



Report 4th quarter 2021

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SOFT·OX

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 subsidiaries SoftOx Defense Solutions AS and SoftOx Disinfection 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 4th quarter 2021 and subsequent events

(Figures in brackets are comparable figures for 2020)

- SoftOx successfully raised NOK 50 million through a private placement December 15th.
- The Danish Medicines Agency (DKMA) approved the Phase I clinical trials for the SoftOx Inhalation Solution (SIS), and the first subjects are enrolled in the first-in-human trial to explore the safety and tolerability of single and multiple doses of inhaled nebulised SIS in healthy subjects.
- The first-in-human clinical study for the SoftOx Biofilm Eradicator (SBE) for infections in chronic wounds has improved its enrolment of patients and has completed the two first dose-level cohorts.
- SoftOx won a tender by the Swedish Purchasing organization for chemical-technical products in both categories of “surface disinfection with sporicidal effect” and “hypochlorite-based surface treatment with sporicidal effect”.
- The 4Q pre-tax results ended with a loss of NOK 20,5 million (loss of 20,5 NOK million). The year end result ended with a loss of NOK 86,3 million (loss of 49,7 million), pre-tax. Results are characterized by high levels of activity in research and development where approx. 50 % of costs are related to R&D.
- SoftOx Defense Solutions (SDS) submitted a grant application to the European Defence Fund for a pan-European consortium project, and the Norwegian Ministry of Defence has committed to co-financing NOK 10.6 million for the proposed project.
- The EU Commission’s interpretation of the Biocidal Products Regulation allows SoftOx to enter the market with all its disinfectant products in the EU and EEA area. The Norwegian Environment Agency maintains its original interpretation that SoftOx is not allowed to sell during the transitional period, but SoftOx will defer to the EU Commission’s interpretation.

Key figures for the SoftOx Solutions Group (SoftOx) as of 31.12.2021

Key figures (NOK 1,000)	Fourth quarter		Year	
	2021	2020	2021	2020
SoftOx Solutions Group				
Total operating revenue	2 307	596	7 901	9 839
Total operating expenses	22 647	22 588	94 004	61 203
Operating result	-20 339	-21 992	-86 101	-51 364
Profit before tax	-20 480	-20 469	-86 290	-49 714
Net proceeds from equity issues	47 809	27 135	89 018	27 135
Net change in cash and cash equivalents	40 389	9 432	22 183	-41 194
Cash and cash equivalents at end of period	56 984	34 802	56 984	34 802
Outstanding shares, beginning of the period	9 168 468	7 829 900	8 329 900	7 751 000
Outstanding shares, end of the period	10 342 871	8 329 900	10 342 871	8 329 900
Employees, end of the period	21	21	21	21

A statement from CEO Geir Almås

(Further details are also given later in the report)

The last quarter of 2021 solidified SoftOx's role as a developer of antimicrobial technology designed to address some of the world's biggest health challenges. The urgent need for our technology has only become more prevalent. The new COVID-19 variant is record-breaking despite widespread immunity from past infections and vaccinations — the application of our technology is clear. The SoftOx Inhalation Solution (SIS) can supplement vaccines as a broad spectrum, antiviral treatment that is independent of viral mutations. The SIS-01 study is making good progress in the first test of the inhalation technology in humans. We look to aid in not only the treatment but also the prevention of infections and illness, hopefully developing a new first line of defence for future pandemics. SoftOx Defense Solutions (SDS) is also working on an inhalation solution as a countermeasure for which we have applied for funding from the European Defence Fund (EDF) in cooperation with 19 partners including 9 EU countries.

In December, we received the long-awaited news that the EU Commission's interpretation of the Biocidal Products Regulation can allow SoftOx to enter the market with its disinfectant products in the EU and EEA area. The Norwegian Environment Agency (Miljødirektoratet) defends its previous decision of ineligibility for the transitional period; however, SoftOx will defer to the interpretation of the EU Commission and continue to sell. We look forward to rebuilding our sales force, and we are pleased that we were able to maintain our core sales team during this difficult period. The Norwegian hospital purchasing (HINAS) agreement is in place, and we have started to sell in 2022. On a larger scale, we have ongoing talks with international partners on the widespread potential of our disinfection line.

