Report 2<sup>nd</sup> quarter 2021



SOFTOX

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SoftOx Solutions AS is a biotech company listed on Euronext Growth Oslo with ticker 'SOFTX'. SoftOx Solutions AS was founded in 2012 and is headquartered in Oslo. The SoftOx Solutions Group includes the holding company SoftOx Solutions AS, the Malmö and Copenhagen subsidiaries, and subsidiary SoftOx Defense Solutions AS. SoftOx has developed a highly effective antimicrobial solution which eradicates and prevents biofilm, viral, and antimicrobial resistant infections. The technology is based on years of research and development in partnership with leading Nordic research institutes and is protected by patents.

# Highlights for the 2<sup>nd</sup> quarter 2021 and subsequent events

(Figures in brackets apply to 2020)

- The results of the SWIS (SoftOx Wound Irrigation Solutions) study showed both significant improvement in wound healing and reduction in bacterial burden compared to Normal Saline (NS), positioning the product as superior towards today's market leaders. This is regarded an important confirmation on the company's base technology.
- SoftOx Solutions' hand disinfectant SafeDes<sup>®</sup> won the national hospital tender (HINAS) in Norway and will be listed in Norwegian hospitals as the only alternative to alcohol-based products.
- SoftOx has submitted a new application for national approval of its biocidal products in Norway. The application addresses the objections raised in the first application and only applies to the Norwegian market.
- The Danish Medicines Agency (DKMA) has given a conditional approval for the first-in-human study for SoftOx Inhalation Solution (SIS) for the treatment of respiratory infections. The company expects the clinical study start to be autumn 2021.
- The 2Q pre-tax results ended with a loss of NOK 21.2 million (loss of NOK 9.8 million). Results are in line with our business plan and the increased costs are due to high activity in research and development, costs which are being expensed not capitalized.
- The SoftOx Biofilm Eradicator (SBE) study started as planned at the end of May, but due to the nurses' strike in Denmark patient recruitment has been delayed. As of August 28th, the strike has ended, and SoftOx expects patient recruitment to improve.

# Key figures for the SoftOx Solutions Group (SoftOx) as of 30.06.2021

Key figures (NOK 1,000)

	Q2 2021	Q2 2020	H1 2021	H1 2020	FY 2020
SoftOx Solutions Group					
Total operating revenue	2 599	6 2 6 6	4 081	7 505	9 839
Total operating expenses	24751	16 160	47 928	24 654	61 203
Operating result	-22 152	-9 894	-43 847	-17 148	-51 364
Profit before tax	-22 220	-9 801	-43 774	-17 046	-49 714
Net proceeds from equity issues	0	1 010	41 209	1 0 1 0	27 135
Net change in cash and cash equivalents	-24 812	-18 934	-3 672	-40 564	-41 194
Cash and cash equivalents at end of period	31 131	35 431	31 131	35 431	34 802
Outstanding shares, beginning of the period	8 329 900	7 751 000	8 329 900	7 751 000	7 751 000
Outstanding shares, end of the period	9 168 468	7 829 900	9 168 468	7 829 900	8 329 900
Employees, end of the period	21	13	21	13	21

#### A statement from CEO Geir Almås

(Further details are also given later in the report)

It has been an exciting first half of 2021 – filled with opportunities for advancement and growth. Our vision is for SoftOx Solutions to become a world-leading antimicrobial company. In working to achieve this goal, we are focused on two main areas: *infection prevention* and *infections removal* in tissue. During this year, we have progressed significantly in these areas and are working to develop and commercialize the products to improve the quality of health for society.

For *infection prevention*, we are still working with the launch of our alcohol-free hand and surface disinfectants (SafeDes<sup>®</sup> and EffectDes<sup>®</sup>) while we have completed the clinical development of the **SoftOx Wound Irrigation Solution (SWIS)** for wounds. In parallel, we are developing the *infection removal* product **SoftOx Biofilm Eradicator (SBE)** for chronic wounds. We continue our R&D on the **SoftOx Inhalation Solution (SIS)** for the respiratory tract which will be both an infection prevention and infection removal product.

