# Annual report 2022

SoftOx Solutions

Organisation number: 998 516 390

SoftOx Solutions (ticker: SOFTX) is a medtech and clinical-stage pharmaceutical company that has developed a non-toxic and highly effective antiseptic technology which eradicates and prevents biofilm infections and is fully virucidal. SoftOx is based in Oslo, Norway with subsidiaries in Malmö, Sweden and Copenhagen, Denmark.



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## Overview Highlights 2022 KEY ACHIEVEMENTS

## SoftOx Disinfection (hand and surface disinfection):

- Delivered disinfection products to Hospital Purchasing (HINAS) in Norway and other companies within and outside the health sector.
- The Norwegian Defence Research Establishment (FFI)'s field experiment in Hemsedal evaluating non-alcohol disinfectants. SoftOx's alcohol-free hand disinfectant, showed that alcohol-free disinfectants reduced the level of volatile organic compounds (VOCs) in the air when compared with alcohol disinfectants.
- Final approval received on biocidal products application for hand and surface disinfection from the Swedish Chemicals Agency (KemI) which allows SoftOx to sell disinfection products in Sweden outside the healthcare segment.

## SoftOx Biofilm Eradicator (SBE):

- The SBE-01 Phase 1 study confirmed safety and tolerability in patients with chronic leg wounds and provided indications of clinical efficacy with dose dependent reductions in bacterial burden and wound size (NCT05710094).
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## SoftOx Inhalation Solution (SIS):

- Phase 1 study, SIS-01, which evaluated the safety and tolerability of the SoftOx Inhalation Solution, met its primary objective in healthy subjects (NCT05188638).
- The University of Copenhagen on behalf of SoftOx established proof of concept in mouse models for the use of SIS for both treatment and preventive use against viral infections in the respiratory track.
- Working on collecting the necessary documentation for applying for a phase 2 study, which is planned to go at the University of Copenhagen with connected hospitals, when the necessary financing is in place.

## SoftOx Defense Solutions (SDS)

 SoftOx was granted approx. NOK 97 million from the European Defense Fund to develop an inhalation solution for the armed forces within the EU and its allies. SDS is a part of a pan-European consortium of 20 international R&D and industry partners from 10 nations, which will develop military medical countermeasures (MCMs) against chemical, biological, radiological, and nuclear threats.

## **Operational highlights**

- SoftOx entered into a loan agreement of NOK 15 million with Almhaug Bolig AS, main shareholder is one of the shareholders in SoftOx.
- 11<sup>th</sup> of October 2022 a convertible loan was secured from existing shareholders of NOK 25 million and SoftOx refinanced the NOK 15 million convertible loan as reported on 28 June 2022.
- Following the extraordinary general meeting on 9 December 2022, the Board of Directors strengthened with the additions of Henrik Nielsen, Adrian Bignami and Jørgen Berggrav,

together with the existing members Kari Myren and Olav Jarlsby. Geir Almås was elected. Executive Chairman of the Board and has stepped down from his role as Chief Executive Officer of SoftOx.

## Peer-reviewed scientific publications 2022

- Effect of Stabilized Hypochlorous Acid on Re-epithelialization and Bacterial Bioburden in Acute Wounds: A Randomized Controlled Trial in Healthy Volunteers. Burian, E.A., Sabah, L., Kirketerp-Møller, K., Gundersen, G., & Ågren, M. Acta Dermato-Venereologica, https://doi.org/10.2340/actadv.v102.1624
- Effect of stabilized hypochlorous acid on oral biofilm bacteria. Aherne, O., Ortiz, R., Fazli, M.M. & Davies, J. R. BMC Oral Health. https://doi.org/10.1186/s12903-022-02453-2

#### **Financial highlights**

#### **Key Financial Figures**

NOK 1,000	SoftOx Solutions Group SoftOx Solutions AS			
	2022	2021	2022	2021
Total revenue and other income	7 114	7 901	5 984	6 149
Total operating expenses	98 169	94 004	94 840	50 427
Operating profit (loss)	-91 055	-86 102	-88 856	-44 278
Net profit (loss) for the year	-93 700	-86 291	-90 605	-42 745
Net proceeds from equity issues	-	89 018	-	89 081
Net cash flow	-50 077	22 182	-49 319	27 374
Cash and cash equivalents at end of period	6 907	56 984	6 757	56 076
Outstanding shares, beginning of the period	10 342 871	8 239 900	10 342 871	8 239 900
Outstanding shares, end of the period	10 342 871	10 342 871	10 342 871	10 342 871
Rnd costs	43 772	44 255		
Direct RnD costs of total operating expenses	45 %	47 %		
Employees, end of the period	25	21	17	19

## SoftOx in brief

#### Mission

Helping the world Fighting infections

#### Vision

#### To become a world-leading developer of antimicrobial technology

SoftOx Solutions ("SoftOx"/ "The Company") is a Scandinavian medtech and clinical-stage pharmaceutical company that has developed a non-toxic and highly effective antiseptic technology which eradicates and prevents biofilm infections and is fully virucidal. The Company is building its product pipeline based on its patented antimicrobial technology platform. The Company seeks to create value for patients, society, and shareholders through discovering and developing novel medicines.

SoftOx Solutions is dedicated to developing a completely new class of antimicrobials (infection prevention and infection treatment), which are effective against bacterial infections, viruses, and fungi. This new type of antimicrobial is developed to work locally and non-systemic on tissue, whether it is intended for treatment in wounds, the oral cavity or in the respiratory tract, and has not been shown to induce microbial resistance.

#### **Current projects**

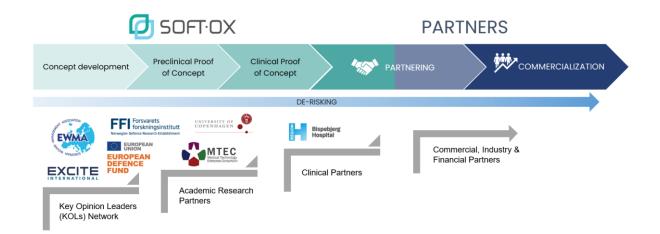
- SoftOx Wound Care Solution with the preventive irrigation solution (SWIS) and SoftOx Biofilm Eradicator (SBE) for treatment of infections in chronic wounds
- SoftOx Inhalation Solution (SIS) for both preventive use and treatment of viral infections in respiratory track. This solution will also establish base for the military counter measurement solution, which SoftOx develops under the European Defense Fund program and SoftOx Disinfection for hand and surface disinfection.

#### The SoftOx technology – human body's natural defence system

SoftOx has developed a breakthrough antimicrobial technology designed to address some of the world's greatest health challenges including viruses, biofilm resistance and antimicrobial resistance. The SoftOx technology is built around hypochlorous acid which is produced by white blood cells as the human body's natural defence system. Therefore, the SoftOx technology reinforces nature's own ability to eradicate unwanted microbes.

## Global network of researchers and key opinion leaders

SoftOx has a unique collaboration network of world-leading scientists and key industry leaders. SoftOx's scope is expanded and strengthened through the support and interest of influential collaborators in the US and Europe. The Company has a close relationship with leading Nordic universities and research institutions as academic research partners including the University of Copenhagen, University of Oslo, University of Malmö, the European Wound Management Association, and the Norwegian Defence Research Establishment (FFI). SoftOx has a clinical development partnership with Bispebjerg Hospital and receives financial support from the Research Council of Norway, US Medical Technology Enterprise Consortium (MTEC), the Norwegian Ministry of Defence and the European Defence Fund. SoftOx is supported by a resultdriven team and collaboration network.



SoftOx Partner Strategy: Through the years, SoftOx has built a broad network of partners which add value through the stages of development. SoftOx's core competencies are from concept development to the proof-of-concept stage, and then commercial, industry and financial partners will continue the work by funding further development, selling, marketing and distributing the products.

## Protected, versatile and clinically proven technology platform.

All SoftOx products are based on the same technology and tailored for different indications and uses. The clinical documentation has proven that the base technology is safe, skin friendly, antimicrobial and improves wound healing. The technology is scalable, and the Company is developing projects in multiple regulatory areas. The Company has protected this technology with a broad and extensive patent portfolio, and as of year-end 2022, SoftOx has 72 granted and 77 pending patents filed worldwide. With the technology's uniqueness and innovativeness, SoftOx is targeting several market opportunities for product development within disinfection, respiratory and wound care to address the unmet needs for millions worldwide.

## Major milestones of the development of SoftOx Solutions

SoftOx Solutions AS was established in 2012 and is headquartered in Oslo with subsidiaries Water Innovation AB (WIAB), Malmö; SoftOx Disinfection AS, Oslo; SoftOx Defense Solutions AS, Oslo; and SoftOx Solutions Denmark A/S, Copenhagen forming the SoftOx Solutions AS Group. SoftOx Solutions is listed on Euronext Growth Oslo, a multilateral trading facility operated by Oslo Børs ASA. Ticker: SOFTX.

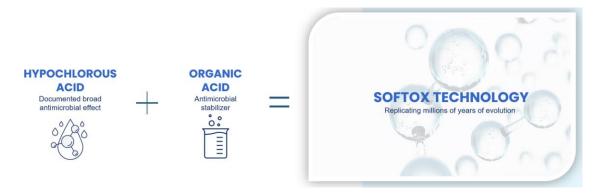
## History

## Below is a brief overview of the Company's history:

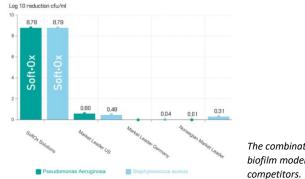
Date	Important event
2012	SoftOx Solutions AS was founded.
2016	First patent was granted.
2018	A scientific collaboration entered with Costerton Biofilm Center, University of Copenhagen.
	Public funding received through the User-driven Research-based Innovation programme ( <b>BIA</b> ) from the Research Council of Norway and from the EU – phase 1 in the Horizon 2020 programme.
	The Company's shares listed on Euronext Growth Oslo.
2019	The Company's first trial involving humans showed positive effects in acute wounds. SoftOx Solutions' first-in-human clinical trial (SWIS-01) with its wound rinsing product SoftOx Wound Irrigation Solution, abbreviated SWIS, was successfully completed.
2020	First production line in Norway established.
	DKMA gives its recommendation for further development of the SoftOx Inhalation Solution (SIS) for the treatment of respiratory infections, including COVID-19, after the positive results of clinical testing in animals.
	SoftOx received USD 1.977 million for research and development of the SoftOx Biofilm Eradicator ( <b>SBE</b> ) from the US Department of Defense ( <b>DoD</b> ).
2021	Results of the clinical investigation of SoftOx Wound Irrigation Solution for acute wounds (SWIS-02) showed both significant improvement in wound healing and reduction in bacterial burden compared to Normal Saline (NS).
	SoftOx's hand disinfectant won the Sykehusinnkjøp HF's national tender (HINAS)
	DKMA approved first-in-human clinical study for SoftOx wound treatment agent for infections in chronic wounds, SBE, and the first patients are enrolled in the study.
	DKMA approved the clinical study SoftOx Inhalation Solution (SIS-01), and the first patients enrolled in the phase 1 trial.
	The EU Commission's interpretation of the Biocidal Products Regulation can allow SoftOx to enter the market with all its disinfectant products in the EU and EEA area.
	SoftOx won Swedish tender for "surface disinfection with sporicidal effect" and "hypochlorite-based surface treatment with sporicidal effect".
2022	Results of SIS-01 show that SIS achieved the primary objective of safety and tolerability in healthy subjects.
	The Norwegian Defence Research Establishment (FFI)'s field experiment in Hemsedal evaluating non-alcohol disinfectants, including SafeDes+, SoftOx's alcohol-free hand disinfectant, showed that alcohol-free disinfectants reduced the level of volatile organic compounds (VOCs) in the air when compared with alcohol disinfectants.
	SoftOx Defense Solutions, a subsidiary of SoftOx Solutions, was granted approx. 97 million from the European Defence Fund to develop an inhalation solution for the armed forces within the EU and its allies. SDS is a part of a pan-European consortium of international R&D and industry partners from 10 nations, which will develop military medical countermeasures (MCMs) against chemical, biological, radiological and nuclear threats.
	The Company received final approval on biocidal products application for hand and surface disinfection from the Swedish Chemicals Agency (KemI)
	SBE-01 Phase 1 study confirmed safety and tolerability in patients with chronic leg wounds and provided indications of clinical efficacy with dose dependent reductions in bacterial burden and wound size

## SoftOx Projects

The SoftOx technology



SoftOx technology: the two natural components of hypochlorous acid and an organic acid form the foundation of the patented technology. The effect replicates millions of years of evolution and reinforces nature's own ability to eradicate unwanted microbes.



## **Reinforcing Nature's Own ability to Eradicate Unwanted Microbes**

The combination effect showed on a surface biofilm model compared to market leading competitors.

In collaboration with leading scientific teams at University of Copenhagen and University of Lund, SoftOx has discovered a unique synergetic effect of two natural components, hypochlorous acid and organic acid, which is proven to be well tolerated by both humans and animals even when used in wounds.

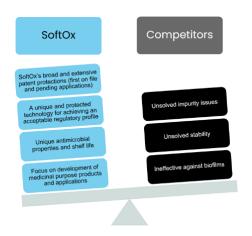
Based on this discovery, SoftOx Solutions has developed a patented antimicrobial solution with a documented strong antimicrobial effect on all types of bacteria (including multidrug-resistant bacteria and those embedded in biofilms), fungi, spores and viruses (fully virucidal). Importantly, the research has also determined that this novel solution does not induce microbial resistance. In contrast to antibiotics, the SoftOx formula consists of small molecules, which can penetrate biofilm and kill the biofilm-associated microbes.

Endogenous production of hypochlorous acid (HOCI) is an integral part of the body's first line defence against infecting viruses and bacteria. HOCI is produced by white blood cells (neutrophils and macrophages) to kill a wide range of pathogens. These molecules attack microbial structures and inhibit microbial repair mechanisms and metabolism, which ultimately inactivates or kills the virus or bacteria.

## The Unique Combination Effect of SoftOx Technology

The SoftOx technology exploits the fact that human bodies are accustomed to handling the natural and potent chemicals that the antimicrobial solution is based on. The safety profile and the antimicrobial efficiency of the technology make it applicable for multiple applications with the aim of preventing and eradicating infections. After thorough and successful laboratory and animal experiments, SoftOx has now entered the clinical phase with several product leads, including i.e., topical wound and inhalation treatments.