However, it should not be forgotten that there is another pandemic looming — antimicrobial resistance (AMR). Chronic wounds are hotbeds for resistant bacteria, and we are developing a product that has the potential to be a great breakthrough in the fight against AMR in wounds. The SoftOx Biofilm Eradicator (SBE) is being tested for tolerability in a dose-finding phase I study, and the early study results are promising. We envision SBE as a replacement to traditional antibiotics in treating chronic

infections, and thereby aiding in the fight of biofilm and antimicrobial resistance. Together with our preventative wound rinse, SoftOx Wound Irrigation Solution (SWIS), we believe that we have an innovative and disruptive technology for the wound care market.

In summary, there are many things happening at SoftOx, and we anticipate that 2022 will bring new opportunities and accomplishments in helping the world fighting infections. In November, we hosted a Strategy and Capital Markets Day to communicate our strategies and near-term goals for commercializing SoftOx's innovative technology. I strongly encourage all our investors and those who follow SoftOx to watch this presentation to understand the company's position and plans to come. Following a successful yet challenging year, we are energized by our plans for 2022.



Geir Hermod Almås, Chief Executive Officer

Operational update on research and operations in 4Q 2021

Research and product development

Product development methodology

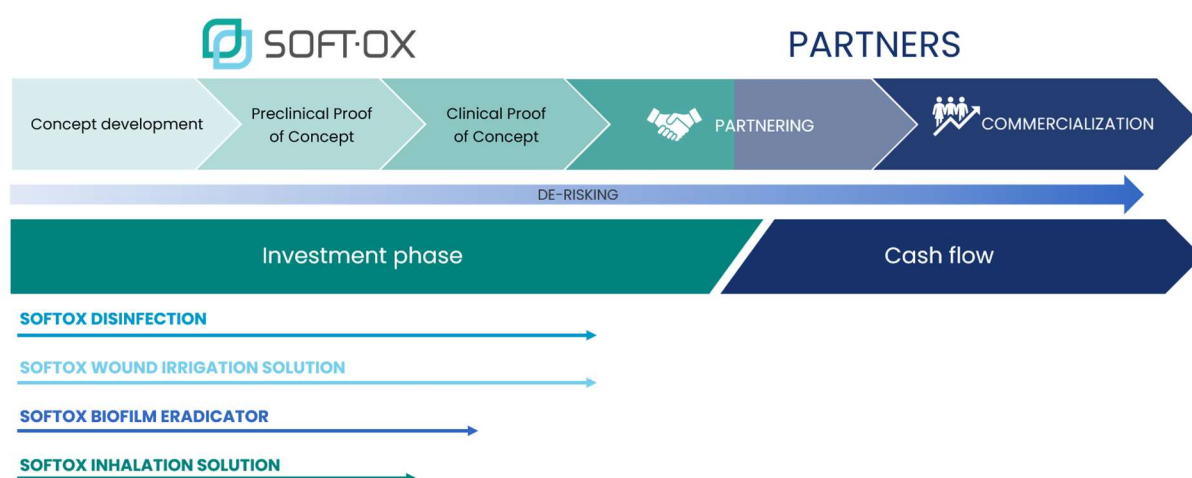


Figure 1. SoftOx product pipeline

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. SoftOx has filed 84 patents worldwide, of which 58 are granted addressing formulations, uses, methods of making and devices.

The SoftOx technology has proven strong antimicrobial effects on various bacterial species (including multidrug-resistant bacteria and those embedded in biofilms), fungi, spores and viruses. 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 make 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.

