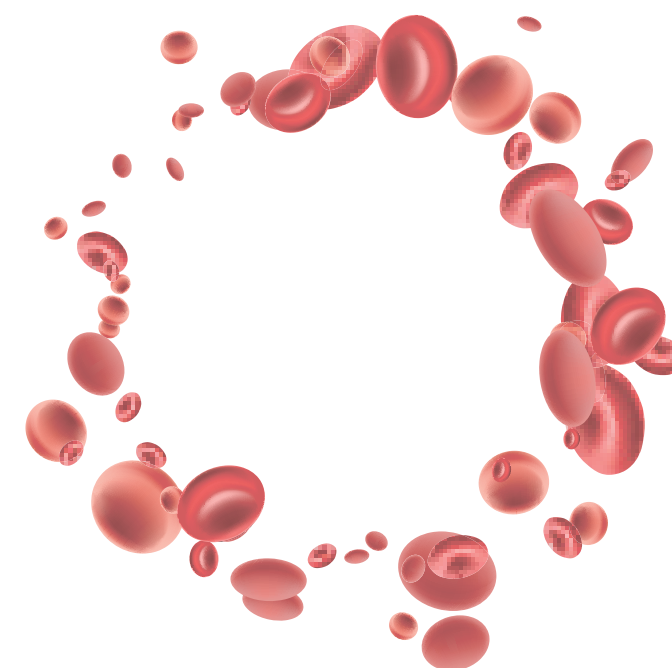
### About severe malaria and sevuparin

One key event in severe malaria is when red blood cells that are infected with malaria parasites stick to the very deep parts of the blood vessels. This occurs throughout the body causing poor blood flow to the tissues which leads to a build-up of body acids (called lactate) and inflammation. Currently, there are no treatments available to prevent, reverse or stop cells from sticking to the blood vessels when infected with malaria parasites. In addition to counteracting harmful mediators from white blood cells (Rasmuson et al 2019), sevuparin acts by preventing malaria parasites getting into red cells (necessary for parasite survival). Furthermore, sevuparin prevents red cells infected with malaria parasites from sticking to the blood vessels and is also able to 'detach' cells infected with malaria parasites already stuck to the blood vessel with a potential for positive effects on blood flow (Leitgeb et al 2017, Saiwaew et al 2017).

### Sevuparin in kidney disease

In January this year, Modus submitted a patent application claiming the use of sevuparin for the treatment of chronic kidney disease also with concomitant anemia. 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.

From a future scientific and development angle, with the establishment of potentially new and patent protected indications for sevuparin, the prospect of value generation by research and development has the potential to increase significantly. An initial assessment of the commercial potential for the use of sevuparin in kidney disease indicated a >\$1 billion market potential. Going forward Modus will be looking at the possibilities to address this new indication clinically in parallel with the sepsis program.



## KEY REASONS TO INVEST

The main indication, sepsis represents a major unmet medical need.

Sevuparin is Phase 2 ready; toxicology and safety package + extensive clinical safety data significantly de-risk the program.

Positive top line data from the Phase 1b LPS challenge study shows clinically relevant and differentiated effects

Fast to market approach. Strong upside with billion \$ commercial potential in sepsis indication alone – no approved specific products available.

Extensive patent portfolio, continuously developed in parallel with project activities.

- Sevuparin per se substance patent protection to 2032 plus up to 5 years, based on regulatory approval.
- New priority Patent application filed Dec 2022 for a new use in chronic kidney disease (CKD) and anemia in CKD.
- New priority patent application filed Feb 2023 based on LPS challenge study.

## SHARE PRICE DEVELOPMENT IN 2022

Modus Therapeutics share was listed on Nasdaq First North Growth Market in Stockholm on July 22, 2021. At the end of 2022, the total number of Modus shares amounted to 16 100 050 and the number of shareholders was 1 010.

### Share capital and ownership

At the end of 2022, Modus share capital amounted to SEK 966 003 distributed between 16 100 050 shares. All shares have equal voting rights and right to dividend. The company's principal owners are Karolinska Development AB (37.9%), KDev Investment AB (17.1%) and John Öhd (10.7%).