This unique technology is protected by a robust patent portfolio which provides multiple degrees of freedom to expand into new therapeutic applications.



Patented and well protected technology: The SoftOx technology platform is protected by a broad and extensive patent portfolio consisting of U.S. and international patents and applications.

## Key benefits:

- Unique chemical stability and safety profile
- Strong antimicrobial effects
- Non-toxic, excellent tolerability
- Does not induce microbial resistance
- Technology protected with extensive patent portfolio
- Technology platform suitable for several needs

## **Product development**

#### SoftOx Project Pipeline

All SoftOx products utilise the same technology, but the concentrations are tailored for different uses and indications. Both hypochlorous acid and organic acid are naturally occurring chemicals that harbour broad antimicrobial effects without inducing resistance. Studies have documented the strong antimicrobial effect of this technology against all bacteria (including resistant bacteria), fungi and viruses. The Company is developing a range of products that can be classified as either biocides, medical devices or medicinal products (drugs) for human use. The current business segments can be divided into wounds, disinfection and respiratory. In addition, the Company is also in the concept phase of developing a separate segment for countermeasures against chemical and biological weapons together with the Norwegian Defence Research Establishment (FFI).



Business Segments: SoftOx is currently developing products for three core business segments – wounds, disinfection and respiratory.

**Research and Development** 

## SoftOx Wound Care technology

## SoftOx Biofilm Eradicator ("SBE")

SoftOx Biofilm Eradicator (SBE) is an anti-infective treatment in chronic wounds and is formulated to penetrate and kill microbes within biofilms. Studies have shown that antimicrobial-resistant bacteria are present in more than 50 percent of chronic wounds. Due to broad spectrum and multi-targeted antimicrobial effects, SBE has been shown to kill antibiotic-resistant bacteria (such as Methicillin Resistant Staphylococcus aureus (MRSA)) and is unlikely to induce new antimicrobial resistance. Preclinical studies demonstrate the SBE formulations as non-toxic, and the first-in-human Phase 1 clinical study (SBE-01) has been completed.

#### **Unmet needs**

All wounds are susceptible to acquiring infections due to the absence of a protective skin barrier. Current approaches for managing infections in wounds are not effective in eradicating biofilm infections without having adverse effects on the host. Furthermore, in the current era of antibiotic stewardship, the inappropriate use of antibiotics to treat infections in wounds and their inability to eradicate biofilms in these wounds place patients at high risk for acquiring antibiotic-resistant organisms and develop new superbugs (bacteria resistant to several or possibly even all types of antibiotics). Globally, it is estimated that 40 million wounds fail to proceed through an orderly and timely healing process and become classified as chronic wounds<sup>1</sup>, resulting in two million amputations annually. Treatment of chronic wounds is necessary at an early stage; otherwise, patients can risk severe health consequences such as amputations as well as the rising cost burden due to hospital stays, wound dressings, and the use of regenerative medicine.<sup>2</sup>

1-2 % of the population in developed countries are projected to have a chronic wound. Chronic wounds represent a silent epidemic that affects a large fraction of the world's population and poses a major growing threat to patients, public health and the economy. As these wounds last on average 12/13 months and recur in up to 60/70% of patients, they can lead to loss of function and decreased quality of life as well as are significant cause of morbidity. In the US alone, wound care treatment exceeds \$50 billion per year.<sup>3</sup> In a decision-analytic model developed by MedValue and Radboud University, the results suggest that the use of SBE could reduce annual treatment costs for chronic wounds by up to approximately \$3,500 per patient compared to today's standard care. The Company is currently exploring different indications such as venous leg ulcers and diabetic foot ulcers to lower healthcare expenses as well as improve the treatment and quality of life for these patients.



#### 1-2% of population are projected to have a chronic wound in developed countries<sup>2</sup>

## **How SBE works**

To avoid further complications, infections in chronic wounds must be removed to facilitate the healing process. SBE contains an optimal formulation based on the SoftOx technology platform with the aim to achieve a pronounced antimicrobial effect with an adequate safety profile. SBE works by penetrating and killing microbes within biofilms. The dual activity of hypochlorous acid and compatible organic acids have synergistic antimicrobial properties and the ability to exert its effect on the surface and deeper in the wound bed. The scientific proof of principle of the lead SBE candidates on killing bacteria in biofilms, has been achieved by using in vitro wound simulation models, which were designed to mimic both surface and deep tissue embedded biofilms. In these models, the candidates were able to eradicate mature biofilms of both Pseudomonas aeruginosa and Staphylococcus aureus, which are the two most prevalent bacterial species found in complicated "hard-to-heal" wounds. The killing effects of SoftOx in clean conditions are more than log 8 (e.g., 99.999999%).

## **Today's solutions**

Antibiotic resistance and biofilm formation by pathogenic bacteria in wounds limit the possibilities of using antibiotics in treatment of infections in chronic wounds. Currently, debridement of wounds is one of the most important treatment strategies against biofilms. However, debridement cannot remove all biofilms, and hence should be used in combination with an effective topical antimicrobial agent. SBE will enable complete eradication of biofilms in wounds and help restore the normal

<sup>&</sup>lt;sup>1</sup> European Union - HEXKIN - Delivering Healing EXosomes for sKIN (2019)

<sup>&</sup>lt;sup>2</sup> Technavio (2016). Global Negative Pressure Wound Therapy Market.

<sup>&</sup>lt;sup>3</sup> FDA Executive Summary, Classification of Wound Dressings Combined with Drugs (2016).

wound healing process, thereby reducing the need for repeated debridement of wounds and hospitalization of patients. SBE will in many cases enable wound care professionals to eradicate biofilm, reducing the need for extensive debridement and radical surgery. This will make efficient wound management available to more patients, including the vast majority who are treated in the community (outpatients). The result will be wound healing at a faster speed and lower cost, with a gentler and less painful procedure for the patients. For the healthcare system, SBE will reduce the pressure on highly restricted resources and reduce the cost of wound care substantially. In addition, the quality of life for a large group of patients will improve.

SBE seeks to replace traditional topical antibiotics and other antiseptic solutions with an equally as effective solution that does not induce antibiotic resistance.

## Key results to date

The early clinical development (Phase 1 and 2) of SBE is co-funded by the US Naval Medical Research Center under the Medical Technology Enterprise Consortium, a biomedical technology consortium that collaborates under a transaction agreement (OTA) with the US Army Medical Research and Development Command.

The final report from the Phase 1 clinical study (SBE-01, NCT05710094), evaluating the safety and tolerability of single and multiple ascending doses of SBE in patients with chronic leg ulcers, was received in December 2022. The first-in-human clinical study concluded that SBE applied on chronic leg wounds was safe and well-tolerated. Treatment with all SBE formulations consistently reduced the absolute number of bacteria in the wound compared with pre-treatment, and a dose-dependent reduction in wound size was observed in the multiple-dosing SBE treatment groups. The company is currently preparing the regulatory documentation required to conduct the Phase 2 study in the US.

Having demonstrated early proof-of-concept for the SBE project and in accordance with the company's corporate strategy, SoftOx will seek a strategic partner to further develop and advance its wound care segment within acute and chronic indications.

## SoftOx Wound Irrigation Solution ("SWIS")

SoftOx Wound Irrigation Solution (SWIS) is a wound rinse for acute wounds. The current recommended treatment for acute wounds is saline, which holds 80 percent market share. Based on clinical evidence of safety and efficacy compared to saline, the company aims to establish SWIS as the preferred wound cleansing product.

## **Unmet needs**

There are 180 million skin wounds treated in hospitals worldwide each year<sup>4</sup>. Surgical site infections (SSI) are the most common preventable complication after surgery and occur in 2% to 4% of all inpatient surgical procedures. The cost per infection is estimated to be \$12-25,000 and can cost as much as \$90,000 depending on the severity and infection complications.<sup>5</sup> The market potential is high, and there have been little or no innovations in this market for a long period of time.

<sup>&</sup>lt;sup>4</sup> Wound prevalence and wound management (2011): 2012-2020, MedMarket Diligence.

<sup>&</sup>lt;sup>5</sup> Berríos-Torres SI, Umscheid CA, Bratzler DW, Leas B, Stone EC, Kelz RR, et al. Centers for Disease Control and Prevention Guideline for the Prevention of Surgical Site Infection, 2017. JAMA surgery. 2017;152(8):784-91.

#### **How SWIS works**

SWIS uses a lower concentration of active ingredients which makes it well-tolerated and safe when applied to wounds. SWIS is safe to use and non-toxic to host cells and tissue. The solution effectively kills antibiotic resistant bacteria without inducing new resistance.

#### **Today's solutions**

Saline water is the most common treatment for acute wounds and holds 80% of the current market. SSIs can be treated with antibiotics but remain as a significant cause of morbidity and mortality after surgery.<sup>6</sup> Currently available topical antibiotics have side effects and limitations including, but not limited to, allergic reactions, poor penetration into the wound and ineffectiveness against antibiotic-resistant organisms and fungal infections.

#### Key results to date

The final confirmatory clinical investigation (SWIS-02 trial) was completed in June 2021. SWIS-02 demonstrates and confirms previous findings (from SWIS-01) to be safe and well tolerated as a wound irrigation solution for acute wounds and not associated with any major risks. The SWIS-02 study showed both significant improvement in wound healing and significant reduction in bacterial burden compared to Normal Saline (NS), positioning the product as superior towards today's market leaders. This is regarded as an important confirmation of the Company's base technology.

The results of SWIS-02 have been published in the peer-reviewed *Acta Dermato-Venereologica* and presented at the 2022 European Wound Management Association Conference in Paris.

Having demonstrated early proof-of-concept for the SBE project and in accordance with the company's corporate strategy, SoftOx will seek a strategic partner to further develop and advance its wound care segment within acute and chronic indications.

## SoftOx Inhalation Solution ("SIS")

SoftOx Inhalation Solution (SIS) is undergoing development for the treatment of respiratory tract infections caused by viruses and bacteria. SIS is an aerosolized form of the SoftOx technology, designed to be safe and effective in the treatment and prevention of respiratory tract infections. SoftOx hypothesizes that SIS inactivates and kills the intracellular and extracellular virus and bacteria in the upper and lower respiratory tract, resulting in fewer symptoms, faster recovery and reduced disease transmission.

#### **Unmet needs**

Prior to the COVID-19 pandemic, it was estimated that between 5 to 20% of the population experiences flu-like symptoms each year. Despite being generally mild and self-limiting, non-influenza-related viral respiratory tract infection is associated with an enormous economic burden, both in lost productivity and drives a large proportion of consumption of over-the-counter (OTC), non-pharmaceutical and/or non-approved products. In peak influenza season, flu-like symptoms account for up to 13% of all outpatient visits; however, only a small group of patients have laboratory-confirmed influenza A or B and are candidates for currently approved anti-viral

<sup>&</sup>lt;sup>6</sup> Surgical Site Infections (SSI). PSNet Rockville, MD: Agency for HealthCare Research and Quality; 2019 [Available from: https://psnet.ahrq.gov/primer/surgical-site-infections.

medications. In addition, delays in diagnosis and treatment may attenuate the potential benefit of these drugs. There are no approved treatments for many of the other viruses causing flu-like illness, yet the total economic impact of non-influenza-related upper respiratory tract infection is estimated to \$40 billion annually in the US alone (direct costs, \$17 billion per year; and indirect costs, \$22.5 billion per year).

## How it works

SIS is an aqueous, isotonic formulation of hypochlorous acid, stabilised for aerosolisation and suitable for administration to the respiratory tract (e.g., using a standard nebuliser). SoftOx hypothesizes that SIS inactivates and kills intracellular and extracellular virus in the upper and lower respiratory tract, resulting in a reduction in viral load, thereby improving symptoms, shortening disease duration, and preventing onward disease transmission. Such a drug would be ideal in the efforts to limit the health and societal impact of SARS-CoV-2 and future pandemics.

## **Today's solutions**

Approximately 60 million people living in Europe and North America experience influenza like symptoms annually and 25% of those experiencing influenza-like symptoms seek physician care. Only a small proportion (<5%) of these cases are ever confirmed as being caused by influenza virus, and thereby amenable to approved influenza medications. Prescription influenza drugs, such as oseltamivir (Tamiflu), targets just 3% of the market but still has a market value just under \$1 billion over the next 10 years, despite going off patent. The rest are caused by one or more of a myriad of viruses (including: rhinovirus, adenovirus, parainfluenza virus, respiratory syncytial virus, human metapneumovirus, parvovirus) for which there are no approved antiviral medications.

#### Key results to date

The safety of single and multiple ascending doses of SIS in healthy volunteers (Safety of Ascending Single and Multiple Doses of Nebulized SoftOx Inhalation Solution in Healthy Subjects, NCT05188638) was completed on 13 April 2022. The study met its primary endpoint and demonstrated safety and tolerability in healthy subjects over a range of potentially therapeutic formulations and dosing regimens.

Preparations for a Phase 2 clinical trial application, including additional non-clinical toxicology studies, contracting with a contract manufacturing organization for Phase 2 production, and scientific interactions with the European Medical Association on Phase 2 study design are ongoing.

The SoftOx Research Department led by Prof. Thomas Bjarnsholt has demonstrated reproducible dose dependent virucidal effects in in vivo mouse models of Influenza A. The team continues to investigate the effects of SIS in mouse models with other infectious agents.

## SoftOx Disinfection; Market trends, distribution and sales

SoftOx disinfection products are safe, well tolerated and do not dry out healthy or compromised skin. The products are effective against all relevant microbes (bacteria, viruses, fungi, Mycobacterium, and spores) and have been tested in accordance with European Norm (EN) criteria. SoftOx disinfection products have documented full virucidal efficacy on both naked and enveloped viruses (e.g., coronaviruses, influenza virus, norovirus, and others) and are effective towards biofilms. The formula is alcohol-free and non-flammable making it safe for critical areas such as airplanes/airports, kindergartens, and schools. SoftOx's hand disinfectant is clinically documented as skin friendly, making it an ideal disinfectant for healthcare settings.