The clear clinical results from the SWIS confirmatory study have likely marked the greatest company achievement thus far. As all our products are based on the same patented SoftOx technology, the superior findings were a proof of concept for the SoftOx technology as a whole. Our technology, therefore, has proven to be highly effective in wound healing and reducing bacterial burden with even better results and an equal safety profile as today's standard treatment. This novel technology is protected by more than 57 patent filings which gives the company a unique advantage and position within the infection prevention and infection removal markets.

The value of our technology is not only evidenced by the broad international IP portfolio but also by our esteemed collaboration partners and market approval. We also have proven market relevance in

the following segments: healthcare, defence and business-to-business markets. The market approval of winning a competitive tender for the Norwegian healthcare system (HINAS), a highly sophisticated and critical customer, is a huge achievement. The military interest into our projects are a confirmation of the necessity and urgency of our research objectives. The business-to-business recognition of supplying disinfectants to a successful Norwegian airline has shown the market's need for new solutions. The fact that we are on our way to establish ourselves in these three important segments gives us the confidence that we shall succeed with our disinfection products, even if we must admit that it takes more time than we anticipated, especially considering the challenges of receiving approval from the European Chemical Agencies and the new biocidal regulations.

Moving into the second half of this year, we anticipate more positive results. We expect to be able to start the SIS phase I study in the autumn, hope to complete the first half of the SBE study, and file an application to receive CE marking for SWIS. As of October 2021, hospitals in Norway may begin using the SoftOx alcohol-free hand disinfectants, and we are continually working to increase the sales. Despite issues exacerbated by the COVID-19 pandemic and the inherent obstacles of developing biotech products, we remain focused on our mission of "helping the world fighting infections" and have made considerable progress in our research and development during this period.

Geir Hermod Almås, Chief Executive Officer

# Operational update on research and operations in 2Q 2021

#### Research and product development



Figure 1. SoftOx product pipeline.

#### **Platform technology**

In collaboration with leading scientific teams, SoftOx has discovered a unique synergetic effect of two natural components, proven to be well tolerated by both humans and animals even when used in wounds. This unique technology is protected by a robust patent portfolio which provides multiple degrees of freedom to expand into new therapeutic applications and hold its own against future competition. SoftOx has filed 87 patents worldwide, where of 57 are granted addressing formulations, uses, methods of making and devices.

The SoftOx technology exploits the fact that our bodies are accustomed to handling the natural and potent chemicals that we base our antimicrobial solution on. We have proven strong antimicrobial

effects on various bacterial species (included multi-drug resistant bacteria and those embedded in biofilms), fungi, spores and viruses (fully virucidal). Importantly, our research has also determined that this novel solution does not induce microbial resistance.

The safety profile and the antimicrobial efficiency of the technology makes it acceptable for multiple applications with the aim of preventing and removing 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. The safety profile and antimicrobial efficiency has been confirmed by the SWIS study results elaborated in the next section.

#### Infection prevention

#### SoftOx Wound Irrigation Solution (SWIS):

SWIS is intended for acute and chronic wounds and was developed to rinse wounds to prevent infections and biofilm formation. The medical device uses a lower concentration of active ingredients compared to SBE, which makes it well-tolerated and gives a softer sting when applied to wounds. SWIS is safe to use and non-toxic to host cells/tissue. The current recommended treatment solution for acute wounds is saline water, which holds 80% market share. Based on the clinical evidence generated on safety and effect, the goal of SWIS is to replace today's wound wash products with a product with an equal risk profile and profound antimicrobial effect.

Finalization of the SWIS-02 study concludes the clinical evaluation part of the SWIS documentation package. 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 study concludes with faster wound healing compared to traditional therapy, also showing a highly significant effect on bacterial loads in wounds. In parallel, the company is investing on the remaining issues (Quality and Manufacturing) to prepare for design dossier submission to Notified Body to obtain CE-mark designation.