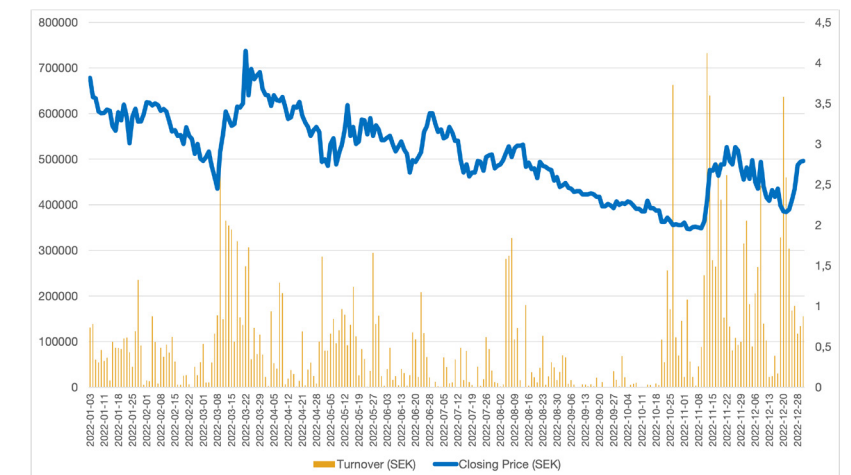
### Dividend policy

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 2023	May 9, 2023
Annual General Meeting 2023	May 11, 2023
Interim Report Q2 2023	August 23, 2023
Interim Report Q3 2023	November 22, 2023

### Share price development in 2022



### Largest shareholders on December 31, 2022

Owner	No. of shares	Share capital %
Karolinska Development AB	6 104 821	37.9%
KDev Investments AB	2 752 516	17.1%
Öhd, John	1 730 591	10.7%
Hans Wigzell	632 392	4.0%
Bladh, Anders	348 000	2.2%
Nordnet Pensionsförsäkring AB	260 625	1.6%
Kinson Donnelly, Ellen	195 073	1.2%
Försäkringsbolaget Avanza Pension	189 154	1.2%
Lindqvist, Per	120 000	0.7%
Hammer, Pauli Martin Per	100 000	0.6%
Hederstedt, Bo	100 000	0.6%
Others	3 541 878	22.2%
<b>Total registered shares</b>	<b>16 100 050</b>	<b>100%</b>

### Certified Advisor

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

Contact information: [www.skmg.se](http://www.skmg.se) Phone: +46 11 32 30 732 e-mail: [ca@skmg.se](mailto:ca@skmg.se)



# LEADERSHIP TEAM AND BOARD



## John Öhd, M.D., Ph.D

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. Öhd's previous qualifications include the 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. Lindblad 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, Lindblad has held several senior positions, including as 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.

**Other current roles:** None

**Holdings:** 10 812 shares and 86 000 warrants of series 2021/2024.



## Viktor Drvota, M.D, Ph.D

Chairman since 2016

**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. Drvota 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 Shares.

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



## Torsten Goesch, M.D, Ph.D

Board Member since 2014

**Born:** 1959

**Education and experience:** Licensed physician, Doctor of Medicine and holds an MBA from the Kellogg School of Management in Chicago. Goesch has more than 25 years of experience from the Life Science sector, including as senior executives within Biogen and Merck KGaA. Goesch 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 shares.

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



## Ellen K. Donnelly, Ph.D

Board Member since 2020

**Born:** 1974

**Education and experience:** PhD in Neuroscience from the Yale School of Medicine. Donnelly has extensive experience from leadership positions within Life Science, including as former CEO of Modus and senior positions within Pfizer and Combinato Rx. Ellen Donnelly 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.

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



# MANAGEMENT REPORT

The board and the CEO of Modus Therapeutics Holding AB (publ) hereby present the annual report for fiscal year 2022-01-01 to 2022-12-31. Unless otherwise specified all amounts are stated in SEK thousand.

## About Modus nature and direction of the business

Modus Therapeutics is a Swedish biotech company developing sevuparin for diseases with high unmet medical need. The Company's focus is currently to develop sevuparin for patients with sepsis/septic shock, a severe and often fatal condition. 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 anti-inflammatory, anti-adhesive and anti-aggregating 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](http://www.modustx.com).

## Ownership structure

At the end of the fourth quarter of 2022 there was a total of 1010 shareholders in Modus Therapeutics Holding AB (publ). The three largest shareholders owned 66% of the capital and votes. The total number of shares was 16,100,050. The main shareholders were, per December 31 2021, Karolinska Development AB 556707-5048 37,9%, KDev Investment AB 556880-1608 17,1% and CEO John Öhd 10,7%

## Important events during the fiscal year

### The annual general meeting was held on May 11, 2022

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 adopt new articles of association whereby the limits of the share capital and number of shares are amended.
- 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.