Wound Care

Infection prevention

SoftOx Wound Irrigation Solution (SWIS):

SWIS is intended for acute 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 safe when applied to wounds. 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 the Company is to replace today's wound rinsing products with SWIS as a low-risk product with added beneficial properties.

As previously announced, the final confirmatory clinical investigation (SWIS-02 trial) was recently completed. 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 of SWIS-02 has now been summarized into a manuscript for publication in an international medical journal. The study has also been reviewed by the European Wound Management Association (EWMA) Scientific Committee and accepted for oral presentation at the EWMA-CICA 2022 Conference in Paris, 23-25 May.

Furthermore, the Company is working diligently on establishing a Good Manufacturing Practice (GMP) pilot facility at Fornebu, setting up a quality management system (QMS) and developing the final design dossier to be sent to a Notified Body and Competent Authority for approval of SWIS as a medical device in Europe. Establishing a high-quality production facility at SoftOx will add value for all future research projects within the medical device and pharmaceutical development areas.

SWIS is expected to be SoftOx's first CE-marked product for the European market. The Company has also started preparing an application to obtain US clearance by the US Food and Drug Administration (FDA) for SWIS as a medical device through the pre-market notification (510(k)) route.

Infection removal

SoftOx Biofilm Eradicator (SBE):

SBE functions as an infection treatment in chronic wounds and is designed to have therapeutic effect by penetrating and killing microbes within biofilms. The formula penetrates deep into the wound bed, yet it is non-toxic and safe to use, based on animal studies. SBE kills antibiotic resistant bacteria and does not induce new resistance which may lead to a reduced use of antibiotics and fewer antimicrobial-resistant microbes. Hopefully, it will also be the first major defence against resistant 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.¹

¹ Trivedi, U., Parameswaran, S., Armstrong, A., Burgueno-Vega, D., Griswold, J., Dissanaik, 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>

As previously reported from Good Laboratory Practice (GLP) animal studies, no adverse local or systemic effects of the test solutions were observed, even at the highest concentrations, and the product candidates were therefore regarded as safe. The SBE solutions have been produced according to GMP, and the study site in Copenhagen was initiated in June. The recruitment of patients has been hampered due to a lengthy nationwide nurse strike in Denmark during Q3 and the COVID-19 pandemic; however, we are pleased to report improved patient uptake in the SBE-01 study. This has led to completion of the first two study cohorts and allowed advancement to the third dose-level cohort. This confirms that SBE has an encouraging safety and tolerability profile given as a single dose. By completing SBE-01, we will be able to determine the optimal concentrations and dosing schedule for treating patients with chronic wounds with SBE.

Respiratory tract

SoftOx Inhalation Solution (SIS) for treatment and prevention:

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.

SoftOx hypothesizes that SIS inactivates and kills intracellular and extracellular virus in the upper and lower respiratory tract, resulting in a reduction in symptoms, shortened disease duration and reduction in disease transmission. The safety of single and multiple ascending doses of SIS in healthy volunteers is ongoing (Safety of Ascending Single and Multiple Doses of Nebulised SoftOx Inhalation Solution in Healthy Subjects, NCT05188638) and is scheduled to complete in Q1 2022. Obtaining approval from the Danish Medicines Agency for conducting this trial represented an important milestone for the project and for the company, and it is evidence of the company's deep understanding of the HOCl molecule, the disease-causing viral and bacterial pathogens, and potential clinical applications. In 2022, SoftOx will continue to grow the organisation to encompass additional clinical trial development and pharmaceutical expertise as we move into phase II SIS drug development.

Animal health

As reported in Q3, the small study conducted in 2021 fell short of expectations due to too few cases. The few indications tested were generally positive. Considerations regarding the initiation of possibly another study will be concluded in Q1 2022.

Meanwhile, the search for partners, both regionally and internationally, is in progress. The company is considering several kinds of cooperation including sole distribution and technology transfer and joint product development. The aim to commercialize wound rinse products for animals in late 2022 is upheld.

