
Report Q3 2020 with operational update for Q4

A photograph of three scientists in a laboratory setting. A woman with red hair is on the left, looking towards the center. A man with dark hair is in the center, looking down at something in his hands. A man with grey hair and glasses is on the right, looking towards the center. They are all wearing white lab coats. The background is dark with some lab equipment visible.

WELCOME TO SOFTOX SOLUTIONS

Helping the World Fighting Infections

New ways of eradicating infections and fighting antimicrobial resistance



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 with subsidiaries in Malmoe and Copenhagen.

SoftOx has developed a highly effective antimicrobial solution which eradicates and prevents biofilm, viral and microbial infections. The technology is based on years of research and development in partnership with leading Nordic research institutes and is protected by patents.

Key figures for the SoftOx Solutions Group (SoftOx) as of 30.9.2020

Key figures (NOK 1,000)

	Q3 2020	Q3 2019	YTD 2020	YTD 2019	FY 2019
SoftOx Solutions Group					
Total operating revenue	1 738	1 309	9 243	3 866	4 099
Total operating expenses	13 962	7 314	38 615	19 041	25 969
Operating result	-12 224	-6 005	-29 372	-15 175	-21 870
Net result before taxes	-12 199	-6 004	-29 245	-15 137	-22 178
Net proceeds from equity issues			1 010	17 894	89 903
Net change in cash and cash equivalents	-10 061	-1 562	-50 625	63	70 246
Cash and cash equivalents at end of period	25 370	1 300	25 370	1 300	75 995
Outstanding shares, beginning of the period	7 829 900	4 626 000	7 751 000	3 778 650	2 488 500
Outstanding shares, end of the period	7 829 900	4 626 000	7 829 900	4 626 000	7 751 000
Employees, end of the period			20	11	12

Highlights – Q3 2020, including selected information for Q4

(figures in parentheses apply to 2019)

- Year to date pre-tax results ended 30.9.2020 with a loss of NOK 29 million (loss of NOK 15 million). Results are characterised by high levels of activity in research and development in addition to preparatory work ahead of the launch of our disinfectants in new markets
- Clinical study of the SoftOx Wound Irrigation Solution (SWIS) was approved and has commenced
- The Danish Medicines Agency recommended further development of the SoftOx Inhalation Solution (SIS) for the treatment of respiratory infections, including COVID-19
- The US Department of Defence (DoD) awarded SoftOx app. USD 2 million for the research and development of the SoftOx Biofilm Eradicator (SBE). SoftOx considers the

funding and support from one of the world's leading research organisations as a great honour

- SoftOx has been awarded conditional certification of its disinfectants in the EU as of December 10th. The Swedish Chemicals Agency has processed and recommended SoftOx Solutions' disinfectants, including AntiVir, for certification. This opens the possibility for certification in all EU member states
- On 16 June 2020, the Biocidal Products Committee (BPC) of ECHA recommended that the EU create a separate class for active chlorine from hypochlorous acid. In order to operate in line with the new European guidelines and after a dialogue with the Norwegian Environment Directorate, it was decided by SoftOx to withdraw and change the label on the products sold before the EU change took place. The practical consequence is that SoftOx chose to take back products for approximately NOK 1 million to ensure correct labeling. This decision will reduce revenues in the Q4. Except of this, the Q4 will end relatively similarly to the Q3.

A statement from CEO Geir Almås

(Further details are also given later in the report)

SoftOx is developing an entire new category of antimicrobials (antibiotics) that do not develop resistance

Our technology is now used in several research and development projects for different indications both in the prevention and treatment of various infections. As our projects are completed, we envisage that they will create a completely new class of antibiotics, which are also effective against viruses and fungi. In contrast to traditional antibiotics, no development of resistance has been demonstrated when using our products. We see that our products also kill all multi-resistant bacteria. At the same time, the products are used locally and not systemically, which is important to avoid weakening the body's own immune system. In the news, we often hear about the fear that vital antimicrobial drugs will no longer have an effect due to the development of resistance. What we now see the beginning of, with our products, is a new type of antibiotic that works where it should, whether it is in the wounds, oral cavity or in the lungs, without the development of resistance.