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

On May 12, 2022 Modus announced that it has secured access to bridge financing of up to

SEK 11.5 million from its largest shareholder, Karolinska Development. Access to this potential funding will ensure that momentum of clinical development of the company's lead asset, sevuparin, for the treatment of sepsis is sustained.

### Modus Therapeutics Updates on Sevuparin Phase 1b Clinical Trial Timelines

On May 25, 2022 Modus provides an update on its ongoing Phase 1b LPS-challenge study and its other clinical activities with sevuparin.

Modus observed that the ongoing effects of the Covid-19 pandemic throughout spring slowed down enrolment for the Phase 1b trial, causing a delay to the anticipated timelines. This is largely attributed to subjects being unable to take part if they have contracted Covid-19 or have had a Covid vaccination within the screening/enrolment period. The company now expects to finalize recruitment by end Q3. Due to the delay caused by external circumstances mainly relating to the pandemic and outside of company control, the previously announced interim analysis cannot be performed within the anticipated timelines and is therefore cancelled.

Modus is now focused on improving the pace of recruitment into the trial and has taken several initiatives to ensure acceleration for full enrollment. These include updates to the selection criteria which now allows the enrolment of female subjects into the study.

### Modus Therapeutics Holding AB announces outcome of warrant redemption

On June 9, 2022, the exercise period for Modus Therapeutics Holding AB's warrants of series TO 1 ended. No warrants of series TO 1 were exercised. The background to the lack of interest was deemed to be that the price for exercising warrants of series TO 1 during the entire exercise period exceeded the prevailing share price.

During the period from and including 19 May 2022 to and including 9 June 2022, holders of warrants of series TO 1 had the right to subscribe for one (1) new share in Modus Therapeutics at a price of SEK 7.30 per share for each warrant. No warrants have been exercised and thus the share capital and the number of shares in the Company are unchanged.

### Modus Therapeutics announces first patient enrolled in the Phase I SEVUSMART clinical trial evaluating sevuparin in paediatric patients with severe malaria

On September 1, 2022 Modus announced the inclusion of the first patient and the start of SEVUSMART, an Imperial College London/ Wellcome sponsored phase I clinical trial evaluating the Company's proprietary drug sevuparin in paediatric patients with severe malaria. The SEVUSMART phase I trial will evaluate the safety and tolerability of escalating doses of sevuparin in up to 20 paediatric patients aged 3 months to 12 years presenting with severe malaria at the Kilifi County Hospital, Kilifi, Kenya. The study is designed to identify the appropriate dose of sevuparin together with standard of care in severe malaria to be taken forward in future clinical studies.

Sevuparin has already shown promising effects on the malaria parasite in patients with uncomplicated malaria and in human samples (Leitgeb et al 2017, Saiwaew et al 2017).

The trial is the result of a collaboration between Modus and a team led by Professor Kathryn Maitland from Imperial College London, UK. The project is funded by a collaborator grant in science from Wellcome (209265/Z/17/Z) to Professor Maitland's research group at KEMRI-Wellcome Trust Programme, Kilifi Kenya and to the international consortium "Severe Malaria Africa – a consortium for Research and Trials" (SMAART), the goal of which is to identify and research new treatments for severe malaria.

Modus is currently developing sevuparin in sepsis/septic shock, and other conditions with systemic inflammation, of which severe malaria constitutes an example.

Severe malaria remains an unaddressed medical problem in the parts of the world with endemic malaria. The condition primarily affects young children infected with the parasites. In severe malaria, the parasitic infection causes a systemic inflammation syndrome that shares similarities with sepsis and other severe conditions which uncontrolled may then progress into shock and multi-organ failure.

#### **Modus Therapeutics completes recruitment for Phase 1b LPS provocation study**

On September 27, 2022 Modus announced that recruitment had been completed into the company's clinical Phase 1b LPS provocation study evaluating the potential of its lead asset, sevuparin, for the treatment of sepsis and septic shock.

#### **Important events after year-end 2022**

#### **Modus Therapeutics submits patent application for sevuparin in kidney disease**

On January 23, 2023 Modus announces 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**

On 21 February, 2023 Modus announced positive top-line data from its Phase 1b lipopolysaccharide (LPS) provocation study, a key step in evaluating the potential of its lead asset, sevuparin, as a treatment for sepsis and other conditions with systemic inflammation. All three doses of sevuparin were found to be safe and tolerable throughout the study period, confirming the candidate drug's favorable safety profile under induced inflammatory conditions. Furthermore, sevuparin treatment caused statistically significant and dose-dependent increases in the levels of certain white blood cells as well as a dose-dependent inhibition of the LPS induced increase in respiratory rate. Sevuparin was also found to be safe and tolerable when combined with a blood thinning heparin (enoxaparin).