SWIS is expected to be SoftOx's first CE-marked product for the European market. As SWIS and SBE are products based on the same technology with different concentrations, the study findings encourage the development of the SBE and show promise in aiding in the fight against antimicrobial resistance.

#### Scientific update

We are pleased to state that the final confirmatory clinical investigation (SWIS-02 trial) was completed during the quarter and the results became available end of June 2021, ref Stock Notice (23. June). The SWIS-02 study showed both significant improvement in wound healing and reduction in bacterial burden compared to Normal Saline (NS), positioning the product as superior towards today's market leaders. The results indication that rinsing wounds with SWIS every other day achieved clinically meaningful bacterial control. Likewise, the immediate effect of SWIS was significantly better than rinsing with saline. In total, the "global" bioburden was significantly lower in the SWIS group than for the saline group. Also, overall usability aspects of SWIS handling were reported to be satisfactory. No adverse device reactions were reported as causally linked to the irrigation of SWIS.

#### Infection removal

#### SoftOx Biofilm Eradicator (SBE):

SBE functions as an infection remover in chronic wounds and is designed to have therapeutic effect by penetrating and killing microbes within biofilms. The formula penetrates deep into wound bed, yet it is non-toxic and safe to use based on findings from the animal studies. SBE kills antibiotic resistant bacteria and does not induce new resistance. This, in turn, may lead to a reduced use of antibiotics and fewer antimicrobial-resistant microbes. Hopefully, it will also be the first major defence against antimicrobial bacteria, which spread rapidly and develop new resistances quickly. Studies have shown that antimicrobial resistant bacteria are found in more than 50% of chronic wounds.<sup>1</sup> Today's recommended solution, debridement, only partly removes the bacterial infection and involves the surgical removal of the wound bed. SBE represents an innovative treatment principle in how to prevent and treat biofilm infections in wounds.

As previously reported, the toxicity study performed on mini pigs showed that even at the highest concentrations of SBE solution, no adverse local or systemic effects of the test solutions were observed, and the product candidates can therefore be regarded as safe. With these important preclinical results together with Chemical, Manufacturing and Control (CMC) quality measures, we have during Q2-2021 been successful in submitting, gaining approval, and starting our Clinical Trial SBE-01 phase I study. The SBE solutions have been produced according to Good Manufacturing Practice (GMP), and the study started as planned at the end of May. Due to the nurses' strike in Denmark from mid-June until the end of August, patient recruitment has been delayed; however, the company will strive to make up for the lost time with patient recruitment expected to increase in the near future.

The promising results of SWIS mentioned above create great optimism for the effectiveness and potential of SBE. The ongoing study in Copenhagen is a dose-finding study in chronic leg wounds to establish a tolerable dose and treatment schedule, which does not cause toxicity or interfere with the product's effects. With the clinical relevance of the SWIS results, we expect to see similar significant improvements in wound healing and reduction in the bacteria load. After the phase I study, we will know how SBE performs in chronic wound healing and treatment and eventually establish the optimal formulation of SBE as a safe and efficacious wound treatment solution.

#### SoftOx Inhalation Solution (SIS):

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 upper airways and in the lungs. Although there may be many indications for use, SoftOx has at the present time focused on treatment concerning the COVID-19 pandemic and COVID-19 patients.