Our vision is that SoftOx products overall should represent a significant breakthrough in the fight against infection in a way that the world has not seen since Fleming discovered penicillin in 1928. The fact that our work is supported by leading international research institutions to help us fulfil this vision is an important confirmation that we are on the right path.

Status of our investment in the disinfectant market

Our disinfection products are clinically proven to be skin-friendly, and we have shown through extensive testing that the product has a better effect than today's alcohol-based solutions.

The World Health Organization is now also recommending an alternative to alcohol-based disinfectants for healthcare workers. We aim for our products to be the skin-friendly and effective alternative.

The Norwegian Institute of Public Health (FHI) has not yet updated its hand hygiene guidelines to recommend active ingredients other than alcohol. Unfortunately, this has meant that many potential customers have not yet started to use SoftOx products.

The Swedish Chemicals Agency has processed and recommended SoftOx Solutions' disinfectants, including AntiVir, for certification. This creates the opportunity for certification in all EU member states. This also means that we are now in a position in which our hand disinfectant is in line with the EU Biocidal Products Regulation and the EU Biocidal Products Directive, and we expect and hope that the Norwegian Institute of Public Health will update its hand hygiene guidelines to allow for hand disinfectants that have been certified under new EU regulations. Certification will also consolidate our position in the forthcoming HINAS tender, a framework agreement for hospital procurement.

Over the past six months, we have negotiated several new and important distribution agreements with operators in the Nordics. Next year, we are planning a product launch in several European countries, and we are already well under way with preparations for market entry. We are also experiencing a growing interest from several countries in Asia for our hand disinfectant product.

International confirmation with major grants

Biofilm is a significant factor in resistant infections, especially in chronic wounds. The FDA estimates that more than 40% of all chronic wounds contain resistant bacteria. At the same time, wound infections are a major problem for the military with more than 30% of all wounds becoming infected, often with antibiotic-resistant bacteria. As a measure in relation to this problem, the US Navy announced in February 2020 an open competition for the development of new antimicrobial solutions that will prevent and remove wound infections. In this competition, SoftOx was awarded maximum financial support.

Inhalation project with potential to treat all types of respiratory infections

"My team and I believe that we are on the brink of a breakthrough in the treatment of complicated infections – both viral and bacterial. We have tested the effect of the SoftOx solutions in the respiratory tract, and we believe that this may be an important treatment principle which can contribute to fighting the ongoing pandemic as well as future epidemics and pandemics," says Professor of Microbiology and Study Director Thomas Bjarnsholt from the University of Copenhagen.

Respiratory infections cost society enormous sums; in the ongoing pandemic, we see how entire societies have to shut down due to the danger of a pandemic out of control. Fortunately, many of the ongoing vaccine projects look promising, but the need for alternative treatment solutions such as the SoftOx inhalation solution is still important. For the future, our vision is that SIS shall be an alternative treatment in the period up to a new vaccine is developed, to avoid pandemics like we see today. The solution will be a new type of antibiotic

that will also be effective against viruses and could be a completely new causal treatment for all types of respiratory infections. After dialogue meetings with the Danish Medicines Agency, SoftOx has received the preliminary go-ahead for a development pathway where we will be able to start testing in humans in the second quarter of 2021. If we succeed in this, we may be in the market for treating seriously ill patients much faster than normal. In that case, this will be a complete "game changer" and represent a paradigm shift in how we treat respiratory tract infections.

Operational update on development and operations so far in 2020

Research and product development

SoftOx Inhalation Solution (SIS):

In response to the significant challenges facing the world with COVID-19, SoftOx launched a new research project in partnership with the University of Copenhagen. The unique and broad-spectrum mechanism of the SoftOx technology is also effective against viruses. Particularly enveloped viruses (e.g. corona, influenza etc.) can be destroyed relatively easily by chemical modification of surface molecules on the virus (proteins and lipids). This can prevent the virus from infecting cells and creating new viruses. The research project has examined the effect of SoftOx as an inhalation solution for the treatment of viral and bacterial infections in the respiratory tract. Studies in animal models have shown that the inhalation solution reaches the lung tissue and has good tolerability within a given concentration range. SoftOx has also recently obtained results on the anti-viral effects in the same concentration range which constitutes a good starting point for further drug development. We are now working intensively on further safety studies in animal models and the development of regulatory documentation with a view to apply for approval of the first study in humans (Phase I).