## **Unmet needs**

For health professionals, it is a well-known problem that today's hand rub and disinfection solutions dry out and damage the skin. Due to the increased use and attention around hand disinfection during the COVID-19 pandemic, this issue has become even more relevant. Particularly vulnerable groups such as children, young people, the elderly and people with sensitive, damaged skin or eczema need a safe and skin-friendly alternative to alcohol-based disinfectants. 25-55% of healthcare workers have hand eczema on their hands', and 70% of healthcare workers report that they have experienced skin problems due to alcohol-based solutions.

There are an estimated 31.5 million healthcare workers in the EU<sup>®</sup>, and the US<sup>®</sup>, whereof 10 million have irritated skin and eczema.<sup>10</sup> Due to these skin conditions, 1 million healthcare workers in the EU and the US have a proportionally higher number of sick days and are at risk of losing their jobs which could lead to an increased need for disability benefits. The results from a decision model developed by MedValue and Radboud University show that the effective prevention of hand eczema is valued at an estimated USD 1,080 per healthcare worker.<sup>11</sup> Altogether, this issue creates an estimated USD 30 billion economic burden for US and Europe hospitals.

## How it works

The formulation has been tested in clinical trials as well as pre-clinical biocompatibility studies which have documented its excellent safety and tolerability profile. Even in situations of broken/breached or compromised skin, e.g., often experienced by healthcare workers, it does not sting, burn, or dry out the skin, which makes it an ideal alternative to alcohol-based hand rub. Importantly, the SoftOx formula does not induce microbial resistance. The use of the SoftOx solution can help prevent and reduce hand eczema and irritated skin among healthcare workers, increase hand hygiene compliance and reduce hospital-acquired infections and antimicrobial resistance. SoftOx surface disinfectants are also surface friendly, sporicidal and noncorrosive at normal use conditions.

## Today's solutions

Hand disinfectants are usually a liquid or gel formulation containing 70-85% alcohol. These products work by drying out the bacterial cell walls, thereby destroying them. As a consequence, people using alcohol-based hand disinfectants will risk damaging the skin, and the more often alcohol-based products are used, the higher the risk. Therefore, WHO Guidelines on Hand Hygiene in Health Care (2019) recommend an alternative for those who do not tolerate alcohol-based hand rub in health care.

There are also other limitations of using alcohol-based disinfection products. A product without alcohol makes it easier to use an effective and complete solution both in institutions such as prisons, airports, public transport hubs, substance abuse care centres, kindergartens and elsewhere in the health care system. Alcohol-free disinfection prevents the risk of abuse and does not pose a fire risk.

<sup>8</sup> Eurostat- Majority of Health Jobs Held by Women (2020)

<sup>&</sup>lt;sup>7</sup> World Health Organization – Guidelines on Hand Hygiene in Health Care

<sup>&</sup>lt;sup>9</sup> Kaiser Family Foundation – Total Health Care Employment (2018)

<sup>&</sup>lt;sup>10</sup> National Eczema Association – Hand Eczema Common Among Health Care Workers

<sup>&</sup>lt;sup>11</sup> MedValue+, Radbound University Medical Center and Exite International's Panel of 11 KOL/experts – "2019 Health Technology Assessment; SoftOx Hand-wash for Health Care Workers with Eczema"

In addition, much of the equipment in the healthcare system does not tolerate alcohol, which means that there is a need for other alternative cleaning routines than standard alcohol-based disinfections.

## Key Results to Date

SoftOx won a Norwegian hospital purchasing tender (HINAS) for alcohol-free hand disinfectant and a Swedish purchasing tender (Varuförsörjningen) for sporicidal surface disinfectant. With the demonstrated proof of sales, the next stage is to find the right strategic partners to bring SoftOx products to market worldwide.

The company received the final approval from the Swedish Chemicals Agency (KemI) on its application for the SoftOx biocidal product family for hand and surface disinfection. The approval allows the company to sell its disinfection products in Sweden. With the approval from KemI, talks with potential strategic partners can advance as the company can apply for mutual recognition in sequence in any EU market.

## **Other Research and Development projects**

## Industrial PhD projects

SoftOx currently has two PhD fellows working in the research and development team. One of the projects involves the "next generation" products which are designed to give the product new and enhanced attributes. This work is conducted through parts of a doctoral research project, which is partially financed by the Research Council of Norway and in partnership with the Department of Pharmacy at the University of Oslo.

## Board of directors' report 2022

In 2022, SoftOx continued to strengthen its development activities within the infection prevention and treatment market. During the year, SoftOx has achieved significant milestones in the disinfection, wound care and respiratory projects. SoftOx delivered promising results from two clinical trials, gained approval for the hand and surface disinfectant in Sweden, and started a project with funding from the European Defence Fund.

## ABOUT SOFTOX

SoftOx Solutions AS is a Scandinavian medtech and pharmaceutical company, founded in 2012. SoftOx develops products that will help the world fight infections from viruses, biofilm resistance and antimicrobial resistance. SoftOx's unique platform technology reinforces nature's own ability to eradicate unwanted microbes, and the goal is to improve health outcomes for patients worldwide. SoftOx is headquartered in Oslo, Norway and listed on the Euronext Growth Oslo, Oslo Stock Exchange (Ticker: SOFTX).

## SoftOx is addressing major global issues

SoftOx is working to solve three main global challenges consistent with the company mission of "helping the world fighting infections".

## 01 Viral outbreaks and pandemics

A virus is a submicroscopic infectious agent that only replicates inside the living cells of an organism.<sup>12</sup> Over the past 50 years, more than 300 pathogens have emerged or reemerged, including Zika, yellow fever, Ebola and recently SARS-CoV-2. Such epidemics and pandemics have been predicted and are anticipated in the future. There remains an unmet need for effective and well tolerated virucidal solutions to aid infection prevention and control. Respiratory infectious diseases are the third leading cause of death with more than 3 million deaths annually.<sup>13</sup>

The WHO monitors viral outbreaks closely and develops guidelines for infection prevention and control (IPC) strategies. Proper hand hygiene measures for the general public and for healthcare workers specifically are of crucial importance.

## 02 Biofilm infections in chronic wounds

Biofilms are aggregates of microorganisms (e.g. bacteria) embedded in a slime-like matrix, which protect the bacteria from the immune system and the effects of antimicrobials (e.g. antibiotics). Biofilms have been observed in various conditions, such as chronic wounds, cystic fibrosis and eczema, and there is growing evidence indicating the adverse role of biofilms in delaying normal wound healing. There are approx. 40 million chronic wounds worldwide each year, and 1-2% of the population in developed countries are projected to experience a chronic wound during their lifetime.<sup>14</sup> Moist chronic wounds are an ideal environment for bacterial growth and genetic

<sup>&</sup>lt;sup>12</sup> Wu, Katherine J. National Geographic Society. April 2020

<sup>&</sup>lt;sup>13</sup> Forum of International Respiratory Societies (2017). The Global Impact of Respiratory Disease – Second Edition. Sheffleld, European Respiratory Society.

<sup>&</sup>lt;sup>14</sup> Sen, C.K. et al. (2009) Human Skin Wounds, Wound Repair Regen,

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2810192/

exchange among bacteria, which can lead to antimicrobial resistance.<sup>15</sup> The inappropriate use of antibiotics and their inability to eradicate biofilms further contributes to the development of antimicrobial resistance and places patients at high risk for acquiring or spreading multidrug-resistant microorganisms. To be truly effective, antimicrobial agents must be able to penetrate and kill microbes embedded in the biofilms of wounds without impeding the wound healing process of the host.

## 03 Emergence of antimicrobial resistance (AMR)

According to the World Health Organization (WHO), antimicrobial resistance (AMR) is one of the largest threats to global health. New forms of resistance are emerging and can spread with remarkable speed between continents. Therefore, it is important to find new ways of treating infections without triggering resistance. Antibiotic resistance refers specifically to resistance to antibiotics occurring in common bacteria that cause infections. AMR is a broader term, encompassing resistance to drugs that treat infections caused by a variety of microbes, such as parasites (e.g., malaria), viruses (e.g. influenza, COVID-19 and HIV) and fungi (e.g. Candida). In 2019 alone, AMR contributed to 4.95 million deaths worldwide.<sup>16</sup> Without innovative solutions, modern treatments for organ transplants, advanced surgery and spinal therapy will fail.

The goal is that the SoftOx technology will effectively eradicate bacteria and viruses without triggering resistance unlike traditional antibiotics. The technology platform is highly versatile, in which different formulations and product categories can create the potential for a new generation of antibiotics (antimicrobial agents) treating all kinds of infections without generating new antimicrobial resistance.

## **Strategic Direction**

## Becoming a world-leading developer of antimicrobial technology

SoftOx is committed to developing new ways of eradicating infections and fighting antimicrobial resistance. The focus is to deliver projects from the concept development phase to a partnering phase with the necessary preclinical and clinical documentation. SoftOx is a research and development company, which creates value through developing applications for the antimicrobial technology. SoftOx is responsible for progressing projects to achieve the proof of concept or proof of sales stage where it is suitable to be taken over by partners. SoftOx is seeking strategic partners depending on the project – industrial, financial, institutional – to help us bring the projects to the market and meet user needs.

## SOFTOX – a networking company

SoftOx currently develops projects in three regulatory classifications: biocides, medical devices and drugs. The risk profile of the Company's development products varies from lower risk and investment projects such as biocides and medical devices to high risk and investment drug development projects each with a different payment and reimbursement structure.

<sup>&</sup>lt;sup>15</sup> FDA Executive Summary, Classification of Wound Dressings Combined with Drugs (2016).

<sup>&</sup>lt;sup>16</sup> Antimicrobial Resistance Collaborators (2022). Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis, The Lancet. https://doi.org/10.1016/S0140-6736(21)02724-0

The Company's partner strategy is to find the right partner at the different levels of product development. SoftOx's core activities involve research and development and taking the products from a concept to completing the required preclinical and clinical documentation.

Collaboration is central to the operations and goals. SoftOx seeks like-minded partners for the different development steps. These established collaborative partnerships are instrumental in the future partnerships SoftOx is seeking to take products into the commercialisation phase. The product development process begins with concept development by establishing the user need and willingness to pay. Supporting partners include EXCITE International, a collaboration with industry leaders such as Blue Cross/Blue Shield and Mayo Clinic; the World Health Organization's project group Private Organizations for Patient Safety ("POPS") and the European Wound Management Association (EWMA). SoftOx also entered a collaboration agreement with the Norwegian Defence Research Establishment (FFI), the primary institution responsible for defence-related research and development in Norway, to develop and field test SoftOx's technology and civilian products for military purposes.

The next step involves in vitro and animal studies to obtain preclinical proof of concept (**PoC**). This stage normally includes testing of the drug in non-human subjects to gather efficacy, toxicity and pharmacokinetic information. SoftOx has strong connections with leading Nordic universities, including Malmö University, University of Copenhagen and University of Oslo, and the Norwegian Defence Research Establishment who serve as opinion leaders and academic research partners moving into the clinical phase.

The following step involves pilot and confirmative studies or clinical trials phase 1/2 to reach PoC in humans. Bispebjerg Hospital has been a long-standing partner of SoftOx in testing the effectiveness and safety of products. In the final step, the Company reaches out to partners for market adoption. As SoftOx's strengths and business objectives do not involve these commercialisation operations, the Company is seeking strategic partnerships with external partners for the distribution, sales and marketing of the SoftOx products.

SoftOx continuously considers collaborations with industry and academic groups to develop and strengthen the Company's strategic and competitive position as well as ways to expand its technology platform to offer better treatments for patients.

## **Operational Review**

All SoftOx products utilise the same technology, but the concentrations are tailored for different uses and indications. The technology is based on a combination of naturally occurring chemicals that harbour broad antimicrobial effects without inducing resistance. The Company is today developing a range of products that can be classified as either medical devices or medicinal products (drugs) for human use. The current business segments can be divided into wounds, disinfection and respiratory. In addition, the Company is also in the concept phase of developing a separate segment for countermeasures against chemical and biological weapons together with the Norwegian Defence Research Establishment (FFI).

## SoftOx Disinfection (hand and surface disinfection):

In 2021, SoftOx won a Norwegian hospital purchasing tender (HINAS) for alcohol-free hand disinfectant and a Swedish purchasing tender (Varuförsörjningen) for sporicidal surface disinfectant. These achievements are regarded as proof of sales.

In October 2022, the company received the final approval from the Swedish Chemicals Agency (KemI) on its application for the SoftOx biocidal product family for hand and surface disinfection. The approval allows the company to sell its disinfection products in Sweden.

**SoftOx Wound Irrigation Solution (SWIS):** The final confirmatory clinical investigation (SWIS-02 trial) was completed in June 2021. SWIS-02 demonstrates and confirms previous findings (from SWIS-01) to be safe and well tolerated as a wound irrigation solution for acute wounds and not associated with any major risks. The SWIS-02 study showed both significant improvement in wound healing and significant reduction in bacterial burden compared to Normal Saline (NS), positioning the product as superior towards today's market leaders. This is regarded as an important confirmation of the Company's base technology.

A review of the Premarket Notification (510(k)) application to the US Food and Drug Administration (FDA) to obtain clearance for SWIS as a medical device class II in the US market is ongoing.

**SoftOx Biofilm Eradicator (SBE):** The final report from the Phase 1 clinical study (SBE-01, NCT05710094), evaluating the safety and tolerability of single and multiple ascending doses of SBE in patients with chronic leg ulcers, was received in December 2022. The first-in-human clinical study concluded that SBE applied on chronic leg wounds was safe and well-tolerated. Treatment with all SBE formulations consistently reduced the absolute number of bacteria in the wound compared with pre-treatment, and a dose-dependent reduction in wound size was observed in the multiple-dosing SBE treatment groups.

**SoftOx Inhalation Solution (SIS):** The safety of single and multiple ascending doses of SIS in healthy volunteers (Safety of Ascending Single and Multiple Doses of Nebulized SoftOx Inhalation Solution in Healthy Subjects, NCT05188638) was completed on 13 April 2022. The study met its primary endpoint and demonstrated safety and tolerability in healthy subjects over a range of potentially therapeutic formulations and dosing regimens.

Preparations for a Phase 2 clinical trial application, including additional non-clinical toxicology studies, contracting with a contract manufacturing organization for Phase 2 production, and scientific interactions with the European Medical Association on Phase 2 study design are ongoing. The SoftOx Research Department led by Prof. Thomas Bjarnsholt has demonstrated reproducible dose dependent virucidal effects in in vivo mouse models of Influenza A. The team continues to investigate the effects of SIS in mouse models with other infectious agents.