After presenting our preclinical evidence to the Danish Medicines Agency (October 2020), we obtained important feedback on our development plans, and we aim to bring SIS to market as soon as possible. During H1-2021, we have advanced considerably on all areas, including preclinical research, product quality and regulatory preparedness. This enabled us to complete the scientific documentation and submit a full Clinical Trial Application (CTA) for the "first-in-human" phase I study (SIS-01) to the relevant regulatory bodies by the end of March and obtaining full acceptance from the Ethics

<sup>&</sup>lt;sup>1</sup> Trivedi, U., Parameswaran, S., Armstrong, A., Burgueno-Vega, D., Griswold, J., Dissanaike, S., & Rumbaugh, K. gP. (2014). Prevalence of Multiple Antibiotic Resistant Infections in Diabetic versus Nondiabetic Wounds. Journal of pathogens, 2014, 173053. https://doi.org/10.1155/2014/173053

Committee (VEK) and conditional approval from DKMA – i.e., reaching important milestones. The conditions for approval relate to providing data for antimicrobial effectiveness and preliminary data from the ongoing GLP toxicity in minipigs. We expect these conditions will be met and results available autumn 2021. A re-submission for SIS-01 study will be performed as soon as all data are available hoping for a fast-track decision to start the SIS-01 study.

The development of SIS has also given us a unique patent situation, where we have patented methods for reducing infections by using the SoftOx technology in the lungs. In this way, the company has managed to position itself where it is difficult for competitors to commercialize competing solutions.

#### Animal health

The scheduled small study on companion animal wounds was initiated as planned in Q2. The progress of the study is dependent on the incoming cases, which is a matter outside our control. Unfortunately, the number of cases has been smaller than anticipated, hence the study is progressing at a somewhat slower pace than desired. The study continues as scheduled, and an extension of the time frame may be considered in order to reach the desired number of cases.

#### **Next Generation**

In addition, SoftOx is already working on "next generation" products which are designed to give the product new and enhanced attributes, which the company has sought to secure by a separate patent pending filed in summer 2020. This technology development program also includes 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.

#### Market trends and sales of our disinfection products

#### Strategy and Market trends

The company's long-term ambition is to establish a new class of highly effective antimicrobials that do not induce antimicrobial resistance. SoftOx's current efforts have focused on three main markets: healthcare, business-to-business (B2B) and the defence sector. In the future, SoftOx also has plans to expand into the consumer and animal health markets.

SoftOx's first product on the market is skin-friendly hand disinfectants. The target group is primarily healthcare workers (HCWs) with irritated, compromised, and eczematous skin. This is a well-known problem for health professionals, which is substantiated by the fact that an estimated 21% of all Nordic healthcare workers report a prevalence of skin problems and eczema.<sup>2,3</sup> As a result of increased attention to and use of hand disinfectants due to the COVID-19 pandemic, SoftOx's products have become even more relevant, as they are clinically documented as skin-friendly and do not sting when used on compromised skin. In addition to healthcare workers, vulnerable groups with sensitive skin, such as people with eczema and allergies, children and elderly people, see the need for a safe and skin-friendly alternative to alcohol.

**The healthcare market** is a strategically important market for SoftOx, and the opening of a separate class for alcohol-free disinfectants in the national hospital tender in Norway (HINAS) was a great

<sup>&</sup>lt;sup>2</sup> Thyssen JP, Johansen JD, Linneberg A, Menné T., The epidemiology of hand eczema in the general population– prevalence and main findings. Contact Dermatitis. 2010;62(2):75–87.

<sup>&</sup>lt;sup>3</sup> Ibler KS, Jemec GBE, Flyvholm M, Diepgen TL, Jensen A, Agner T. Hand eczema: Prevalence and risk factors of hand eczema in a population of 2274 healthcare workers. 2012;(1):200–7

recognition when published in May 2021. In August 2021, it was announced that SafeDes<sup>®</sup> won the hand disinfectant category, where our clinically documented skin friendliness stands out with top scores in the evaluation criteria of "properties on skin" and quality.

By winning the hand disinfection category, SoftOx gains access for all 70 public hospitals in Norway to purchase SafeDes<sup>®</sup>, which is important both regarding direct market access and revenue potential. As the Norwegian hospital market is the company's pilot customer, this endeavour is not expected to provide profitability during the first years but will certainly provide valuable home market recognition, references, and Key Opinion Leader (KOL) support for a newcomer with a disrupting technology challenging the alcohol status quo. This recognition will be of great importance also entering other business segments and regions outside Norway.