Over time, SoftOx has been in close dialogue with the Danish Medicines Agency (DMA) in Denmark where many of the studies have so far taken place. Recently, a scientific advice meeting was held to discuss the company's development plans for SIS. DMA provided valuable feedback on the company's plans and has clarified important aspects of the best possible way of developing SIS further. Since our priority target group is COVID-19 patients, we also qualify for regulatory schemes for accelerating the development of possible treatments of COVID-19.

SoftOx Biofilm Eradicator (SBE):

A 28-day toxicity study (GLP standard) has been conducted at the European Research Biology Center (ERBC) in Pomezia, Italy to examine the company's SBE product candidates for tolerance and toxicity in minipigs (which is the recommended animal model for toxicological studies in injured skin for drug testing). Even at the highest concentrations, no adverse local or systemic effects were observed. These results are very important. The study facilitates

further development of SBE in patients with infected, chronic wounds. The company plans to submit a pre-IND / pre-submission application to the FDA in the United States to ensure important feedback on product classification and the planned development process. This is being done to reduce the risk in the development of SBE and for adaptation to US regulatory requirements.

An important prerequisite for further product development is public funding. SoftOx has already received a grant from the Research Council of Norway (NFR) which has been vital to the basic scientific research that has already been completed. SoftOx and NFR reviewed the project status in the middle of October to ensure that all parts of the project plan have been followed and implemented. NFR was very pleased with the status and implementation of the development project.

As part of securing further funding for the clinical development of SBE, SoftOx applied for a public grant from the US Department of Defense and the US Naval Medical Research Center earlier in 2020. The company succeeded in its application for further development of SBE and has been granted a financial grant close to USD 2 million. This support and close cooperation will be extremely valuable and crucial for developing the project up to the concept proof stage (Proof of Concept) in humans. In addition, it is a fantastic recognition of the work we have done so far. For us, this will be a prestigious project that may have major consequences for how to prevent and treat wound infections.

For the US military, wound infections are considered a major risk for soldiers in combat situations. For civilians, a 2019 analysis of Medicare recipients in the United States shows that approximately 8.2 million people had wounds with or without infections. Medical cost estimates for acute and chronic wound care ranged from \$ 28.1 billion to \$ 96.8 billion. The support from the US Naval Medical Research Center clearly demonstrates that SoftOx has a technology that has a huge potential to help solve the challenge of chronic wounds.

In parallel, SoftOx is working on further development of the technology that will give the product new and improved properties. This also includes the work of a PhD, partly financed by the Research Council of Norway in collaboration with the Department of Pharmacy at the University of Oslo.

SoftOx Wound Irrigation Solution (SWIS):

The development of SoftOx Wound Irrigation Solution (SWIS) is in good progress. The latest clinical study (SWIS-02), which is designed to confirm the results of the first pilot study, has been approved by the Danish Medicines Agency and the Danish Research Ethics Committee. The study was started as planned in November and has already included four individuals (as of mid-December). The study is being performed at the renowned wound treatment centre at Bispebjerg University Hospital in Copenhagen and will document safety and efficacy compared to the current standard solution which is physiological salt water in acute wounds. The study is estimated to be completed in the first half of 2021.

In parallel with the clinical study, SoftOx's quality system and full-scale production are being developed to meet the requirements (CE marking) for SWIS being certified as a medical device (Class III) in the European market.

Market trends, distribution, and sales

Market trends and distribution

The company's long-term ambition is to establish itself and become the market leader in a new category for alcohol-free 'highly effective and skin-friendly hand disinfectants' which especially address the needs of 25-55% of today's healthcare workers who struggle with sores and damaged skin on their hands. Hand eczema and cracked skin are a common problem among health professionals which has become widely recognised due to the COVID-19 pandemic with its increased use and attention to hand disinfection. Particularly vulnerable groups outside the healthcare system are children, young people, the elderly and people with sensitive skin or eczema at the same time as we see a clear need of an alcohol-free alternative in sectors like public transport, aviation, and the military.

National guidelines currently promote alcohol-based disinfectant products despite the WHO's recommendation that healthcare institutions should offer alternative products to healthcare workers. SoftOx works to ensure that products based on new technology, as a minimum, are equated, provided that the product meets adopted documentation requirements for disinfectants with alcohol.