Market trends and sales of our disinfection products

Strategy and Market trends

SoftOx's strategy is (1) to achieve proof of sales in Norway and increase our disinfectant segment value in the home market and (2) to partner up with international players in relevant segments to complete a wider product portfolio. The overall mission to help the world fight infections can be realized through a multiple segment partnering strategy. SoftOx's current efforts have focused on three main markets: healthcare, business-to-business (B2B) and the defence sector.

In August 2021, it was announced that SafeDes® won the Norwegian national (HINAS) tender for alcohol-free hand disinfection in bottles, where our clinically documented skin-friendliness stood out with top scores in the evaluation criteria of "properties on skin" and quality. We now have full focus on benefitting from this success and are preparing the Norwegian market for SafeDes®, despite the delays in the BPR approval process. By winning the hand disinfection category, SoftOx gained access to 70 public hospitals in Norway, which is important both regarding direct market access and revenue potential. The tender is valid from January 10, 2022, and the first sales have been registered.

In December, it was announced that SoftOx won two categories in one of the larger regions in Sweden (Varuforsörjningen). This win marks a milestone for SoftOx as this is the first tender SoftOx has won outside of Norway. The accomplishment provides a very good foundation for SoftOx's future investments internationally. The tender is valid from April 1, 2022.

The Biocidal Products Regulation (BPR) approval

Early December, the company received the European Union's (EU) interpretation of a crucial point regarding transitional periods that allows SoftOx to sell its disinfectant products in the EU/EEA area, contradicting the decision of The Norwegian Environment Agency (Miljødirektoratet). SoftOx has appealed the Agency's interpretation of BPR and will while awaiting a final assessment from the Norwegian Ministry of Climate and Environment (Klima og Miljødepartementet) remain in the market and service our customers. The company is committed to taking the necessary steps to pursue the case.

The Norwegian Medicines Agency (Statens Legemiddelverk), the body that regulates surface disinfection within the health sector, has approved both the multipurpose product for hand and surface disinfection as well as the pure surface disinfection product for use within the Norwegian health sector for the period 2022-2026.

In Sweden, the process with the new application progresses. In March 2021, the Swedish Chemicals Agency (KemI) requested additional data after our first application in 2018. As reported in Q3, the new data, have once again shown excellent low values with respect to formation of the chlorate impurities in the products, a matter of concern for the relevant authorities. The announced timeline KemI promised us in November 2021 never came. The company therefore still finds it difficult to estimate the future timeline for the Swedish application process.

Collaboration agreements

We continue our focus on the defence sector as a parallel priority to our healthcare and B2B work. During Q4-2021, SDS has together with the Norwegian Defence Research Establishment (FFI) finalized the randomized behavioral field experiment researching the indoor climate effects replacing alcohol disinfection with SoftOx products in Hemsedal municipality. A safety concern published by the FDA, regarding side effects such as headache, nausea and dizziness after the application of alcohol-based

hand rubs, influenced the work. The FDA highlights that these symptoms are likely caused by the vapors from the sanitizer and potentially from exposure in enclosed or poorly ventilated spaces². Our work and findings will be finalized during Q1-2022. The preliminary results indicate that SoftOx disinfectant products, in several analysed areas, improve the indoor climate for a more comfortable work environment, relevant both in the civilian sector and for military purposes.

In December 2021, SDS delivered, in collaboration with a European consortium, an application for developing the SoftOx technology for use as military countermeasures against biological warfare, both for the EU and Norwegian armed forces. The consortium, which is operating under the European Defence Fund (EDF), is led by the French state-owned company Commissariat à l'Energie Atomique et aux Energies Alternatives. The consortium submitted an EU application for approx. 500 MNOK to develop various military medical countermeasures against Chemical, Biological, Radiological and Nuclear (CBRN) drugs³. The consortium consists of 10 nations and 20 partners, and SoftOx's technology is one of three main technologies that form the basis for the application. If the consortium is granted the application by the EU Commission, SoftOx will develop a military inhalation solution for the EU, based on the company's inhalation technology - SoftOx Inhalation Solution (SIS). SDS will be a part of the consortium in which five internationally recognized research institutions from France, Poland, Denmark, Ireland and Sweden will participate in addition to FFI.