The contract will be negotiated during September and implementation of SoftOx products will start from October 1<sup>st</sup>. Entering the healthcare market through winning this tender represents a major game changer for our disinfectant products and shows the market's approval of SoftOx's base technology. This Norwegian healthcare system is among the most advanced in the world and the tender process for hospitals is highly competitive with decisions made every four years. SoftOx has designed a product to meet the challenge set by the World Health Organization (WHO) for a safe and effective alternative to traditional alcohol-based sanitizers. SoftOx disinfectants are now that alternative in Norway.

In **the business-to-business market segment**, the company has identified several opportunities including schools, kindergartens, and transportation. These businesses need a safe, effective and non-flammable alternative to alcohol-based disinfectants and the company is working on specific projects to realize the potential in these segments. SoftOx has signed an agreement with a respected Norwegian airline company and has plans to expand within the transportation sector.

SoftOx expects that the market for disinfectants will continue to stay at a high level in 2021 because of the ongoing COVID-19 pandemic before falling back somewhat to a more stable, but substantially higher level post-COVID-19 in 2022 or 2023. As a result of vaccination efforts, the gradual opening of society will most likely add further focus to infection control measures and thus keep the use of disinfectants at a high level in the medium term.

#### The Biocidal Products Regulation (BPR) approval

SoftOx continues the work to obtain BPR approval for its biocidal family. Future actions imply meetings with the Swedish Chemicals Agency (KemI) to discuss issues concerning the rejection of the application in March 2021 and how to move on with the clear target to get a BPR approval from Swedish authorities. SoftOx is determined to present the data KemI has demanded prior to a renewed submission later this year. In parallel, SoftOx has initiated a process for BPR approval in Norway with Norwegian Environment Agency (Miljødirektoratet).

An updated biocidal application for Norway was submitted in June. The application addresses the objections raised in the first application, in addition to change of active substance. There are certain unsolved regulatory issues at government level, e.g. relating to chemistry categorization, product documentation and implementation of the relevant EU regulation into Norwegian law. Amongst others, the Norwegian Environment Agency has published a consultation draft, according to which our disinfection product should be able to be in the market. Until the final regulations are approved by the parliament, there is a risk that the views in the said consultation draft changes, which may imply that SoftOx' disinfection products may not rely on the intended temporary scheme. SoftOx is working with the relevant authorities and is confident that there are several alternative solutions to keep its



disinfection product in the market. Updates on the process can be expected in subsequent reports. In addition, SoftOx is pursuing the administrative appeals made in both Sweden and Norway following the rejection in March of the initial application. There are still unsolved regulatory issues with the authorities in this very complex matter that are being addressed on a continuous basis.

#### Collaboration agreements - entering new markets

In addition to the healthcare and B2B sectors, our principal focus will be the **defence/humanitarian sector**.

The market potential of these partnerships is estimated to 3,5 million users considering the size of NATO's active forces. Working in close collaboration with the defence sector, we are facilitating the transition to commercialization while garnering strong interest and support in our products. Collaborations such as these are valuable for the network, market entry, feedback and guidance during the product development process.

In April 2021, SoftOx signed a three-year cooperation agreement with the Norwegian Defence Research Establishment (FFI), the primary institution responsible for defence-related research and development in Norway. Within the cooperation agreement, SoftOx and FFI, together with the Norwegian Armed Forces (NorAF), will develop and field test SoftOx's technology and civilian products to tailor-make new products for preventive and treatment purposes in the defence sector.

Entering the military segment, SoftOx established the subsidiary SoftOx Defense Solutions AS (SDS) in April 2021. The main purpose of SDS is to develop military products through research, testing, development, validation and procurement of military applications, both nationally and internationally. Our aim is to strengthen and maintain the combat readiness for our troops and forces.