Data from the Phase 1b study will be used to inform the protocol of the planned Phase 2 study with sevuparin in patients with sepsis. This study is expected to start in 2023.

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

On March 29, 2023, Modus Therapeutics 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, expected to commence at the end of 2023. The funding will also allow Modus to continue exploring the development of new indications for sevuparin with promising potential such as chronic kidney disease.

## **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.

Modus is dependent on additional capital contributions during 2023 for the continued development of sevuparin in the aforementioned areas. The ability to raise capital to support research and development activities is critical for development companies such as Modus.

Russia's invasion of Ukraine and the coronavirus's global spread 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 general downturn in the stock market and the increase in interest rates may also affect Modus and its opportunities to secure financing for its continued development. The Board monitors the evolution of the crises closely and Modus is working intensively to minimize the impact of these crises.

During the beginning of 2022, the global vaccination programs and the attenuation of pandemic waves have led to a gradual return of life to a more normal state in society. However, the introduction of the new COVID mutation Omicron at the end of 2021 led to the reintroduction/prolonging of restrictions in many countries.

In December 2021, Modus started its phase 1b clinical study in the Netherlands and upon close monitoring, a pattern of higher recruitment variability from month to month compared to expected was observed during conduct in 2022. The COVID effects contributed to a delay of recruitment in the Phase 1b study which was communicated in May 2022.

In June 2022, Modus secured access to bridge financing of up to SEK 11.5 million from its largest shareholder, Karolinska Development. The loan was implemented on 30 August 2022 and has made it possible for the momentum of the development projects to be maintained.

On March 29, 2023, Modus announced that it had secured access to an additional 7.0 million from its largest owner. The bridge financing facility will be submitted to the annual general meeting, to be held on 11 May 2023, for approval. Draw down of the capital in its entirety is subject to such approval being obtained. Access to this funding ensures a continued high pace for the clinical development while the company continues to explore licensing and partnership opportunities.

Modus is investigating future possibilities for the funding required to realize the clinical activities that are to follow upon the recently finalized Phase 1b study. 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 delivers 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.

Consequences of the pandemic in the bigger perspective that may have a potential effect on Modus business activities can be, for example, the uncertainty of the negative effects that might linger on into 2023 - such as a lack of resources or staff, lack of material supply to production and manufacturing and/or disruptions in logistical chains. Another factor could be macro-economic effects with a consequential uncertainty on the financial markets impacting the willingness to invest

## Financial overview (TSEK)

Group Company	2022	2021	2020	2019	2018
Net sales	-	-	-	-	-
Profit/Loss after financial items	-18 320	-20 691	-6 020	-43 575	-49 651
Balance sheet total	11 271	21 191	7 491	2 051	46 951
Quick asset ratio, %	Neg	74,3	93,4	Neg	50,9
Average number of employees	2	2	1	4	4

Parent Company	2022	2021	2020	2019	2018
Net sales	740	505	609	1 491	2 954
Profit/Loss after financial items	-6 646	-6 525	63 115	-233 478	-3 838
Balance sheet total	79 824	89 871	77 314	2 414	243 843
Quick asset ratio, %	61,6	82,0	98,5	Neg	87,7
Average number of employees	2	2	1	2	2

### Definitions

1) Equity in relation to balance sheet total.

## Proposed distribution of earnings

Share premium reserve	295 800 403
Accumulated loss	-223 057 800
Net loss for the year	-24 546 169
<b>SEK</b>	<b>48 196 434</b>

The Board of Directors proposes that the accumulated	
loss be carried forward as retained earnings	48 196 434
<b>SEK</b>	<b>48 196 434</b>

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.