## **Financial Review**

## **Operating income**

Operating income for the full year 2022 amounted to NOK 7,1 million (NOK 7,9 million) for the Group and NOK 6 million (NOK 6,1 million) for Solution. The income consists primarily of grants from the Research Council of Norway, and reimbursement from Department of Defence.

## **Operating expenses**

Total operating expenses for 2022 for the Group amounted to NOK 98 million (NOK 94 million), and NOK 94,8 million (NOK 50,4 million) for Solution. Employee costs in the Group were NOK 26,4 million (NOK 21 million), and NOK 16,7 million (NOK 16,3 million) for Solution for full year 2022. For the full year 2022, other operating costs for the Group amounted to NOK 67,9 million (NOK 69,1 million) and NOK 78 million (NOK 68,7 million) for Solution.

The operating loss for the Group in 2022 was NOK 91 million (NOK 86 million) and NOK 88,9 million (NOK 79 million for Solution). Net financial profit for the Group was NOK -2,6 million (NOK –0,2 million) and NOK –1,7 million (NOK 113 thousand) for Solution for the full year 2022. Losses after tax for the Group was NOK 71,1 million (NOK 65,4 million) and for Solution NOK 68,6 million (NOK 59,8 million) for the full year 2022.

#### Statement of financial position

Total assets 31 December 2022 for the Group decreased to NOK 100,6 million (128 million) for the Group and to NOK 114,8 million (NOK 141,2 million) for Solution. Total liabilities were NOK 61,8 million (NOK 18,3 million) for the Group and NOK 59,2 million (NOK 17 million) for Solution. The increase is mainly driven by a convertible loan.

Total equity as of 31 December 2022 was NOK 38,7 million (NOK 109,7 million) for the Group and NOK 55,6 million (NOK 124 million) for Solution, corresponding to an equity ratio of 38,5 percent (85,7 percent) for the Group and 48,4 percent (87,9 percent) for Solution.

## Statement of cash flow

Net cash flow from operating activities was negative by NOK 85,9 million (NOK 72,6 million) for the Group and negative by NOK 88,3 million (NOK 71,6 million) for Solution for the full year 2022, mainly driven by the level of activity related to the research and development.

Net cash flow used in investing activities during the full year 2022 was negative by NOK 4,8 million (NOK 4,6 million) for the Group and NOK 1,7 million (NOK 79 thousand) for Solution. Net cash flow from financing activities was NOK 40,7 million (NOK 99,3 million) for the Group and NOK 40,7 million (NOK 99 million) for Solution for the full year 2022.

Cash and cash equivalents decreased to NOK 6,9 million (NOK 56,7 million) for the Group and NOK 6,8 million (NOK 56 million) for Solution.

#### DIVIDEND

The Company is in an investment phase and expects to be there in the coming years. Soft-Ox is focusing its resources on becoming a world-leading developer of antimicrobial technology and the Board of Directors will recommend payment of dividends in line with the Company's results, financial position, product and market development plans and outlook. Soft-Ox does not expect to pay dividends in the near future. The board will recommend dividends when the Company has results that can justify such a payment.

#### SHARE CAPITAL AND BOARD MANDATES

As of 31 December 2022, there were 10 342 871 ordinary shares outstanding, the same as at year end 2021.

The Company has one class of shares, and all shares carry equal voting rights. The Company had more than 2 200 shareholders 31 December 2022. The results for Groups for 2022 show a loss of NOK 93,7 million. The Board proposes that the loss should be covered by share premium.

## Going Concern and Subsequent Events

Pursuant to § 3.3 (a) of the Norwegian Accounting Act, it is confirmed that the conditions for assuming that the Group is a going concern are present, and that the financial statements have been prepared based on this assumption. Events have occurred since the end of 2022, which is stated in this report that are of major significance for the assessment of the Company's financial position and results. In mid-February 2023 the company was informed that the payment from EDF was due to the financial condition of the company postponed at the same time as the payment schedule would be changed. Since the company in its liquidity budgets had expected a cash payment from EDF, this situation created major problems for the company, something the stock market were informed about in the Q4 report for 2022 the 15<sup>th</sup> of February. At the same time the Silicon Valley Bank collapsed and the market for raising funds for biotech company become extremely difficult. In the period between February and June 14<sup>th</sup> the company has worked on establishing a sufficient financing. Due to the underlaying values of the IP and the technology the Board of Directors has not considered the company to be insolvent, only illiquid. At the time of this report the company has cut costs, raised cash, closed down SoftOx Solutions AS Denmark and signed an agreement with its creditors, so the company now has a runway till end of year. That Board of Directors are in the opinion that the actions taken are sufficient to establish a sufficient long-term financing for the company.

## Risk Factors and Risk Management

SoftOx is subject to several operational and financial risk factors and uncertainties which may affect parts or all of the activities in the Group. The Company proactively manages such risks, and management and the Board of Directors analyse operations and potential risk factors to take measures to reduce risk exposure.

## **FINANCIAL RISKS**

## Interest rate risk

The Group holds cash and cash equivalents and does not have any borrowings. The Group's interest rate risk is therefore in the rate of return of its cash on hand. Bank deposits are exposed to market fluctuations in interest rates, which affect the financial income and the return on cash.

## Exchange rate risk

The value of non-Norwegian currency denominated costs will be affected by changes in currency exchange rates or exchange control regulations. The Group undertakes various transactions in foreign currencies and is consequently exposed to fluctuations in exchange rates. The exposure arises largely from the clinical trials and research expenses. The Group is mainly exposed to fluctuations in Danish kroners (DKK), euro (EUR), and US dollar (USD). The Group holds part of the bank deposit in DKK depending on the need for such foreign exchange.

The foreign currency exposure is also mostly linked to trade payables with short payment terms. The Group might consider changing its current risk management of foreign exchange rate if it deems it appropriate.

## **Credit risk**

Credit risk is the risk of counterparty's default in a financial asset, liability or customer contract, giving a financial loss. The Group's receivables are generally limited to receivables from public authorities by way of government grants. The credit risk generated from financial assets in the Group is limited since it is cash deposits. The Group places its cash in bank deposits in recognised financial institutions to limit its credit risk exposure. The Group has not suffered any loss on receivables during 2022 and the Group considers its credit risk as low.

## Liquidity risk

Liquidity is monitored on a continued basis by The Board of Directors and Group management. The Group works continuously to ensure financial flexibility in the short and long term to achieve its strategic and operational objectives. In mid-February 2023 the company was informed that the payment from EDF was due to the financial condition of the company postponed at the same time as the payment schedule would be changed. Since the comkpany in its liquidity budgets had expected an cash payment from EDF, this situation created major problems for the company, something the stock market were informed about in the Q4 report for 2022 the 15<sup>th</sup> of February. At the same time the SVB collapsed and the market for raising funds for biotech company become extremely difficult. In the period between February and June 14<sup>th</sup> the company has worked on establishing a sufficient financing. Due to the underlaying values of the IP and the technology the Board of Directors has not considered the company to be insolvent, only temporary illiquid. At the time of this report the company has cut costs, raised cash and signed an agreement with its creditors, so the company now

has a runway till end of year. That period the Board of Directors think is sufficient to establish a sufficient long-term financing for the company.

## **OPERATIONAL RISKS**

## **Research and development**

Developing medtech and pharmaceutical products inherently involves high risk, both in regard to the outcome of clinical trials, completion of clinical trials in a timely fashion, changes in clinical programmes and results of product development. The Company seeks to mitigate risk through appropriate measures. The Company designs its clinical studies according to best practice and in compliance with international regulations to minimise risk. Specialised Clinical Research Organizations ("CRO") are contracted to help in these efforts. The clinical studies are carried out in collaboration with world-class international partners with solid experience in conducting such studies and are conducted according to all applicable quality standards.

## **Commercial risk**

Commercial risks include the time and costs involved in developing products, market competition, regulatory approvals, patent protection and the ability to attract partners. The Company focuses on ensuring sufficient patent protection and works closely with external patent counsels to minimise the risk of patent infringement claims as well as to prepare any patent defence should this be necessary. SoftOx has been successful in forming partnerships with leading companies in its field. They contribute both financially and with R&D expertise, thereby helping to reduce risk.

## Market risk

The Company's ability to successfully commercialise its products is dependent on several factors, including the receipt of the necessary marketing approvals, established commercial manufacturing and supply arrangements, the ability to establish a commercial infrastructure and a general acceptance of the products among physicians, patients and/or the medical community. The Company's ability to commercialise its products is also dependent on the Company's ability to compete with other products, successfully execute the Company's pricing strategy, in addition to qualify for, identify, register, maintain, enforce and defend the intellectual property rights and claims covering the product. The development methodology starts with an evaluation of unmet market need and willingness to pay, usually in close cooperation with Key Opinions Leaders, to reduce the market risk as much as possible.

## **Collaborations and partnerships risks**

To successfully conduct its business and operations, the Company is dependent on the ability to develop and sustain successful partnerships and collaborations with different partners within several fields. These partners may include suppliers, the third parties necessary to conduct clinical trials, distributors, marketing partners and key customers or licensees. The different partnerships and collaborations are necessary for the Company to be able to successfully develop, produce, distribute and attain sufficient market acceptance of its product and product candidates. In addition, the Company is dependent on a third-party distribution network, domestic and internationally in order to secure sales of its products. To mitigate the risk SoftOx has a partner strategy – to find the right partner at the different levels of product development. We seek like-minded partners for the different steps, and these collaborative partnerships we have established are fundamental in future

partnerships we are seeking to take our products into the commercialisation phase. Examples are FFI and Navy for the defence sector.

## Intellectual property rights

The Company's success, competitive position and future revenue is dependent on its intellectual property rights and the Company's ability to protect its rights and know-hows. Adequate protection of its intellectual property will require the Company to obtain and maintain patent protection for its methods, products, processes, technologies and to preserve the Company's trade secrets. Adequate protection will also require the Company to operate without infringing the intellectual rights of third parties and preventing third parties from infringing on the Company's intellectual rights. SoftOx has a close cooperation with Brown Rudnick LLP which is the main architect behind the Company's IP strategy. The Company has an ongoing patent application process to secure new inventions and have key patents filed in US, Europe, Asia and several South American countries.

## Human resources

As a highly specialised and scientifically focused company, SoftOx relies on its ability to attract, train and retain talent and expertise. The Company has implemented a compensation scheme and strives to be an attractive employer by offering an inspirational and flexible working environment.

## Organization

The Group's Leadership Team at year-end consisted of Christian Harstad, Interim CEO, Kristine Rød, CFO, Christopher Burton, CMO, Thomas Bjarnsholt, CRO and Ingrid Juven, COO. The Board of Directors held 21 meetings in 2022. All members of the Board of Directors are shareholder-elected. The members of the Board of Directors were at the end of 2022: Geir Almås (Executive Chairman of the Board), Kari Myren, Olav Jarlsby, Henrik Nielsen, Adrian Bignami and Jørgen Berggrav.

Soft-Ox has offices in Oslo, Norway, and in Copenhagen, Denmark.

The Soft-Ox organisation comprised of 25 employees at the end of 2022. In addition, the Company has a strong network of consultants to support the operations and development. The Company's policy is to outsource noncore operations and highly specialised services. The work environment within the Company is a good, positive environment.

No accidents or injuries resulting in absence were registered in 2022. SoftOx aims to be a workplace with equal opportunities in all areas. The Company has traditionally recruited from environments where the number of women and men is relatively equally represented. In terms of gender equality within the Company, 17 % of board members are women, as are 50% of the senior management team at the end of 2022. Working time arrangements at the Company, independent of gender, strive to enhance the individual work-life balance. SoftOx policy is to promote equal rights and opportunities and prevent any kind of discrimination based on gender, ethnicity, nationality, sexual orientation, ancestry, or religion. SoftOx is working actively to promote the Anti-Discrimination Act. These activities include recruitment, salary and working conditions, promotion, professional development, and protection against harassment. Furthermore, SoftOx aims to be a workplace where there is no discrimination based on disability. A diverse and inclusive workplace supports innovation and contributes to a positive work environment in which people can grow both professionally and personally.

## Corporate Social Responsibility (CSR)

Infections and antimicrobial resistance remain one of the most pressing healthcare challenges in the world. Respiratory infectious diseases are the third leading cause of death while antimicrobial resistance is regarded as one of the biggest threats to global health. Our vision is to become a world leading developer of antimicrobial technology and help the world fight infections, and thereby create value for patients, society and shareholders through our work in discovering and developing novel medicines.

CSR is therefore important to us as it is the foundation of our activities and directly linked to our long-term success. In order to have a real impact, we will in the coming years work towards strengthening our sustainability management. The aim will be to identify environmental, social and governance (ESG) topics in SoftOx value chain that are material for us and our stakeholders. Our key stakeholders include our patients and their families, our employees, investors, regulators, suppliers and other business partners, such as research organisations and academic institutions.

Today's CSR strategy focus on three main areas:

- 1. Employees
- 2. Environment and climate
- 3. Business ethics

We believe responsible behaviour is key to build trust and protect the reputation of the Company, and our CSR main areas provide an important means for us to prioritise our activity in these areas.

SoftOx's ability to succeed also depends on the interest, trust, relationships and reputation among all key stakeholders including R&D partners, employees, regulatory authorities, and shareholders. This applies across the value chain of each product candidate and in every phase of the R&D cycle.

#### **Employees**

The primary focus of SoftOx's corporate social responsibility ("CSR") efforts is its employees. SoftOx's employees are essential for delivering on the Company's ambitions and goals. SoftOx aspires to attract, develop and retain the best people in the sector. The Company strives to be a company where employees thrive and develop, regardless of their background or nationality. The Company works continuously to ensure the wellbeing of and a safe and healthy work environment for its employees.

SoftOx promotes an open and strong corporate culture with a healthy, safe and fair work environment in accordance with applicable laws and regulations. SoftOx will not use force of any form or involuntary labour or employ any persons below the legal minimum age. At the end of 2022, the group employed 25 people, of which 1 were part-time employees and 7 were employed in subsidiaries. SoftOx aims to foster a workplace with equal opportunities for women and men in all areas. The group has traditionally recruited from environments with relatively equal representation of women and men. The team of employees consists of 56 percent women and 44 percent men, representing 7 different nationalities. The board consists of 17 percent women. The executive management team consists of 50 per cent women and 50 per cent men.