One recent initiative has been to facilitate and host a debate at "Arendalsuka" highlighting how societies build preparedness for future pandemics and epidemics. Another initiative, together with FFI, has been to establish a collaboration agreement with Hemsedal municipality, testing SoftOx disinfectant products versus other disinfectants using innovative real-time sensor technology to track and document indoor climate effects on public employees and community users such as children, pupils and care needing citizens. Testing SoftOx alcohol-free products through a randomized behavioural field experiment, we are convinced that the Hemsedal project will provide solid documentation for a healthier and more comfortable work environment, relevant both in the civilian sector and for military purposes.

### Organization

In July 2021, the SoftOx team in Oslo moved offices to Technopolis at Fornebu. This new office space will facilitate better team collaboration and position SoftOx in a community with other growing and tech-forward companies. The research lab will also be located at Fornebu and work will begin in September for GMP standards to be met in the new facility. The production of disinfectants has been moved to Ose Water in Setesdalen.

There have been several new changes within the organization's management. SoftOx has filled management positions within medical affairs, sales, and quality assurance. Christopher Burton, MD, PhD, has been hired as the Chief Medical Officer, SoftOx Solutions DK. Burton has many years of



experience as a Medical Director working in mid- and small-sized pharmaceutical companies, in addition to extensive experience in the field of Respiratory and Immunology. He comes to SoftOx from a position as Senior Director of Clinical Development at Savara, where he was Clinical Lead and Medical Expert for two phase 3 trials, evaluating nebulized antibiotic and nebulized products.

Kent Ghose has been hired as Quality Manager in CMC and will begin in September 2021. Ghose was previously the Quality Manager at Diatec Monoclonas AS and has nearly 20 years of experience in GMP compliance within pharmaceutical drug production.

## **Financial matters**

Financial figures for the SoftOx Solution Group are not audited (figures in brackets are comparable figures for 2020).

#### Profit and loss statement

In 2021, the company's revenue for hand disinfectants and surface disinfectants reached approx. NOK 1,2 million (NOK 2,7 million). Revenue for disinfectants in Q2-2020 was originally reported as NOK 5 million but adjusted to 2,7 at year end due to requirements from the Norwegian Environment Agency regarding name of active substance specified on the product label and subsequent product withdrawal. Revenue is slowly growing with sales of NOK 0,8 million in Q2-2021 and NOK 0,4 million in Q1-2021. In addition, NOK 2,8 million (NOK 3 million) has been recognised as income in connection with funding from The Research Council of Norway and the U.S. Department of Defense.

For the first half year 2021, salary costs were NOK 9,4 million (NOK 6,6 million), an increase of 42 % compared to 2020, but approximately on the same level as year-end 2020. Other operating costs have increased to NOK 37 million (NOK 17,1 million) in 2021. The gradual increase relates mainly to increased activity for R&D projects which are expensed instead of capitalised due to accounting principles. Approximately NOK 24 million of operating expenses in 2021 are related to R&D activities. The main contributor to increased costs are the SIS project, which are approximately 50% of the R&D costs.

SoftOx continues to build up its organization for future growth and development, and pre-tax results ended with a loss of NOK 21,2 million (loss of NOK 9,8 million) for Q2, and loss of NOK 43,8 million (NOK 17) for year to date.

#### Cash flow and consolidated balance sheet

Of the capitalized assets, the company has activated its IP and patent cost worth NOK 6,2 million (NOK 5,7 million). These are capitalized patent costs in the Swedish subsidiary, which are depreciated over 5 years. Deferred tax assets stand at NOK 30,8 million (NOK 18,4 million), adjusted for tax in Sweden. Tax calculations will be performed at the end of the year on revised figures.

Production has been initiated and investments of approx. NOK 3,8 million (NOK 5,8 million) have been capitalized. This mainly applies to production equipment that have been put into operation and been physically transferred to Ose Water AS. Due to low sales in H1-2021, stocks have been reduced by a value of approx. NOK 2 million since year end. Trade receivables are NOK 8,9 million (NOK 12,6 million) and consist mainly of public grants.