# FINANCIAL STATEMENTS

## Consolidated income statement

TSEK	Note	2022-01-01 - 2022-12-31	2021-01-01 - 2021-12-31
Net sales		-	-
Research and development costs	3	-10 898	-13 544
Administration costs	3	-6 988	-7 094
Other operating income		-	-
Other operation expenses		-120	-52
<b>Operating profit/loss</b>		<b>-18 006</b>	<b>-20 690</b>
Other interest received and similar items		-	-
Interest expenses and similar profit/loss items		-314	-1
<b>Total results from financial investments</b>		<b>-314</b>	<b>-1</b>
<b>Profit/loss after financial items</b>		<b>-18 320</b>	<b>-20 691</b>
Income tax		-	-
<b>Profit/loss for the period</b>		<b>-18 320</b>	<b>-20 691</b>
Profit/loss attributable to Parent company shareholders		-18 320	-20 691
Earnings per share before and after dilution (SEK)		-1,14	-1,67
Average number of shares, thousands		16 100	12 376

## Consolidated balance sheet

TSEK	Note	2022-12-31	2021-12-31
<b>Assets</b>			
Financial assets	5		
Other long-term receivables		50	50
<b>Total financial assets</b>		<b>50</b>	<b>50</b>
Other receivables		230	249
Prepaid expenses and accrued income	8	567	244
<b>Total short-term receivables</b>		<b>797</b>	<b>493</b>
Cash and bank		10 424	20 648
<b>Total current assets</b>		<b>11 221</b>	<b>21 141</b>
<b>Total assets</b>		<b>11 271</b>	<b>21 191</b>
<b>Equity and liabilities</b>			
Share capital		966	966
Additional paid-in capital		295 926	295 926
Retained earnings including net loss for the year		-299 477	-281 158
<b>Total equity attributable to equity holders of the parent company</b>		<b>-2585</b>	<b>15 735</b>
<b>Total equity</b>		<b>-2585</b>	<b>15 735</b>
Convertible loan		11 500	-
Accounts payable - trade		1 361	4 485
Current tax liabilities		36	-
Other liabilities		101	139
Accured expenses and deferred income	7	858	833
<b>Total current liabilities</b>		<b>13 856</b>	<b>5 457</b>
<b>Total equity and liabilities</b>		<b>11 271</b>	<b>21 191</b>



## 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
<b>Equity at 2021-01-01</b>	<b>44</b>	<b>257 226</b>	<b>-250 275</b>	<b>6 995</b>	<b>6 995</b>
Profit/loss for the year			-20 691	-20 691	-20 691
<i>Transactions with the shareholders:</i>					
New issue of shares by IPO	309	32 691		33 000	33 000
Cost attributable to new share issue		-3 695		-3 695	-3 695
Subscription of convertible loans	141	-141		-	-
Interest on convertible loans from shareholders		10 000	-10 000	-	-
Option premiums		-155	281	126	126
Capitalization issue	472		-472	-	-
<b>Equity at 2021-12-31</b>	<b>966</b>	<b>295 926</b>	<b>-281 157</b>	<b>15 735</b>	<b>15 735</b>
<b>Equity at 2022-01-01</b>	<b>966</b>	<b>295 926</b>	<b>-281 157</b>	<b>15 735</b>	<b>15 735</b>
Profit/loss for the year			-18 320	-18 320	-18 320
<b>Equity at 2022-12-31</b>	<b>966</b>	<b>295 926</b>	<b>-299 477</b>	<b>-2 585</b>	<b>-2 585</b>

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

### Share capital and share classes

The share capital consists of 16 100 050 ordinary shares.

## Consolidated cash flow statement

TSEK	Note	2022-01-01 - 2022-12-31	2021-01-01 - 2021-12-31
Operating profit/loss		-18 006	-20 690
Interest paid		-	-1
<b>Cash flow from operating activities before changes in working capital</b>		<b>-18 006</b>	<b>-20 691</b>
Increase (-) Decrease (+) in current receivables		-304	-347
Increase (-) Decrease (+) in current liabilities		-3 414	4 960
<b>Cash flow from operating activities</b>		<b>-21 724</b>	<b>-16 078</b>
Acquisition of financial assets		-	-50
<b>Cash flow from investment activities</b>		<b>-</b>	<b>-50</b>
New issue of shares		-	33 000
Cost attributable to new share issue		-	-3 695
Option premiums received		-	126
Convertible loans		11 500	-
<b>Cash flow from financing activities</b>		<b>11 500</b>	<b>29 431</b>
<b>Cash flow for the period</b>		<b>-10 224</b>	<b>13 303</b>
Cash and equivalents at the beginning of the year		20 648	7 345
<b>Cash and cash equivalents at year-end</b>		<b>10 424</b>	<b>20 648</b>