Financial matters

Financial figures for the SoftOx Solutions Group are 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 1,9 million (NOK 3,7 million). In addition, NOK 6 million (NOK 6,1 million) has been recognised as income in connection with funding from The Research Council of Norway and the U.S. Department of Defense.

For 2021, salary costs were NOK 21,2 million (NOK 18,9 million), an increase of 12 % compared to 2020, and approx. at the same level as each quarter in 2021. Other operating costs have increased to NOK 69,1 million (NOK 39,6 million) in 2021. For Q4, total operating expenses are NOK 22,6 million (NOK 22,6 million) and have been at the same level throughout 2021. The increase in operating expenses in 2021 compared to last year relates mainly to high levels of activity in R&D projects which are expensed instead of capitalised due to accounting principles. Approximately 50 % of operating expenses in 2021 are related to R&D activities. The main contributor to increased costs is the drug development of the SIS project, which constitutes approximately 50 % of the R&D costs.

In addition, challenges in the regulatory process for our disinfectant products, which led SoftOx to withdraw its products in Q4, has had impact on the financial numbers. The practical consequence of this withdrawal is associated with expenses of NOK 16 million considering the labour, application and production costs in 2021.

² FDA; 6-16-2021 FDA Drug Safety Communication Inhalation of Alcohol Vapor

³ https://ec.europa.eu/defence-industry-space/eu-defence-industry/european-defence-fund-edf_en).

SoftOx continues to build up its organization for future growth and development, and pre-tax results ended with a loss of NOK 20,5 million (loss of NOK 20,4 million) for Q4, and loss of NOK 86,3 million (NOK 49,7) for the year.

Cash flow and consolidated balance sheet

Of the capitalized assets, the company has activated its IP and patent cost worth NOK 7,4 million (NOK 6,1 million). These are capitalized patent costs in the Swedish subsidiary, which are depreciated over 5 years. Deferred tax assets stand at NOK 30,4 million (NOK 30,5 million), adjusted for tax in Sweden. Tax calculations will be performed at the end of the year on revised figures.

Production was initiated and investments of approx. NOK 3,5 million accumulated (NOK 3,9 million) was capitalized in 2020. The production equipment has been physically transferred to Ose Water AS and have been put into operation. Trade receivables are NOK 8,7 million (NOK 9 million) and consist mainly of public grants.

Outlook

Progressing work on the development of each project:

- Establish an international network of partners for both wound care and disinfection.
- SoftOx Wound Irrigation Solution (SWIS) – Establish a quality system for medical devices and GMP production and apply to the Notified Body for regulatory approval.
- SoftOx Biofilm Eradicator (SBE) – finish Phase Ia of the SBE-01 clinical study and proceed to Phase Ib.
- SoftOx Inhalation Solution (SIS) – finish Phase I of the SIS-01 clinical study and proceed to Phase II.
- Start marketing and sales to the Norwegian healthcare system through HINAS and to Mid-Sweden through the regional tender of Varuförsörjningen.
- Receive disinfectants and wound care approval to launch the products in selected markets.

Significant risk factors for the company

- Research studies always involve an inherent risk of being delayed and not delivering results as expected.
- Lack of approval and delays of applications for conducting clinical studies and products.
- Further delays due to European BPR process.
- 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.
- The continued threat of COVID-19 infection and the lockdown of society entails a risk for the entire value chain in the company.

Declaration by the Board

We confirm, to the best of our knowledge, that the audited, summarised Q4 accounts for the period 1 October to 31 December 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 Q4 report provides a true and fair view of the information specified in Section 5-6, fourth paragraph, of the Norwegian Securities Trading Act.