## Outlook

- Progressing work on the development of each individual project:
  - SoftOx Inhalation Solution (SIS) continued progress of preclinical and clinical safety studies in compliance with the advice of the regulatory authorities. Receive full approval from DKMA and start the Phase I study in autumn 2021.
  - SoftOx Biofilm Eradicator (SBE) finish patient recruitment of the SBE-01 clinical study (Phase I, first-in-human) in patients with chronic wounds.
  - SoftOx Wound Irrigation Solution (SWIS) Establishing quality system for medical devices and GMP production and apply to the Notified Body for CE certification.
- The Company's work to boost sales to achieve a positive cash flow continues.
- Focus on marketing and sales to the Norwegian healthcare system through HINAS
- Deliver additional analysis to The Swedish Chemical Agency and receive final confirmation regarding the approval of SoftOx disinfectants.
- Receive disinfectants' approval outside the Nordic region to launch the products in selected markets.
- Establishing of a network of partners and distributors for both wound care and hand disinfectant

#### Significant risk factors for the company

- The continued threat of COVID-19 infection and the lockdown of society entails a risk for the entire value chain in the company from delivery of goods, illness among employees in production, quality control and development and delivery of goods as well as our R&D teams
- Research studies always involve an inherent risk of being delayed and not delivering results as expected. External factors such as labour strikes affect study timing and milestone achievement.
- > Lack of approval and delays of applications for conducting clinical studies and products.
- Further delays by the authorities in updating their recommendations related to hand disinfection in the Nordic countries.
- Lack of approval and further delays in the regulatory process.
- Financial risk mainly consists of currency, credit, and liquidity risk. SoftOx continuously monitors these factors.



### **Declaration by the Board**

We confirm, to the best of our knowledge, that the unaudited, summarised half year accounts for the period 1 January to 30 June 2021 have been prepared in accordance with accounting standards for the group and that the information contained in these accounts gives a true and fair view of the group's assets, liabilities, financial position and profits as a whole, and that the half year report provides a true and fair view of the information specified in Section 5-6, fourth paragraph, of the Norwegian Securities Trading Act.

Oslo, September 7<sup>th</sup> 2021

SIGNED Melvin Teigen, Chairman of the Board

SIGNED Kari Myren, Board Member

SIGNED Claus Seeberg, Board Member

SIGNED Olav Jarlsby, Board Member

SIGNED Geir Hermod Almås, CEO

#### Profit and loss statement

#### Accounts for second quarter and first half year 2021

SoftOx Solutions Group					
NOK 1,000	Q2 2021	Q2 2020	H1 2021	H1 2020	FY 2020
Other operating revenues	2 599	6 2 6 6	4081	7 505	9 839
Total operating revenues	2 599	6 266	4 081	7 505	9 839
Personnel expenses	3 6 1 5	3 304	9 463	6 660	18 869
Other operating expenses	19 479	12 238	37 033	17 093	39 631
Depreciation	710	618	1 433	901	2 703
Depreciation, goodwill	0	0	0	0	0
Total operating expenses	23 805	16 160	47 928	24 653	61 203
Operating result	-21 205	-9 894	-43 846	-17 148	-51 364
Net financial items	-68	93	73	102	1 650
Profit before tax	-21 273	-9 801	-43 774	-17 046	-49 714
Tax					12 308
Annual profit/loss					-37 406

Statement of financial position	30.06.2021	30.06.2020	31.12.2020
SoftOx Solutions Group			
NOK 1,000			
Other intangible assets	6 2 3 6	5 675	6 143
Deferred tax asset	30 862	18 390	30 527
Goodwill from acquisition of subsidiary	0	0	o
Total intangible assets	37 098	24 065	36 670
Production equipment	3 779	5 800	3 909
Total fixed assets	3 779	5 800	3 909
Non-current assets	40 877	29 865	40 578
Inventory	556	0	2 970
Total invetory	556	0	2 970
Other receivables	8 891	12 650	8 961
Total receivables	8 891	12 650	8 961
Cash and cash equivalents	31 131	35 431	34 802
Current assets	40 579	48 081	46 733
Total assets	81 455	77 946	87 311