## Parent company income statement

<i>TSEK</i>	Note	2022-01-01 - 2022-12-31	2021-01-01 - 2021-12-31
Net sales		740	505
		<b>740</b>	<b>505</b>
Research and development costs	3	-1 210	-1 057
Administration costs	3	-5 862	-5 967
Other operating expenses		-	-5
<b>Total operating expenses</b>		<b>-7 072</b>	<b>-7 029</b>
<b>Operating profit/loss</b>		<b>-6 332</b>	<b>-6 524</b>
Interest expenses and similar profit/loss items		-314	-1
<b>Total results from financial investments</b>		<b>-314</b>	<b>-1</b>
<b>Profit/loss after financial items</b>		<b>-6 646</b>	<b>-6 525</b>
Year-end appropriations	4	-17 900	-25 200
Income tax expense		-	-
<b>Net profit/loss for the year</b>		<b>-24 546</b>	<b>-31 725</b>

## Parent company balance sheet

<i>TSEK</i>	Note	2022-12-31	2021-12-31
<b>Assets</b>			
<i>Financial assets</i>	6		
Participations in Group companies		70 000	70 000
Other long-term assets		50	50
<b>Total financial assets</b>		<b>70 050</b>	<b>70 050</b>
<b>Current assets</b>			
<i>Short-term receivables</i>			
Other receivables		78	129
Prepaid expenses and accrued income	8	515	206
<b>Total short-term receivables</b>		<b>593</b>	<b>335</b>
Cash and bank		9 181	19 486
<b>Total current assets</b>		<b>9 774</b>	<b>19 821</b>
<b>Total assets</b>		<b>79 824</b>	<b>89 871</b>
<b>Equity and liabilities</b>			
Share capital		966	966
<b>Total restricted equity</b>		<b>966</b>	<b>966</b>
Share premium reserve		295 800	295 800
Retained earnings		-223 058	-191 333
Profit/loss for the year		-24 546	-31 725
<b>Total non-restricted equity</b>		<b>48 196</b>	<b>72 743</b>
<b>Total equity</b>		<b>49 162</b>	<b>73 709</b>
Convertible loan		11 500	-
Accounts payable		274	353
Liabilities to Group companies		17 999	15 024
Current tax liabilities		36	-
Other liabilities		101	139
Accrued expenses and deferred income	7	752	646
<b>Total current liabilities</b>		<b>30 662</b>	<b>16 162</b>
<b>Total equity and liabilities</b>		<b>79 824</b>	<b>89 871</b>



## Parent company changes in equity

<i>TSEK</i>	Share capital	Share premium	Retained earnings	Profit/loss for the year	Total equity
<b>Equity at 2021-01-01</b>	<b>44</b>	<b>251 945</b>	<b>-238 975</b>	<b>63 115</b>	<b>76 129</b>
<i>Disposition of previous years' result</i>			63 115	-63 115	-
Profit/loss for the year				-31 725	-31 725
<i>Transactions with shareholders:</i>					
New issue of shares by IPO	309	32 691			33 000
Cost attributable to new share issue		-3 695			-3 695
Subscription of convertible loans	141	14 859	-15 000		-
Capitalization issue	472		-472		-
<b>Equity at 2021-12-31</b>	<b>966</b>	<b>295 800</b>	<b>-191 332</b>	<b>-31 725</b>	<b>73 709</b>
<b>Equity at 2022-01-01</b>	<b>966</b>	<b>295 800</b>	<b>-191 332</b>	<b>-31 725</b>	<b>73 709</b>
<i>Disposition of previous years' result</i>			-31 725	31 725	-
Profit/loss for the year				-24 546	-24 546
<b>Equity at 2022-12-31</b>	<b>966</b>	<b>295 800</b>	<b>-223 057</b>	<b>-24 546</b>	<b>49 163</b>

## Parent company cash flow statement

<i>TSEK</i>	Note	2022-01-01 - 2022-12-31	2021-01-01 - 2021-12-31
Operating profit/loss		-6 332	-6 524
Interest paid		-	-1
<b>Cash flow from operating activities before changes in working capital</b>		<b>-6 332</b>	<b>-6 525</b>
Increase (-) Decrease (+) in current receivables		-258	-313
Increase (-) Decrease (+) in current liabilities		-475	657
<b>Cash flow from operating activities</b>		<b>-7 065</b>	<b>-6 181</b>
Acquisition of other fixed assets		-	-50
Made Group contribution		-14 740	-10 880
<b>Cash flow from investment activities</b>		<b>-14 740</b>	<b>-10 930</b>
New issue of shares		-	33 000
Cost attributable to new share issue		-	-3 695
Convertible loans		11 500	-
<b>Cash flow from financing activities</b>		<b>11 500</b>	<b>29 305</b>
<b>Cash flow for the year</b>		<b>-10 305</b>	<b>12 194</b>
Cash and cash equivalents at beginning of year		19 486	7 292
<b>Cash and cash equivalents at year-end</b>		<b>9 181</b>	<b>19 486</b>

# 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 (37.92%), 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 write-downs. 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 financial instrument 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*

With the securing of bridging financing from Karolinska Development, it is estimated that the operations during the current year can be carried out according to plan regarding the company's development project. The Board and the CEO 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 assesses that the prospects for future capital raising are good provided that the development project delivers according to plan and the annual report has therefore been prepared with assumptions of going concern.