The working environment in the Group is regarded as good. Working time arrangements at the Company, independent of gender, strive to enhance the individual work-life balance. There were no accidents or work-related injuries during the reporting period. SoftOx promotes a productive and inclusive working environment, free from harassment, discrimination and disrespectful behaviour.

All employees are offered equal opportunities with regards to hiring, compensation, training, promotion, termination or retirement regardless of gender, age, ethnic and national origin, cultural beliefs, religion, sexual orientation, social background or other distinguishing characteristics.

## **Environment and climate**

It is SoftOx's mission to bring new innovative products to patients in the most sustainable way and with respect for the environment. SoftOx has a focus on how to minimise the Company's impact on the environment, reducing waste and handling it in a safe and responsible way.

SoftOx is a member of the Grønt Punkt. All company activities are subject to strict requirements in relation to quality, environment, and personal health. SoftOx is consistently working to only outsource production and distribution to selected vendors that fulfil both internal and external requirements. Our technology goal is to substantially reduce the use of dangerous chemicals within disinfection and patient treatment.

An example is our disinfection products. By switching to SoftOx's disinfectants, one can reduce the use of chemicals and chlorine by 99 percent and still achieve the same antimicrobial effects. The use of our products does not induce antimicrobial resistence and will hopefully reduce the dependence on antibiotics.

We also strive towards avoiding unnecessary travel and promote the use of online meeting facilities, when possible, to reduce the Company's CO2 footprint.

## **Business ethics**

SoftOx is committed to lawful and ethical behaviour with all our stakeholders and requires all board of directors and staff to comply with the applicable laws and regulations. SoftOx has a zero tolerance towards corruption and any kind of money laundering. All employees are obligated to avoid any kind of violations of these matters. No violations have been reported in 2022.

In collaboration with external contractors, SoftOx is performing pre-clinical studies in animals and clinical trials. SoftOx is committed and continually working to minimise the risk that both volunteers, patients and animals are exposed to in order to ensure safety, quality and animal welfare.

The pharmaceutical industry is governed by extensive global and European regulations and laws. Pre-clinical and clinical trials must be conducted in compliance with the relevant regulations and laws. SoftOx is committed to operate in accordance with responsible, ethical and sound corporate and business principles and will always strive to comply with applicable laws and regulatory requirements in all areas of research and development. SoftOx complies with international regulations, laws, guidelines and standards for development of new drugs such as:

- Good Laboratory Practice (GLP)
- Good Pharmacovigilance Practice (GVP)
- Good Clinical Practice (GCP)
- Good Clinical Laboratory Practices (GCLP)
- Good Manufacturing Practice (GMP)

The Company also complies with relevant regulation and guidelines issued by the Norwegian Medicines Agency (NoMA), European Medicines Agency (EMA), US Food and Drug Administration (FDA) and others.

All employees and external contractors are strictly obligated to adhere to applicable standards and all studies are performed in accordance with ethical and scientific principles governing both preclinical studies and clinical trials in humans, as set out in the Declaration of Helsinki, the International Conference on Harmonisation (ICH) guidelines on Good Clinical Practice and instructions given by the ethics committee in the specific country. All external contractors are qualified and competent in providing these types of studies and have a strong collaboration with leading experts on how to design and optimise trial conduct.

Our clinical trials and animal trials are only initiated if they are scientifically and medically justified and have been externally validated by clinical and scientific experts, and after approval by the relevant regulatory authorities and ethics committees. Clinical trial subjects (and or the legally authorised representative) must give written consent after being properly and fully informed of the trial, including its risks and potential benefits. Participants are duly informed that they can withdraw from the trial at any time, without any explanation, and then will receive appropriate standard care.

SoftOx and relevant authorities conduct regular site monitoring visits to ensure that clinical trials are conducted in accordance with the applicable approved study protocol. All adverse events are monitored and reported to regulatory authorities and ethics committees as required, and appropriate actions are taken when needed. Our trials ensure all proper indemnification of participants in case a product candidate or trial procedure causes bodily harm. We publish our trials on the appropriate clinical trial registries (e.g clinicaltrials.gov) in a timely manner. We endeavour to publish results in peer-reviewed journals in accordance with Good Publication Practice and at relevant scientific meetings and congresses.

As a publicly listed company, we also have the obligation to communicate important trial results in a timely manner to shareholders and the wider investor community via press releases.

## Governance

Ensuring good governance practices and "doing things the right way" involves all people in SoftOx. This includes governance as documented in the guidelines for corporate governance, local and industry specific guidelines like good pharmacovigilance practice as well as ethical conduct and anticorruption based on the SoftOx values and respect for human rights. SoftOx's supplier requirements in terms of adherence to Company practices, guidelines and values are an integral part of all stages of the procurement process including selection and auditing.

SoftOx considers solid corporate governance as a prerequisite to creating value for shareholders and gaining the confidence of investors. SoftOx will strive to comply with the generally accepted principles of good corporate governance through its internal controls and management structure. SoftOx aim is that its guidelines for corporate governance will be in line with the latest version of the Norwegian Code of Practice for Corporate Governance, and a description of this is given in the annual report. A complete description of the recommendation is available at the Norwegian Corporate Governance Board (NCGB) web pages (www.nues.no).

The Board of Directors and executive management of SoftOx are covered under a Group Directors' and Officers' liability insurance, managed by Riskpoint. The insurance covers personal legal liabilities including defense and legal costs.

The governance principles are based on compliance with relevant parts of the Norwegian Code of Practice for Corporate Governance ("the Code") and the Norwegian Transparency Act and hereby

refer to following paragraphs and the company's homepage <u>www.soft-ox.com</u> for further information.

## Outlook and objectives

SoftOx is a technology company with several products nearing entry into the commercial phase. With resources and efforts focused on the Company's core competencies in research and development, SoftOx is seeking and discussing plans with partners to bring the products to the market. In the coming year, SoftOx anticipates establishing a spin-off company for further drug development and beginning commercial talks for several of the current product portfolio. The strength of the technology platform is that there are many opportunities for development of projects based on SoftOx technology that we are excited about following the completion of the current projects. With a strong patent portfolio and highly skilled researchers, SoftOx is well resourced for future endeavours.

Progressing work on the development of each project:

- SoftOx Inhalation Solution (SIS): Continuing preparations for Phase 2 civilian indication
- SoftOx Biofilm Eradicator (SBE): Continuing preparations for Phase 2 study in chronic wounds
- SoftOx Wound Irrigation Solution (SWIS): Ongoing work to establish the extent of supplemental work and resources needed to secure an approval will start as soon as the company got sufficient funding.
- SoftOx Defense Solutions (SDS): Start-up of development and bridging activities for development of a biological medical countermeasure
- Pursue disinfectant and wound care approvals in selected markets
- Establish a network of partners and distributors for both wound care and disinfectant products

## Confirmation from the Board of Directors and CEO

We confirm, to the best of our knowledge, that the financial statements for the period from 1 January to 31 December 2022 have been prepared in accordance with NGAAP and reflect a true and fair view of the Group and the Company's consolidated assets, liabilities, financial position, results of operations under the assumption of continued current operations, and that the Report of the Board of Directors provides a true and fair view of the development and performance of the business as well as the position of the Group and the Company along with a description of the key risks and uncertainty factors that the Company may be facing.

Oslo, 13th of June 2022 SoftOx Solutions AS

Sign

Geir Almås

Chief Executive Officer and Executive Chairman of the Board

Sign

Olav Jarlsby

Member of the Board

Sign

Adrian Bignami

Member of the Board

Sign

Jørgen Berggrav

Member of the Board

Sign

Henrik Nielsen

Member of the Board

## Governance

## Corporate governance in SoftOx

## SoftOx is committed to Good Corporate Governance

SoftOx considers good corporate governance to be a prerequisite for sustainable value creation and trustworthiness, and for access to capital. SoftOx is committed to good corporate governance practices based on good and healthy business practices, reliable financial reporting and an environment of compliance with legislation and regulations.

The board of directors has established a set of governance principles in order to ensure a clear division of roles between the board of directors, the executive management and the shareholders.

The principles are based on compliance with relevant parts of the Norwegian Code of Practice for Corporate Governance ("the Code") and the Norwegian Transparency Act and hereby refer to following paragraphs and the company's homepage <u>www.soft-ox.com</u> for further information.

SoftOx is not subject to annual reporting requirements on corporate governance but has chosen to issue a corporate governance statement as part of its annual report, with explanations to any deviations from the Code.

The annual statement on corporate governance for 2022 follows below. The statement was approved by the board of directors June 2023 and follows the structure of the latest version of Code, dated 14 October 2021.

## 1. Implementation and reporting on corporate governance

The Company will seek to comply with the Corporate Governance Code. The Board of Directors shall include a report on the Company's corporate governance in its annual report, including an explanation of any deviations from the Corporate Governance Code.

Deviations from the Code: 2021 is the first year SoftOx is reporting on corporate governance, and there are some minor deviations. Although the Company is not a listed company on the main list at Oslo Børs and hence not required to comply or report on compliance with the Code, the Company will seek to comply on all steps in the coming years.

## 2. Business

The Company's operations comply with the business objective set forth in its articles of association section 3: "The Company's objective is to undertake research and development for use in humans and veterinary medicines, including medicines, medical equipment and disinfection products". The Company has developed clear goals and strategies which are further described in the annual report for 2022.

SoftOx Solutions AS is seeking to advance the infection market with a strong science-based technology. By developing and selling new, revolutionary disinfection and infection treatment products, SoftOx is obligated to deliver safe and high-quality innovative products at reasonable prices. SoftOx has developed and established guidelines that lay down the ethical standards and procedures. The Board of Directors of the Company has adopted several corporate governance guidelines, including code of conduct, anti-corruption policy, rules of procedure for the Board of

Directors, corporate governance, guidelines for remuneration, Investor Regulations policy, and guidelines for corporate social responsibility.

## **Deviations from the Code: None**

## 3. Equity and dividends

## Capital adequacy

SoftOx had total equity on 31 December 2022 of NOK 38,7 million, corresponding to an equity ratio of 38,5 percent. The Board of Directors considers this to be an adequate level relative to the risk and scope of operations based on the Company's internal estimated capital requirements. The Company's capital situation is continuously monitored, and the Board of Directors will take adequate steps to capitalise the Company if deemed necessary.

## Dividend policy

SoftOx is focusing on the research and development and does not anticipate paying any cash dividend until sustainable profitability is achieved.

## **Board authorisations**

At the Company's extraordinary general meeting, held on 29 December 2021, the Board of Directors was granted the following authorisation:

• The Board of Directors is granted an authorisation to increase the Company's share capital by up to NOK 105 678,71, which constitute 50 % of the Company's outstanding shares. The purpose of the authorisation is to permit the issue of new shares as consideration in connection with acquisitions, in connection with the exercise of options to subscribe for shares and to raise new equity to strengthen the Company's financing.

For supplementary information on the authorisations, reference is made to the minutes of the annual general meeting held on 30<sup>th</sup> of May 2023, available on the Company's website.

## Deviations from the Code: None.

## 4. Equal treatment of shareholders and transactions with close associates

SoftOx has only one class of shares. Each share in the Company carries one vote, and all shares carry equal rights, including the right to participate in general meetings. All shareholders shall be treated on an equal basis, unless there is just cause for treating them differently.

## Share issues without preferential rights for existing shareholders

In the event of a share capital increase through the issue of new shares, a decision to waive the existing shareholders' preferential rights to subscribe for shares shall be justified. Where the Board of Directors resolves to issue shares and waive the preferential rights of existing shareholders pursuant to an authorisation granted to the Board of Directors by the general meeting, the justification will be publicly disclosed in a stock exchange announcement issued in connection with the share issuance.

## Transactions in treasury shares

Any transactions in treasury shares shall be carried out through Euronext Growth, Oslo, and in any case to prevailing stock exchange prices. In the event that there is limited liquidity in the Company's

shares, the Company will consider other ways to cater for equal treatment of shareholders. There were no such transactions in 2022.

## Approval of agreements with shareholders and close associates

For transactions that are considered to be not immaterial between the Company and its closely related parties, the Board of Directors will arrange for an independent and fair valuation. Members of the Board of Directors and executive personnel are required to notify the Board of Directors when such members have any significant, direct or indirect, interest in a transaction carried out by the Company. In 2022 SoftOx received a short-term loan from Geir Almås (CEO), Pro AS, GH Holding AS, Aubert Invest AS and Almhaug Bolig AS were a total of MNOK 35 out of MNOK 40 million were from existing shareholders. The loan included a one-year option for buying shares equal to the value of stock price of NOK 22,50 or lower if share issues were made to a lower price during the lending period. The Board considered the agreement to be within equal treatment of all shareholders.

## **Deviations from the Code: None**

## 5. Shares and negotiability

The shares of the Company are freely negotiable, and the Company's articles of association do not place any restrictions on the negotiability of shares.

## **Deviations from the Code: None**

## 6. General meetings

The general meeting is open to all shareholders, and SoftOx encourages all shareholders to participate and exercise their rights in connection with the Company's general meetings. The right to participate and vote at the general meeting can only be exercised for shares registered in the shareholders' register by the fifth business day prior to the day of the general meeting.

Notice of a general meeting and any supporting documents, other information on the resolutions to be considered, shall be made available on the Company's website no later than 7 days prior to the date of the general meeting. The deadline for registration will be set as close to the meeting as possible, and all the necessary registration information will be described in the notice.

Shareholders unable to attend may vote by proxy. Whenever possible, the Company will prepare a proxy form that will allow separate votes for the items that are to be considered in the general meeting. The agenda for the annual general meeting is stipulated by the articles of association, and the main topics to be considered include the approval of the annual accounts and the Director's report. The Chairman of the Board is normally the chairperson for the general meeting. If there is disagreement on individual items for which the Board Chairman belongs to one of the fractions or is not regarded as being impartial for other reasons, another chairperson will be appointed to ensure impartiality regarding the items to be considered. The chairperson of the Board of Directors, the CEO and the CFO shall, as a general rule, be present at the annual general meeting. Representatives of the Nomination Committee, as well as the auditor, should be present at general meetings where matters of relevance for such committees/persons are on the agenda.

Minutes from the general meetings will be published in accordance with the stock exchange regulations. In 2022, SoftOx held its annual general meeting on 22<sup>nd</sup> of May. In addition, extraordinary general meetings were held on 9<sup>th</sup> of December. In accordance with Norwegian provisional legislation exempting companies from physical meetings requirements the meetings were held virtually.