Share capital	183	157	167
Share premium reserve	117 244	90 620	76 052
Total paid up capital	117 427	90 777	76 219
Other equity	-43 692	-20 298	0
Total equity	73 735	70 478	76 218
Public duties payable	6	-544	151
Shareholder loans	0	0	0
Other current liabilities	3 188	1742	5 1 4 5
Accounts payable	4 5 2 6	6 2 6 9	5 797
Total current liabilities	7 720	7 467	11 093
Total liabiities	7 720	7 467	11 093
Total equity and liabilities	81 455	77 946	87 311

Cash flow statement	Q2 2021	Q2 2020	30.06.2021	30.06.2020	FY 2020	
SoftOx Solutions Group						
NOK 1,000						
Cash flow from operating activities						
Net result before taxes	-21 273	-9 801	-43 775	-17 046	-49 714	
Tax paid	0	0	0			
Depreciation	710	618	1 433	901	2 703	
Change in current assets	-802	-5 000	2 483	-6 986	-6 090	
Change in current liabilities	-1 456	306	-3 372	-10 915	-7 289	
Net cash flow from operating activities	-22 820	-13 876	-43 231	-34 045	-60 390	
Cash flow from investment activities						
Investments in non-current assets	-1 038	-6 230	-1 395	-7 461	-7 668	
Net cash flow from investment activities	-1 038	-6 230	-1 395	-7 461	-7 668	
Cash flow from financing activities						
Proceeds from equity issues	0	1 0 1 0	41 209	1 0 1 0	27 13	
Other financing activities	0	0	0	-114	-114	
Translation differences	-10	163	-258	46	-157	
Net cash flow from financing activities	-10	1 173	40 952	942	26 864	
Net change in cash and cash equivalents	-23 866	-18 934	-3 672	-40 564	-41 194	
Cash and cash equivalents at begining of period	54 997	54 365	34 802	75 995	75 999	
Cash and cash equivalents at end of period	31 131	35 431	31 131	35 431	34 802	
Statement of changes in equity						
SoftOx Solutions Group						
NOK 1,000	Q2 2021	Q2 2020	H1 2021	H1 2020	FY 2020	
Equity at end of prior period	94 773	79 106	76 218	86 468	86 468	
Share issues	24112	1 0 1 0	41 209	1 010	27 135	
Loss for the period	-21 273	-9 801	-43 775	-17 046	-37 406	
Other changes in equity	236	163	83	46	20	
Equity at end of period	73 735	70 478	73 735	70 478	76 218	

#### Notes to the Q2 accounts for the SoftOx Solutions Group

Note 1 Accounting principles

The accounts for the SoftOx Solutions Group have been prepared according to Norwegian Accounting Act and generally accepted accounting principles for small companies.

#### Glossary

- B2B **Business-to-business** BPR **Biocidal Products Regulation** CFU **Colony Forming Unit** СМС Chemical, manufacturing and control CRO **Clinical Research Organisation Clinical Trial Application** СТА **DKMA** Danish Medicines Agency FDA U.S. Food and Drug Administration FFI Norwegian Defence Research Establishment (Forsvarets Forskningsinstitutt) GLP **Good Laboratory Practice** GMP **Good Manufacturing Practice** HCW Healthcare worker HINAS Upcoming hospital tender for the infection disease control category Keml Swedish Chemicals Agency KOL Key Opinion Leader NorAF Norwegian Armed Forces NS Normal Saline NVK Danish National Committee on Health Research Ethics OCP US Food and Drug Administration Office of Combination Products NMRC Naval Medical Research Center 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
- VEK The Danish Research Ethics Committees
- WHO World Health Organization



#### Contact us

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