### Note 3 Employee salaries and benefits

Average number of employees	Group		Parent company	
	2022	2021	2022	2021
Male	2	2	2	2
Female	-	-	-	-
<b>Total</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>

Gender distribution of senior executives	Group		Parent company	
	2022	2021	2022	2021
<i>Board members</i>				
Female	1	1	1	1
Male	2	2	2	2
<i>CEO and senior executives</i>				
Female	-	-	-	-
Male	2	2	2	2

Salaries, other benefits and social contribution	Group		Parent company	
	2022	2021	2022	2021
Board, CEO and business management	2 789	2 660	2 789	2 660
<b>Total</b>	<b>2 789</b>	<b>2 660</b>	<b>2 789</b>	<b>2 660</b>
Social contribution	731	701	731	701
Pension cost to board and CEO	708	506	708	506
<b>Total salaries, social contributions and pension costs</b>	<b>4 228</b>	<b>3 866</b>	<b>4 228</b>	<b>3 866</b>

Alloted warrants	2022-12-31		2021-12-31	
	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	-	-
Exercised during the period	-	-	172 000	8,32
<b>Total</b>	<b>172 000</b>	<b>8,32</b>	<b>172 000</b>	<b>8,32</b>

### Note 4 Year-end appropriations

TSEK	Parent company	
	2022	2021
Group contribution paid	-17 900	-25 200
<b>Total</b>	<b>-17 900</b>	<b>-25 200</b>

### Note 5 Financial assets

Participation in Group companies		Parent company	
TSEK		2022	2021
Cost of acquisition at opening balance		233 156	233 156
Shareholders contributions, paid		-	-
<b>Total accumulated cost of acquisition</b>		<b>233 156</b>	<b>233 156</b>
Impairment at opening balance		-163 156	-163 156
Reversal of impairment		-	-
<b>Impairment at closing year</b>		<b>-163 156</b>	<b>-163 156</b>
<b>Net book value</b>		<b>70 000</b>	<b>70 000</b>

Subsidiary / Corp. reg. no / Domicile	Equity %	Shares of votes%	Numbers of shares	Carrying amount
				2022
Modus Therapeutics AB	100%	100%	100 000	70 000
556669-2199, Stockholm				
				<b>70 000</b>

Other long-term receivables	Group		Parent company	
	2022	2021	2022	2021
Opening balance	50	-	50	-
Additional receivables	-	50	-	50
<b>Outgoing accumulated acquisition value</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>
<b>Net book value</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>

Long-term receivables are deposits for rent.

## Note 6 Transactions with related parties

	Group		Parent company	
Total	2021	2021	2022	2021
Sales to Group companies	-	-	740	505

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

## Note 7 Accrued expenses and deferred income

	Group		Parent company	
TSEK	2022	2021	2022	2021
Accrued personnel expenses	250	312	250	312
Accrued interest	314	0	314	50
Other accrued expenses	293	520	187	334
<b>Accrued expenses</b>	<b>858</b>	<b>833</b>	<b>752</b>	<b>646</b>
Deferred Income	0	0	0	0
<b>Deferred Income</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Total Accrued expenses and deferred income</b>	<b>858</b>	<b>833</b>	<b>752</b>	<b>646</b>

## Note 8 Prepaid expenses and accrued income

	Group		Parent company	
TSEK	2022	2021	2022	2021
Prepaid rents	7	3	0	0
Prepaid issue expenses	470	0	470	0
Other prepaid expenses	90	241	45	206
<b>Prepaid expenses</b>	<b>567</b>	<b>244</b>	<b>515</b>	<b>206</b>
Accrued income	0	0	0	0
<b>Accrued income</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Total Prepaid expenses and accrued income</b>	<b>567</b>	<b>244</b>	<b>515</b>	<b>206</b>

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

On 21 February, 2023 Modus announced positive top-line data from its Phase 1b lipopolysaccharide (LPS) provocation study, a key step in evaluating the potential of its lead asset, sevuparin, as a treatment for sepsis and other conditions with systemic inflammation. All three doses of sevuparin were found to be safe and tolerable throughout the study period, confirming the candidate drug's favorable safety profile under induced inflammatory conditions.