## **Deviations from the Code: None**

## 7. Nomination Committee

The Nomination Committee of SoftOx consists of two members. The Nomination Committee is responsible for recommending candidates for the election of members and Chairman of the Board of Directors. The current Nomination Committee consists of:

- Dag Vangsnes
- Kristian Almås

All shareholders are entitled to nominate candidates to the Board and contact information for proposing candidates can be found on the Company's website.

Deviations from the Code: The committee not been included in the articles of association and elected by the General Meeting.

## 8. Board of Directors, composition, and independence

Pursuant to Article 5 of the Articles of Association, the Board of Directors shall consist of between one and six members. The current Board of Directors consists of four members, of whom one is a woman and three are men. All members are elected for a term of two years and may be re-elected.

The Board are independent of the Executive Management and material business contacts, more than two members are independent of the main shareholders, and none of the Company's executive managers serve on the Board of Directors. The Company's annual report provides information to illustrate the expertise of the members and their record of attendance at Board meetings. Board members are encouraged to own shares in the Company.

## **Deviations from the Code: None**

## 9. The work of the Board of Directors

The Board of Directors is responsible for establishing a strategy and plans for the Company, a control system that ensure that the Company satisfies the law's requirements, articles of association and requirements for Corporate Governance and ethical standards in addition to monitoring the business operations of the Executive Management.

The Norwegian Companies Act regulates the duties and procedures of the Board of Directors. In addition, the Board of Directors has adopted supplementary rules of procedures, which provides further regulation on inter alia the duties of the Board of Directors and the CEO, the division of work between the Board of Directors and the CEO the annual plan for the Board of Directors, notices of Board proceedings, administrative procedures, minutes, transactions between the Company and the shareholders and confidentiality.

At the meetings of the Board of Directors, which are held approximately every two months, the CEO updates the Board on the operational and financial developments of the Company. The Board of Directors reviews and evaluates its work annually.

Deviations from the Code: The Company does not have an audit committee or Remuneration committee since it is not a requirement for a small and medium sized company. For 2022 a remuneration committee will be established.

## 10. Risk management and internal controls

SoftOx Solutions AS has the responsibility for the establishment of a risk management and internal control system that complies with regulations applicable for the activity. The company are implementing comprehensive set of procedures, risk assessments, policies and manuals that provide detailed descriptions of activities in all aspects of the products, including development, clinical studies, controls, manufacturing, and finance. All procedures always reflect best practice and SoftOx strives for simplicity in all its operations to minimise the risk of mistakes but never to compromise on quality and compliance. SoftOx ensures compliance with the General Data Protection Regulation (GDPR) and human resources process to protect employee data.

Deviations from the Code: The Board of Directors has carried out a review of the Company's most important area of exposure to risk and its internal control arrangements every two years but will in the coming year have an annual review and are continually improving the process.

## 11. Remuneration of the Board of Directors

The remuneration of the Board of Directors shall be decided at the Company's general meeting when they are elected, and should reflect the Board of Directors' responsibility, expertise, time commitment and the complexity of the Company's activities. Consultancy work performed by board members which is not included in this remuneration shall be invoiced according to a written agreement between the rest of the Board and the Board member and the amount invoiced each year will be identified in the annual report. The remuneration to the Board of Directors consists of an annual fee and starting share options.

## Deviations from the Code: None, except starting share options.

## 12. Remuneration of the Executive Management

The Company recognises the importance of attracting and retaining key employees and executive managers, and the compensation package is regarded as an important tool in this respect. The Company has an option scheme which aims to align the long-term interests of the Executive Management with those of the shareholders. The options are granted subject to the achievement of defined targets for the past year. Warrants typically vest over a period of five years and are granted annually with a strike similar or above stock price at the year end. For further information about the remunerations, reference is made to remuneration policies.

## **Deviations from the Code: None**

## 13. Information and Communications

## General

The Company has targeted investor relation activities with the aim to consistently provide the market with timely and accurate information. The Company's reporting of financial and other information is based on openness and considers requirements for equal treatment of all investors. The Board will seek to ensure that market participants receive correct, clear, relevant and up-to-date information in a timely manner, considering the requirement for equal treatment of all participants in the securities market.

The Company will each year publish a financial calendar, providing an overview of the dates for major events such as its ordinary general meeting and publication of interim reports.

## Information to shareholders

All information distributed to the Company's shareholders will be published on the Company's web site approximately at the same time as it is sent to shareholders. The Chairman of the Board and the CEO are authorised to speak on behalf of the Company, and delegate such authority as is appropriate in relevant cases.

## **Deviations from the Code: None**

## 14. Take-overs

There are no defence mechanisms against take-over bids in the Company's articles of association, nor have other measures been implemented to specifically hinder acquisitions of shares in the Company. In the event of a take-over process, the Board of Directors and the executive management will ensure that the Company's shareholders are treated equally and that the Company's activities are not unnecessarily interrupted. The Board of Directors has a special responsibility in ensuring that the shareholders have sufficient information and time to assess the offer. In addition to complying with relevant legislation and regulations, the Board of Directors will seek to comply with the recommendations in the Code of Conduct, including a valuation from an independent third-party. On this basis, the Board of Directors has not established any other written guidelines for procedures to be followed in the event of a take-over bid, as such situations normally are characterised by specific and one-off situations which makes guidelines challenging to prepare.

## Deviations from the Code: The Company has not established separate principles for how to act in a take-over situation as described.

## 15. Auditors

The Company's auditors, Berge Lundal, is regarded as independent in relation to SoftOx. The auditors provide a statement each year confirming their independence. The auditors attend the board meeting at which the Board of Directors discusses the annual financial statements, accounting principles and other relevant matters. At each year's annual general meeting, the Board of Directors discloses the fees paid to the auditors.

## Deviations from the Code: None, except guidelines in respect of use of the auditor has been established.

# Board of Directors

# Geir Hermod Almås, Chairman of the Board

Geir Almås is the CEO of SoftOx and became a co-founder of the Group in 2008. Almås has previously worked for five years as an auditor for Coopers & Lybrand (now PwC) and nine years in governance, risk management and compliance (GRC), including seven years as risk manager for KLP Asset Management. Prior to joining SoftOx Solutions, Almås has since 2004 worked with business development in Norway and Poland, including five years as CEO and part-owner in Polfarm Sp. z o.o. and 9 years as CEO in SoftOx Group. Almås has a broad network both in Norway and internationally. He holds a Master of Science in business from BI Norwegian Business School and he is a Chartered Accountant (Nw: Statsautorisert revisor) with the Norwegian School of Economics (NHH).

Geir Almås holds 740 260 shares and 197 500 share options in SoftOx.

# Henrik J. Nielsen

Henrik J. Nielsen is the founder and CEO of CAP Partner, a conference handling and consulting firm based in Frederiksberg, Denmark, and Director of the European Wound Management Association, which is one of the largest not-for-profit umbrella organisations in the world within the field of scientific and clinical wound care. Nielsen is an expert in association management, advocacy, fundraising and organization and has provided many years of expertise in the medical device area as a consultant.

Henrik J. Nielsen holds 111 561 shares and 20 000 share options in SoftOx.

# Adrian Bignami

Adrian Bignami is one of the early co-inventors of the SoftOx technology and is currently the Vice President of Finance, Business Planning and Analysis at C4 Therapeutics, Inc., a clinical-stage biotechnology company in the US. He has over 20 years of experience in management consulting, investment banking, entrepreneurship, business development and corporate finance across the pharmaceutical and biotechnology sectors.

Adrian Bignami holds 0 shares and 20 000 share options in SoftOx.

# **Olav Jarlsby**

Olav Jarlsby has been serving as a board member on the board of directors from the start of SoftOx Solutions. Jarlsby currently holds the position as General Counsel and attorney-at-law at Elopak AS. In addition to being a board member of the Company, Jarlsby is a board member in other companies within several different areas such as fish protein, fasteners and real estate. Jarlsby holds a Master of Law from the University of Oslo.

Olav Jarlsby holds 24 100 shares and 32 500 share options in SoftOx.

# Jørgen Berggrav

Jørgen Berggrav (Rear Admiral Rtd) has served as the Senior Advisor of SoftOx Defense Solutions since September 2022. Berggrav has held many diverse roles in the Armed Forces including as Director General in the Ministry of Defence, representative of Europe to the Supreme Allied Commander Transformation and representative of the Chief of Defence at NATO's operational command, SHAPE.

Jørgen Berggrav holds 0 shares and 20 000 share options in SoftOx.

### Kari Myren (stepped down March 2023)

Kari Myren has more than 10 years' experience within the medical field and clinical development from biotechnology and pharmaceutical industries, as well as extensive clinical experience in the field of surgery. Myren is also a specialist in medical affairs management and drug development and has broad experience within business development, commercialisation strategy and health economics. Myren holds a medical degree from the University of Oslo.

Kari Myren holds 0 shares and 32 500 share options in SoftOx.

# Management Team

# Johan Christian Harstad, CEO

Christian Harstad has a long military career including serving as a submarine commanding officer and roles in the Norwegian special forces, US Joint Forces Command, US Naval War College, Norwegian Defence Staff, and the Norwegian Ministry of Defence. He retired from the Military as Flag Officer and second-in-command for Norwegian Special Operations Forces. In September 2022, Harstad joined SoftOx as the Project Director for SoftOx Defense Solutions AS.

# Kristine Mundal Rød, Chief Financial Officer (stepped down 31<sup>st</sup> of January 2023)

Kristine Mundal Rød joined SoftOx in 2020 as the CFO. She has more than 15 years of financial management, corporate development, corporate governance and advisory experience with public and private companies across multiple industry sectors. The majority of her career was spent at EY as financial auditor for listed companies, various organisations and publicly funded projects, in addition to advisory services related to procedures, processes and controls in financial and non-financial (sustainability) reporting, before joining the Salvation Army where she was in charge of P&L, analysis, forecasting and strategy for one of the subsidiaries. Rød is a State Authorized Public Accountant (Nw: Statsautorisert revisor) and holds a Master of Business Administration in economics from the Norwegian School of Economics (NHH).

# Finn Ketler, Chief Commercial Officer (laid off in 2023)

Finn Ketler is the Company's Chief Commercial Officer and is responsible for commercialising Softox's medical device ambitions, establishing proof of sales and negotiating partnership agreements with distributors and the industry. Ketler has experience from LEGO, Arla and Coloplast where he served as SVP until 2010. At Coloplast he was both country manager in the Danish Subsidiary, Sales & Marketing Director of Wound Care in the UK, Managing Director of Coloplast GmbH and SIEWA, Coloplast German Homecare company, and global head of the Wound & Skincare Division. Since his corporate days, Ketler has supported several start-up companies and as a CEO listed Vigmed AB at NASDAQ (First north) in Stockholm. Finn is an ambitious entrepreneur with passion for the commercial development of a company. Ketler holds a MSc in Economics and Cand merc. in Strategy & Management from Aarhus University.

# Trine Hasselknippe Olsby, HR manager (stepped down end April 2023)

Trine Hasselknippe Olsby is responsible for human resources and HR management. Olsby has more than 14 years of experience with personnel management, recruitment, labor law, project management, HMS, development of employee surveys and employee interviews. She is an experienced HR manager with a focus on management coaching and previous experience from the legal and financial sectors. Olsby holds a bachelor in HR management and completed a master's program in Norwegian Labor Law from BI Norwegian Business School.

# Ingrid Juven, Project Manager

Ingrid Juven is the Company's project manager. Juven has over 25 years of consulting and management expertise within a variety of industries. Her previous roles include Director at EY, Partner at Frost Nordic, Senior Consultant at D'Arcy and Marketing Manager at Egmont Entertainment. Juven holds an MBA in management and marketing from BI Norwegian Business School.

# Christopher Burton, Chief Medical Officer – SIS (stepped down end May 2023)

Christopher Burton, MD PhD, is the Chief Medical Officer for SoftOx Inhalation Solution ("SIS") and is responsible for the overall project and clinical development of this aerosolised antimicrobial drug. Burton is a specialist in internal medicine physician with a PhD in lung transplantation, and more than 15 years' work experience within the pharmaceutical industry. He possesses a strong clinical and research background with special interests in respiratory and immunology therapy areas, risk analysis, translational medicine, and real-world evidence (RWE). Prior to joining SoftOx, Burton was the Senior Director of Clinical Development at Savara Pharmaceuticals where he served as the clinical lead and medical expert for three phase 3 trials evaluating nebulised antibiotics and nebulised GM-CSF products in two different orphan diseases. Burton holds a PhD from Copenhagen University and is a member of the Royal College of Physicians (London), with a Bachelor of Medicine and Bachelor of Surgery degree from Imperial College (London) and a Master of Arts (MA) in Medicine from University of Cambridge.

# Thomas Bjarnsholt, Chief Scientific Officer - SIS

Professor Thomas Bjarnsholt, MSc, MD and PhD, is the Chief Scientific Officer of SoftOx Solutions and leads the SoftOx Inhalation Solution (SIS) project together with Christopher Burton. Bjarnsholt is an expert in bacterial, viral and fungal biofilms in chronic and acute infections with more than 210 peer-reviewed publications. He is a member of the Global Wound Biofilm Expert Panel, among the most cited researchers in the world (only 60 in Denmark) according to the list based on Web of Science and the number 1 biofilm researcher worldwide according to ExpertScape. Bjarnsholt holds a part-time position at SoftOx and also works as a professor at the Costerton Biofilm Center in the Department of Immunology and Microbiology at the University of Copenhagen and Department of Clinical Microbiology at Copenhagen University Hospital. Bjarnsholt took his PhD on biofilm infections in lungs of cystic fibrosis patients. Bjarnsholt is the co-inventor of the SoftOx technology and has previously served on the SoftOx advisory board.