Oslo, February 15th 2022

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 fourth quarter and year to date 2021				
SoftOx Solutions Group NOK 1,000	Fourth quarter		Year	
	2021	2020	2021	2020
Other operating revenues	2 307	596	7 901	9 839
Total operating revenues	2 307	596	7 901	9 839
Personnel expenses	5 691	7 940	21 113	18 869
Other operating expenses	15 326	13 424	69 107	39 631
Depreciation	1 630	1 223	3 784	2 703
Depreciation, goodwill	0	0	0	0
Total operating expenses	22 647	22 588	94 004	61 203
Operating result	-20 339	-21 992	-86 101	-51 364
Net financial items	-141	1 523	-189	1 650
Profit before tax	-20 480	-20 469	-86 290	-49 714
Tax				12 308
Annual profit/loss				-37 406

Statement of financial position	31.12.2021	31.12.2020
SoftOx Solutions Group		
<i>NOK 1,000</i>		
Other intangible assets	7 370	6 143
Deferred tax asset	30 459	30 527
Goodwill from acquisition of subsidiary	0	0
Total intangible assets	37 829	36 670
Production equipment	3 494	3 909
Total fixed assets	3 494	3 909
Non-current assets	41 323	40 578
Inventory	196	2 970
Total inventory	196	2 970
Other receivables	8 675	8 961
Total receivables	8 675	8 961
Cash and cash equivalents	56 984	34 802
Current assets	65 855	46 733
Total assets	107 177	87 311

Share capital	207	167
Share premium reserve	175 034	76 052
Total paid up capital	175 241	76 219
Other equity	-86 392	
Total equity	88 849	76 218
Other long term debts	350	0
Other non-current liabilities	350	0
Public duties payable	38	151
Shareholder loans	0	0
Other current liabilities	11 912	5 145
Accounts payable	6 029	5 797
Total current liabilities	17 979	11 093
Total liabilities	18 328	11 093
Total equity and liabilities	107 177	87 311

Cash flow statement	Fourth quarter		Year	
	2021	2020	2021	2020
SoftOx Solutions Group				
<i>NOK 1,000</i>				
Cash flow from operating activities				
Net result before taxes	-20 480	-20 469	-86 290	-49 714
Tax paid	0	0	0	0
Depreciation	1 630	1 223	3 784	2 703
Change in current assets	-3 709	1 775	3 061	-6 090
Change in current liabilities	6 943	1 060	6 886	-7 289
Net cash flow from operating activities	-15 617	-16 410	-72 560	-60 390
Cash flow from investment activities				
Investments in non-current assets	-2 387	6	-4 596	-7 668
Net cash flow from investment activities	-2 387	6	-4 596	-7 668
Cash flow from financing activities				
Proceeds from equity issues	47 809	26 125	89 018	27 135
Other financing activities	10 355	0	10 355	-114
Translation differences	229	-289	-34	-157
Net cash flow from financing activities	58 393	25 836	99 339	26 864
Net change in cash and cash equivalents	40 389	9 432	22 183	-41 194
Cash and cash equivalents at beginning of period	16 596	25 370	34 802	75 995
Cash and cash equivalents at end of period	56 984	34 802	56 984	34 802

Statement of changes in equity				
SoftOx Solutions Group				
	Fourth quarter		Year	
	2021	2020	2021	2020
<i>NOK 1,000</i>				
Equity at end of prior period	51 923	58 365	76 218	86 468
Share issues	57 813	27 135	99 022	27 135
Loss for the period	-20 480	-8 161	-86 290	-37 406
Other changes in equity	-408	-1 121	-101	20
Equity at end of period	88 849	76 218	88 849	76 219

Notes to the Q4 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
CBRN	Chemical, Biological, Radiological, and Nuclear
DKMA	Danish Medicines Agency
EDF	European Defence Fund
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
KemI	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 us

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