Furthermore, sevuparin treatment caused statistically significant and dose-dependent increases in the levels of certain white blood cells as well as a dose-dependent inhibition of the LPS induced increase in respiratory rate. Sevuparin was also found to be safe and tolerable when combined with a blood thinning heparin (enoxaparin).

Data from the Phase 1b study will be used to inform the protocol of the planned Phase 2 study with sevuparin in patients with sepsis. This study is expected to start in 2023.

On March 29, 2023, Modus announced that it had secured access to an additional 7.0 million from its largest owner. The bridge financing facility will be submitted to the annual general meeting, to be held on 11 May 2023, for approval. Draw down of the capital in its entirety is subject to such approval being obtained. Access to this funding ensures a continued high pace for the clinical development while the company continues to explore licensing and partnership opportunities.



## CERTIFICATION

This report has been prepared in both Swedish and English. In the event of discrepancies between the versions, the Swedish version applies.

Stockholm 13/4 2023

Viktor Drvota,  
Chairman of the board

Torsten Goesch,  
Board member

John Öhd,  
CEO

Ellen K. Donnelly,  
Board member

Our audit report was given on 13/4 2023  
Ernst & Young AB

Oskar Wall,  
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 2022-01-01 – 2022- 12-31. The annual accounts and consolidated accounts of the company are included on pages 30-52 in this document.

In our opinion, the annual accounts and consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of parent company and the group as of 31 December 2022 and their financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

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

#### Basis for Opinions

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

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

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

This document also contains information other than the annual report and consolidated accounts found on pages 1-29. 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 2022-01-01 – 2022-12-31 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

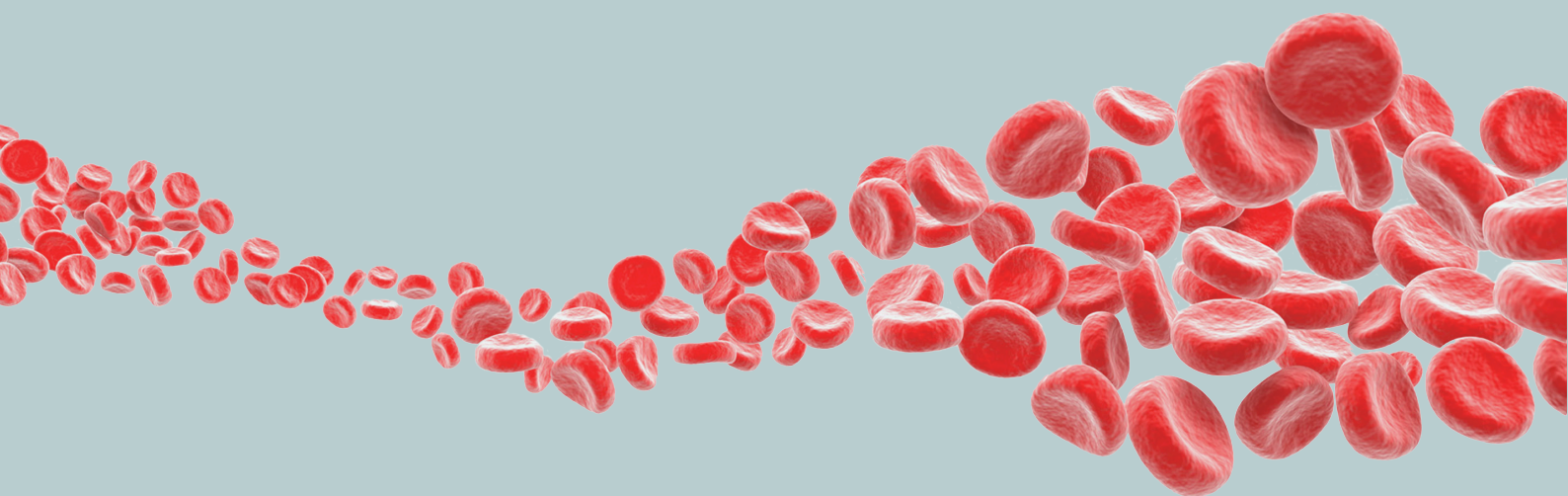
proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships 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, 13/04-2022, as stated in our digital signature Ernst & Young AB

Oskar Wall

Authorized Public Accountant





# MODUS

## THERAPEUTICS

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