# Financial statements

Profit and Loss SoftOx Solutions Group

Profit and loss						
SoftOx Solutions Group						
	Notes	2022	2021			
Other Income		7 113 601	7 901 399			
Total operating income		7 113 601	7 901 399			
Operating expenses						
Personnel expenses	1, 2	26 382 512	21 113 457			
Other operating expenses		67 885 921	69 106 608			
Depreciation	3	3 900 135	3 783 605			
Total operating expenses		98 168 569	94 003 670			
Operating result		-91 054 968	-86 102 271			
Financial income and financial expenses						
Interest income		735 520	32 905			
Other financial income		94 119	202 684			
Other interest expense		-2 237 774	-87 807			
Other financial expenses		-921 970	-336 856			
Profit and loss on financial activities		-2 645 440	-189 074			
Profit before tax		-93 700 407	-86 291 345			
Taxes	4	22 559 282	20 888 057			
Profit on ordinary activities		-71 141 125	-65 403 288			
Extraordinary income and expenses						
Transfers						
Allocated to/- reduction of share premium reserve		-71 141 125	-65 403 288			
Total transfers		-71 141 125	-65 403 288			

# Balance sheet SoftOx Solutions Group

Balance sheet						
SoftOx Solutions Group						
	Notes	2022	2021			
Assets						
Intangible assets						
Other intangible assets	3	7 927 485	7 370 186			
Deferred tax assets	4	74 053 460	51 347 221			
Non-tangeble assets		81 980 945	58 717 407			
Fixed assets						
Production assets	3	3 890 646	3 493 602			
Fixed assets		3 890 646	3 493 602			
Tangible assets		85 871 591	62 211 009			
Financial fixed assets						
Shares in subsidiaries	5					
Loans to subsidiaries	6					
Total financial fixed assets						
Total Non-Current assets		85 871 591	62 211 009			
Current assets						
Inventory	8	-	196 794			
Sum inventory		-	196 794			
Receivables						
Other short-term receivables	7	7 789 973	8 674 826			
Total receivables		7 789 973	8 674 826			
Deposits, cash, etc.	9	6 906 522	56 983 910			
Total current assets		14 696 495	65 855 530			
Total assets		100 568 088	128 066 539			

Balance sheet				
Soft	Ox Solution	is Group		
Equity and debt	Notes	2022	2021	
Paid-up capital Share capital	10, 12	206 857	206 857	
	-		109 530 368	
Share premium reserve	10, 12	38 534 337 38 741 194	109 737 225	
Total paid-up capital		56 /41 194	109 / 3/ 225	
Retained earnings				
Other equity				
Total retained earnings				
Total equity	10, 12	38 741 194	109 737 225	
Other long term debts				
Other long term debts	13	41 064 697	349 697	
Total long term debts		41 064 697	349 697	
Short-term debt				
Unpaid public duties		619 369	37 989	
Short-term debt to owners		015 505	4 994 826	
Other short-term debt	14	8 826 246	6 916 870	
Supplier debt	14	11 316 584	6 028 934	
Total current liabilities	14	20 762 198	17 978 619	
		20102 200	2, 2, 0 0 0 1 2	
Total debt		61 826 894	18 329 314	
Total equity and debts		100 568 088	128 066 539	

# Profit and Loss SoftOx Solution AS

Profit and loss						
SoftOx Solutions AS						
Operating income and operating expenses	Notes	2022	2021			
Other Income		5 983 776	6 019 466			
Total operating income		5 983 776	6 019 466			
Operating expenses						
Personnel expenses	1, 2	16 684 850	16 271 341			
Other operating expenses	-,-	77 930 753	68 732 404			
Depreciation	3	224 302	75 266			
Total operating expenses		94 839 905	85 079 011			
Operating result		-88 856 128	-79 059 545			
Operating result		-00 000 120	-79 035 545			
Financial income and financial expenses						
Interest income		735 353	32 902			
Other financial income		809 158	140 950			
Other interest expense		-2 321 173				
Other financial expenses		-972 447	-287 000			
Profit and loss on financial activities		-1749109	-113 148			
Profit before tax		-90 605 238	-79 172 693			
Taxes	4	22 025 478	19 365 432			
Profit on ordinary activities		-68 579 760	-59 807 261			
Extraordinary income and expenses						
Annual profit/loss		-68 579 760	-59 807 261			
Transfers						
Allocated to/- reduction of share premium reserve		-68 579 760	-59 807 261			
Total transfers		-68 579 760	-59 807 261			

# Balance sheet SoftOx Solution AS

Balance sheet						
SoftOx Solutions AS						
Assets	Notes	2022	2021			
Intangible assets						
Other intangible assets	3	14 600	14 600			
Deferred tax assets	4	69 338 280	47 312 802			
Non-tangeble assets		69 352 880	47 327 402			
Fixed assets						
Production assets	3	1 394 012	640 003			
Fixed assets		1 394 012	640 003			
Tangible assets		70 746 892	47 967 405			
Financial fixed assets						
Shares in subsidiaries	5	9 407 048	9 407 048			
Loans to subsidiaries	6	21 374 313	20 650 323			
Total financial fixed assets		30 781 361	30 057 371			
Total Non-Current assets		101 528 253	78 024 776			
Current assets						
Receivables						
Other short-term receivables	7	6 474 820	7 118 655			
Total receivables		6 474 820	7 118 655			
Deposits, cash, etc.	9	6 757 318	56 076 495			
Total current assets		13 232 139	63 195 150			
Total assets		114 760 392	141 219 926			

Balance sheet						
SoftOx Solutions AS						
Equity and debt	Notes	2022	2021			
Paid-up capital						
Share capital	10, 12	206 857	206 857			
Share premium reserve	10, 12	55 359 219	123 938 979			
Total paid-up capital		55 566 077	124 145 836			
Retained earnings						
Other equity						
Total retained earnings						
Total equity	10, 12	55 566 077	124 145 836			
Long term debts						
Other long term debts	13	40 688 889				
Long term debts to owners	10	40 000 000				
Total long term debts		40 688 889				
Short-term debt						
Unpaid public duties		645 423	71 471			
Short-term debt to owners			4 994 826			
Other short-term debt	14	8 208 216	6 365 784			
Supplier debt	14	9 651 791	5 642 009			
Total current liabilities		18 505 430	17 074 090			
Total debt		59 194 319	17 074 090			
Total Equity and debts		114 760 396	141 219 926			

# Cash Flow statement SoftOx Solutions Group and SoftOx Solution AS

Ca	shflow stat	ement		
SoftOx	Solutions AS ar	nd the Group		
	SoftOx G	roup	SoftOx Solut	tions AS
Liquidity added to and spent on business				
operations	2022	2021	2022	2021
Profit before tax	-93 700 407	-86 291 346	-90 605 238	-79 172 693
Paid tax				
Depreciation of fixed assets, & goodwill	3 900 135	3 783 605	224 302	75 266
Changes short-term receivables	884 853	286 479	643 835	1 695 953
Changes inventory	195 794	2 774 073	-	-
Changes short-term debt	2 783 578	6 886 043	1 431 340	5 830 639
Net Changes resulting from business				
operations	-85 936 047	-72 561 147	-88 305 762	-71 570 835
Added liquidity / Spent on investments				
Investments in property, plant and				
equipment and long-term receivables	-4 854 478	-4 595 815	-1 702 300	-78 899
Net Change resulting from investments	-4 854 478	-4 595 815	-1 702 300	-78 899
LIQUIDS ADDED/SPENT ON FINANCING				
Issues for cash		89 018 192	-	89 018 192
Other financing activities	40 715 000	10 354 870	40 688 889	10 005 174
Translation differences	-1 859	-33 804		-
Net change resulting from financing	40 713 141	99 339 258	40 688 889	99 023 366
Annual Net Liquidity Change	-50 077 384	22 182 298	-49 319 173	27 373 632
Liquidity reserves as of 1 January	56 983 910	34 801 613	56 076 495	28 702 864
Liquidity reserves as of 31 December	6 906 526	56 983 910	6 757 322	56 076 495

# General accounting Principles

The financial statements have been prepared in accordance with the Norwegian Accounting Act and generally accepted accounting principles in small companies in Norway.

# **Basis for consolidation**

The Group's consolidated financial statements comprise SoftOx Solutions AS and companies in which SoftOx Solutions AS has a controlling interest. A controlling interest is normally obtained when the Group owns more than 50% of the shares in the company and can exercise control over the company. Minority interests are included in the Group's equity. Transactions between group companies have been eliminated in the consolidated financial statement. The consolidated financial statement has been prepared in accordance with the same accounting principles for both parent and subsidiary.

The purchase method is applied when accounting for business combinations. Companies which have been bought or sold during the year are included in the consolidated financial statements from the date when control is achieved and until the date when control ceases.

An associate is an entity in which the Group has a significant influence but does not exercise control the management of its finances and operations (normally when the Group owns 20-50% of the company). The consolidated financial statements include the Group's share of the profits/losses from associates, accounted for using the equity method, from the date when a significant influence is achieved and until the date when such influence ceases.

When the Group's share of a loss exceeds the Group's investment in an associate, the amount carried in the Group's balance sheet is reduced to zero and further losses are not recognised unless the Group has an obligation to cover any such loss.

# Use of estimates

The management has used estimates and assumptions that have affected assets, liabilities, incomes, expenses and information on potential liabilities in accordance with generally accepted accounting principles in Norway.

# Foreign currency translation

Transactions in foreign currency are translated at the rate applicable on the transaction date. Monetary items in a foreign currency are translated into NOK using the exchange rate applicable on the balance sheet date. Non-monetary items that are measured at their historical price expressed in a foreign currency are translated into NOK using the exchange rate applicable on the transaction date. Non-monetary items that are measured at their fair value expressed in a foreign currency are translated at the exchange rate applicable on the balance sheet date. Changes to exchange rates are recognised in the income statement as they occur during the accounting period.

### **Revenue recognition**

Revenues from the sale of goods are recognised in the income statement once delivery has taken place and most of the risk and return has been transferred. Revenues from the sale of services are recognised in the income statement according to the project's level of completion provided the outcome of the transaction can be estimated reliably. Progress is measured as the number of hours spent compared to the total number of hours estimated. When the outcome of the transaction cannot be estimated reliably, only revenues equal to the project costs that have been incurred will be recognised as revenue. The total estimated loss on a contract will be recognised in the income statement during the period when it is identified that a project will generate a loss.

### Income tax

The tax expense consists of the tax payable and changes to deferred tax. Deferred tax/tax assets are calculated on all differences between the book value and tax value of assets and liabilities. Deferred tax is calculated as the tax rate of temporary differences and the tax effect of tax losses carried forward. Deferred tax assets are recorded in the balance sheet when it is more likely than not that the tax assets will be utilised. Taxes payable and deferred taxes are recognised directly in equity to the extent that they relate to equity transactions.

# **Balance sheet classification**

Current assets and short-term liabilities consist of receivables and payables due within one year, and items related to the inventory cycle. Other balance sheet items are classified as fixed assets / long term liabilities. Current assets are valued at the lower of cost and fair value. Short-term liabilities are recognised at nominal value. Fixed assets are valued at cost, less depreciation and impairment losses. Long-term liabilities are recognised at nominal value.

### **Research and development**

Development costs are capitalised providing that a future economic benefit associated with development of the intangible asset can be established and costs can be measured reliably. Otherwise, the costs are expensed as incurred. Capitalised development costs are amortised linearly over their useful life. Research costs are expensed as incurred.

# **Plant and equipment**

Plant and equipment are capitalised and depreciated linearly over the estimated useful life. Significant fixed assets which consist of substantial components with dissimilar economic life have been unbundled; depreciation of each component is based on the economic life of the component. Costs for maintenance are expensed as incurred, whereas costs for improving and upgrading property plant and equipment are added to the acquisition cost and depreciated with the related asset. If the carrying value of a non-current asset exceeds the estimated recoverable amount, the asset is written down to the recoverable amount. The recoverable amount is the greater of the net realisable value and value in use. In assessing value in use, the discounted estimated future cash flows from the asset are discounted.

# Subsidiaries

Subsidiaries are valued at cost in the company accounts. The investment is valued as the cost of the shares in the subsidiary, less any impairment losses. An impairment loss is recognised if the impairment is not considered temporary, in accordance with generally accepted accounting principles. Impairment losses are reversed if the reason for the impairment loss disappears in a later period.

# Inventories

Inventories are recognised at the lowest of cost and net selling price. The net selling price is the estimated selling price in the case of ordinary operations minus the estimated completion, marketing and distribution costs. The cost is arrived at using the FIFO method and includes the costs incurred in acquiring the goods and the costs of bringing the goods to their current state and location.

# Accounts receivable and other receivables

Accounts receivable and other current receivables are recorded in the balance sheet at nominal value less provisions for doubtful accounts. Provisions for doubtful accounts are based on an individual assessment of the different receivables. For the remaining receivables, a general provision is estimated based on expected loss.

# Pensions

Under the defined contribution scheme the Group does not commit itself to paying specific future benefits but makes annual contributions to the employees' pension savings. The Group's payment to the defined contribution scheme amounts to 7% of salary for Norwegian employees.

# **Cash flow statement**

The cash flow statement is presented using an indirect method. Cash and cash equivalents include cash, bank deposits and other short term, highly liquid investments with maturities of three months or less.

# Notes to the Financial Statements for 2022

### Note 1 Payroll, holiday pay etc.

	SoftOx Solutions	Solutions SoftOx SoftOx Solutions		SoftOx
	Group	Solutions AS	Group	Solutions AS
	2022	2022	2021	2021
Payroll, holiday pay etc.	24 259 909	15 424 778	19 167 090	15 187 506
Tax refund	-2 375 000	-2 375 000	-2 375 000	-2 375 000
Employer's contribution	2 343 915	2 343 915	2 389 371	2 389 371
Other personnel expenses	2 153 688	1 291 157	1 931 995	1 069 464
Total personnel expenses	26 382 512	16 684 850	21 113 458	16 271 341
Number of employees	21	17	21	19

The company's board of directors received compensation of NOK 125.000,- per member in 2022.

Chairman received compensation of NOK 250.000,-. The CEO received NOK 939.115,- in salary in 2022. Total expenses for auditing and other assistance was NOK 275.703, of with NOK 231.203 was relates to ordinary auditing. The CEO and the members of the Board do not possess any privilege over the rest, should termination of employment occur.

### Note 2 Occupational pension

The company has taken out occupational pension in Gjensidige Insurance Copmany. The pension scheme is a defined contribution plan.

### Note 3 Fixed assets

SoftOx Solutions Group AS	Production	Production assets Other Intangible assets Goodwill		Other Intangible assets		dwill
	2022	2021	2022	2021	2022	2021
Acqusition cost 1.1	5 457 540	5 306 326	16 718 508	12 065 973		617 673
Access	978 310	151 214	3 878 496	4 746 886		
Exchange rate adjustments			-	94 351		
Total acquisition cost	6 435 850	5 457 540	20 597 004	16 718 509		617 673
Accumualted depreciation 1.1	-1 961 760	-1 397 732	- 9306070 -	5 922 988		- 617 673
Yearly depreciation	-580 474	-551 737	- 3 319 661 -	3 383 082		
Exchange rate adjustments		-14 469	- 43 788 -	42 252		
Accumualted depreciation 31.12.	-2 542 234	-1 963 938	-12 669 519	-9 348 323		- 617 673
Book value 31.12	3 890 646	3 493 602	7 927 485	7 370 186		-

SoftOx Solution AS	Decidentia		Interestible.		6	dwill
SoftOx Solution AS	Production	assets	Intangible a	assets	GOO	dwill
	2022	2021	2022	2021	2022	2021
Acquistion cost 1.1	752 658	731 384	14 600	14 600		
Access	978 310	21 274				
Total acquisition cost	1 730 968	752 658	14 600	14 600		
Accumulated depreciation 1.1	-112 655	-37 389				
Yearly Depreciation	-224 302	-75 266				
Accumualted depreciation 31.12.	-336 957	-112 655				
Book value 31.12	1 394 012	640 004	14 600	14 600		

### Note 4 Taxes

	SoftOx	Solutions	Soft	:Ox	
	Group		Solutio	ins AS	
Tax	2022	2021	2022	2021	
Income tax on ordinary profit:					
Tax payable					
Change deferred tax assets	-22 559 282	-20 888 057	-22 025 478	-19 365 546	
Tax ordinary profit	-22 559 282	-20 888 057	-22 025 478	-19 365 546	
Taxable income:					
Ordinary profit before tax	-93 700 407	-86 291 346	-95 355 242	-79 172 693	
Permanent differences	-4 760 049	-8 851 999	-5 560 191	-8 851 999	
Change temporary differences	-7 596 478	-223 683	-71 659	-85 173	
Taxable income	-106 056 935	-95 367 028	-100 987 093	-88 109 865	
Tax payable in the balance sheet: Payable tax on profit for the year	o	0	0	0	
Total tax payable on the balance sheet	0	0	0	0	

The tax effect of temporary differences and loss carried forward have contributed to increased deferred tax assets, specified below.

SoftOx Solutions AS	2022	2021	Changes
Fixed assets	338 392	266 733	-71 659
Inventories	0	0	0
Sum	338 392	266 733	-71 659
Accumulated loss carry-forward	-315 173 483	-215 058 191	100 115 292
Basis for calculation of deferred tax	-315 173 483	-215 058 191	100 115 292
Deferred tax asset (22%)	-69 338 280	-47 312 802	22 025 478

The Swedish subsidiary WIAB Water Innovation AB has carried forward a loss of SEK 4.866.810,- per 31.12.2022.

### Note 5 Shares in other companies and intra-group transactions

In 2013, the company purchased all 1,500 shares with a nominal value of SEK 100,- in WIAB Water innowation AB, with an office address in Malmo, Sweden. The shares are valued at the lower of acquisition cost and fair value. SoftOx Solutions Denmark AS was estabilished in 2018. The company became founded with DKK 500.000,- in share capital.

In 2018 SoftOx Solutions AS established the subsidiary SoftOx Disinfection AS with originally 300 shares. In 2021 the company's share capital has been increased to 400 shares. In 2021 SoftOx Solutions established the subsidiary SoftOx Defense Solutions AS with 30 shares.

### Note 6 Financial Claims and Debt / Accounts receivable on subsidiaries

In 2013, SoftOx SOlutions AS purchased claims on the subsidiary WIAB Water Innovation AB from shareholders and settled the purchase by issuing in the parent company. The receivable balance was valued at an acquisition cost translated from Swedish kroner to Norwegian kroner at the time of the acquisitions. The claim has since increased to NOK 7.420.277,-, and is not expected to be repaid within 12 months. Interest on the claim has not been calculated.

SoftOx Solutions AS has a claim on SoftOx Disinfection AS equal to NOK 14.247.795,- and a claim on Softox Defense Solutions AS equal to NOK 207.601,-.

As of 31 December 2022, Softox Solutions AS has a debt to SoftOx Denmark AS which amounts to NOK 1.301.503,-.

#### Note 7 Other claims / Accounts receivable

As of December 31, 2022, SoftOx Solutions AS has receivables NOK 7.118.655,- including tax foundations grants (Skattefunn) earned in 2022 in the amount of NOK 4.750.000,-

#### Note 8 Inventory

As of 31 December 2022 the inventory was valued to 0,-.

#### Note 9 Tied-up liabilities

Softox Solutions AS has its own account for tax deductions. The balance on this account as of December 31, 2022 was NOK 1.002.510,-. As of December 31, 2021, The SoftOx Group has NOK 1.626.965,- in a deposit account.

### Note 10 Share Capital

The company has per. 31.12.2022 registered 10.342.871 shares with a nominal value of NOK 0,02 per share.

The largest shareholders registered in the Securities Register as of 31.12.2022 is:

# Share %	Name
1	10,8 % DINGE INVEST AS
2	10,8 % NORDNET LIVSFORSIKRING AS
3	7,2 % HERMOD FARMS AS
4	3,3 % PRO AS
5	3,0 % ALMHAUG BOLIG AS
6	3,0 % GH HOLDING AS
7	3,0 % KRISTIAN ALMÅS
8	2,4 % GEMALLO AS
9	1,9 % CS-HOLDING AS
10	1,6 % DEN DANSKE BANK
11	1,4 % LOYD AS
12	1,2 % JOHNSEN, JAN HELGE
13	1,1 % HOLTA&CO
14	1,1 % AUBERT INVEST AS
15	1,1 % JG INVEST
16	1.0 % FALCK FRÅS AS
17	0,9 % WL-01 HOLDING AS
18	0,9 % SONJA OG EMIL AUBERTS LEGAT
19	0,9 % Nordnet Bank AB
20	0.9 % ROCHA INVEST AS
	-,

### Note 11 options and incentive program

In total, the company has issued 817 250 options, with a weighted strike of NOK 57, of which non have a strike price below the share price as of December 30, 2022. After last periods development the Board therefore suggest to change the strike on all contracts to NOK 15 per share, to make sure that the program fullfill its

Name	Role	Subscription rights	No. Shares
Geir Hermod Almås	Chairman	197 500	740 260
Johan Christian Harstad	CEO, Interim	20 000	6 000
Others		599 750	
Total		817 250	

817 250 options include the proposed 281 000 allocations of bonus options to employees for the year 2022 with a redemption price of NOK 15 share with a 5-year term, of which 50,000 is prolongment of Chairman of the board Geir Hermod Almås existing contracts ending the 31st of december 2022. Interim CEO Johan Christian Harstad gets 40.000.

The company's share are listed on Euronext Growth, Oslo Stock Exchange, with ticker SOFTX

### Note 12 Changes in owners capital

SoftOx Solutions Group	Share capital	Share premium reserve	Other owners capital	Total owners capital
Per 31.12.2021	206 857	112 808 634	-3 278 265	109 737 226
Registered capital increase				
Capital increase	0	0		0
Translation differences		145 093		145 093
Annual result		-71 141 125		-71 141 125
Per 31.12.2022	206 857	41 812 602	-3 278 265	38 741 195

SoftOx Solutions AS	Share capital	Share premium reserve	Other owners capital	Total owners capital
Per 31.12.2021	206 857	123 938 979		124 145 836
Capital increase	-	-		-
Correction previous year		-		
Year end result		-68 579 760		-68 579 760
Per 31.12.2022	206 857	55 359 220		55 566 077

Each share has a nominal value of NOK 0,02.

### Note 13 Long term Debt

In 2022 the company raised NOK 40 million in convertible debt. The loan got due date 15th of January 2024. The loan got 10 % annual interest paid in kind. The lender got an option to convert the debt to shares for a price of NOK 8,- per share before due date.

### Note 14 Short term Debt

SoftOx Solutions Group has per. 31.12.2022 incurred costs to suppliers and other short term creditors of 20.762.198,- that will be paid in 2023.

### Note 15 Govermental and Public Funding

SoftOx is developing products to prevent and treat infections. In 2022, the Company had directly NOK 43.8 million in research and development costs. Public funding for R&D was NOK 2.0 million from the Norwegian Research Council and NOK 3.9 million from MTEC. In addition, NOK 4.7 million has been accepted in the Governmental Tax refund program (Skattefunn). Tax findings are entered as a cost reduction in the income statement. The present value of expected earnings from ongoing research and development exceeds the investment cost.

# Independent Auditors report

# berge <sup>•</sup> lundal

To the Shareholders' Meeting of Softox Solutions AS

### Independent auditor's report

### Qualified Opinion

We have audited the financial statements of Softox Solutions AS (the Company), which comprise:

- The financial statements of the company, which comprise the balance sheet as at 31 December 2022, and the income statement and cash flow statement for the year then ended, and notes to the financial statements, including a summary of significant accounting policies, and
- The financial statements of the group, which comprise the balance sheet as at 31
  December 2022, and the income statement and cash flow statement for the year then
  ended, and notes to the financial statements, including a summary of significant
  accounting policies.

#### In our opinion:

- · The financial statements comply with applicable statutory requirements,
- The financial statements give a true and fair view of the financial position of the company as at 31 December 2022, and of its financial performance and its cash flows for the year then ended in accordance with Norwegian Accounting Act and accounting standards and practices generally accepted in Norway, and
- The financial statements give a true and fair view of the financial position of the group as at 31 December 2022, and of its financial performance and its cash flows for the year then ended in accordance with Norwegian Accounting Act and accounting standards and practices generally accepted in Norway.

#### **Basis for Qualified Opinion**

We conducted our audit in accordance with International Standards on Auditing (ISAs). Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Statements section of our report. We are independent of the Company and the Group as required by laws and regulations and the International Ethics Standards Board for Accountants' International Code of Ethics for Professional Accountants (including International Independence Standards) (IESBA Code), and we have fulfilled our other 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 opinion.

#### berge & lundal revisjonsselskap as

statsautorisert revisor, medlem av Den norske Revisorforeningen Tordenskiolds gate 8-10, 0160 Oslo, tlf. 22 01 06 00 www.berge-lundal.no | post@berge-lundal.no Rev.nr./Org.nr. 967 418 064 State abkumentet er signert med PAdES-formatet (PDF Advanced Elactoric Scinaturena) ev Spinicat. Dette abkumentet og dets vedlega mot endringer etter signering. State

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Independent auditor's report 2022 Softox Solutions AS

Material Uncertainty Related to Going Concern:

We draw attention to Financial Review and Going Concern and Subsequent Events in the Board of Directors' report 2022 which indicates that the company's funding is not sufficient to cover ongoing operations after the year ended December 31, 2023.

As stated in the Board of Directors' report 2022, these events or conditions, along with other matters as set forth in the Board of Directors' report 2022, indicate that a material uncertainty exists that may cast significant doubt on the Company's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

#### Other Information

The Board of Directors and the Managing Director (management) are responsible for the information in the Board of Directors' report and the other information presented with the financial statements. Our opinion on the financial statements does not cover the information in the Board of Directors' report or the other information presented with the financial statements.

In connection with our audit of the financial statements, our responsibility is to read the information in the Board of Directors' report and for the other information presented with the financial statements. The purpose is to consider if there is materially inconsistency between the information in the Board of Directors' report and the other information presented with the financial statements and the financial statements or our knowledge obtained in the audit, or otherwise the information in the Board of Directors' report and for the other information presented with the financial statements otherwise appears to be materially misstated. We are required to report that fact if there is a material misstatement in the Board of Directors' report and the other information presented with the financial statements. We have nothing to report in this regard.

Based on our knowledge obtained in the audit, in our opinion the Board of Directors' report

- is consistent with the financial statements and
- · contains the information required by applicable legal requirements

Our opinion on the Board of Director's report applies correspondingly for statements on Corporate Social Responsibility.

#### Responsibilities of the management for the Financial Statements

The Board of Directors and the Managing Director (management) are responsible for the preparation and fair presentation of the financial statements in accordance with the Norwegian Accounting Act and accounting standards and practices generally accepted in Norway, and for such internal control as management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the Company's and the Groups' ability to continue as a going concern, disclosing, as applicable, matters related to going concern and use the going concern basis of accounting insofar as it is not likely that the enterprise will cease operations.

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Independent auditor's report 2022 Softox Solutions AS

### Auditor's Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs 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 financial statements.

For further description of Auditor's Responsibilities for the Audit of the Financial Statements reference is made to: https://revisorforeningen.no/revisjonsberetninger

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Oslo, 13.06.2023 berge & lundal revisjonsselskap as

Eivind Lundal State Authorised Public Accountant (This document is signed electronically)

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# Elektronisk signatur

Signert av

Dato og tid (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockhalm, Vienna

LUNDAL, EIVIND Norwegian Buypass

14.06.2023 09.46.11

Dette dokumentet er signert med elektronisk signatur. En elektronisk signatur er juridisk forpliktende på samme måte som en håndskrevet signatur på papir. Denne siden er lagt til dokumentet for å vise grunnleggende informasjon om signaturen(e), og på de foregående sidene kan du lese dokumentet som er signert. Vedlagt finnes også en PDF med signaturdetaljer, og en XML-fil med innholdet i den elektroniske signaturen(e). Vedleggene kan brukes for å verifisere gyldigheten av dokumentets signatur ved behov.

# Glossary

	,
B2B	Business-to-business
BPR	Biocidal Products Regulation
DKMA	Danish Medicines Agency
EU	European Union
EWMA	European Wound Management Association
FDA	U.S. Food and Drug Administration
FFI	Norwegian Defence Research Establishment (Forsvarets Forskningsinstitutt)
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HINAS	Hospital tender for the infection disease control category
IP	Intellectual property
Keml	Swedish Chemicals Agency
QMS	Quality Management System
R&D	Research and Development
SBE	SoftOx Biofilm Eradicator (SoftOx Infection Remover)
SDS	SoftOx Defense Solutions AS
Shares	SoftOx Solutions' issued and outstanding shares, unless the context indicates otherwise,
	including the Offer Shares offered in the Offering.
SIS	SoftOx Inhalation Solution

SWIS SoftOx Wound Irrigation Solution

# Contact information

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