It is anticipated that changes in the regulations (read: The Hand Hygiene Guidelines) will be able to make marketing of SoftOx's products much easier. The National Institute of Public Health has informed that such an update will be made when they are in control of the ongoing pandemic.

The SoftOx application to the Swedish Chemicals Agency was processed on behalf of the EU and the Nordic countries in December and has now been confirmed to be in accordance with the EU Biocides Regulation. The Swedish Chemicals Agency will shortly forward the application to the Danish Environmental Protection Agency and to the Norwegian Environment Directorate for parallel assessment and ratification. The deadline for replies is 40 days. This is an important milestone for the company and brings us much closer to the goal. We can now prepare for mutual approval processes and launches in several European markets.

In the second half of 2020, the company is working intensively to expand the distributor network in addition to Kiltoclean to increase the availability of SoftOx's products. There has been a strong focus on establishing contacts and product knowledge among key customers in strategic segments, such as MILAS for the kindergarten segment, Bonaventura for groceries, pharmacies and specialty stores and the First Aid section of the Red Cross. SoftOx has entered into several agreements recently, including the sports chain XXL and Stadion Sport, Brødrene Dahl and Maske Gruppen. Maske is a large wholesaler which is able to make SoftOx products available to a wide range of end customers, with a strong position within nursing homes and doctors' offices.

Regarding end customers, our main focus is on the healthcare sector and the upcoming hospital tender (HINAS) in the infection control category. The tender is still delayed due to the pandemic and is expected to be announced in December 2020/January 2021. The tender will for the first time have a separate category for alcohol-free hand disinfectant.

AntiVir™ – patent by SoftOx has been used in some hospital departments of the Southern and Eastern Norway Health Enterprises. Contacts have been established with several other Health Enterprises (West, Mid and North), and customer tests have been arranged or have already been launched. Usage tests with important key customers in a selection of strategic segments in addition to healthcare were initiated in Q3 and will be monitored closely in Q4.

Sales

High demand for disinfectant products as well as the authorities' temporary regulations for biocides (Import until 4 October 2020 and sales amnesty until 2020) have led to many new products entering the market during the second quarter. This in combination with the fact that FHI has postponed its update of the hand hygiene guidelines and the long waiting time for final approval in accordance with the new Biocidal Regulations has contributed to sales of SoftOx products being lower than expected this year. However, we feel confident that the work done towards the end user, distributors and the professional community in the long run will give us a breakthrough.

SoftOx expects that the market will continue to demand large volumes of disinfectants, and well-documented products will gradually increase their market share. In an updated survey from the Norwegian Covid19 monitor, conducted by Opinion, 8 out of 10 individuals thought that implemented infection control measures related to disinfection should continue even in a normal situation. We also do not know of any competitive technology that can challenge SoftOx products' unique combination of key features: highly efficient, skin-friendly and safe.

Organisational information

An efficient sales and marketing team was recruited and became operational in Q3, consisting of a Sales Manager Health, an International Product Manager and a Junior Product Manager in addition to contracted resources with specialist expertise in selected segments in Norway and internationally. This has contributed to extensive customer activities and market visibility increasing significantly in Q3. This will be further consolidated in Q4 and into 2021.

Significant risk factors for the company

- The rise of corona 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

- Research studies always involve an inherent risk of being delayed and not delivering results as expected
- Lack of approval 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

Financial review

Financial figures for the SoftOx Solution Group have not been audited (figures in parentheses are comparable figures for 2019).

Profit and loss statement

So far this year, the company has sold hand disinfectants and surface disinfectants worth approx. NOK 5 million. As predicted in previous reports, sales in Q3 were lower than expected at just over NOK 0.3 million. In addition, just under NOK 4.3 million (NOK 3.9 million) has been recognised as income in connection with funding from the Research Council of Norway so far this year. Compared to 2019, income has increased by approx. 139% so far this year, and 33% in Q3.

Salary costs were NOK 10.9 million (NOK 8 million), an increase of 36% compared to the previous year. This rise is mainly due to increased production, sales and administration which will contribute to boosting business further.

Other operating costs have increased to NOK 26 million (NOK 10 million) so far this year. For Q3, the cost is approx. NOK 9 million (NOK 4 million) against NOK 12 million (NOK 3.5 million) in Q2. The decrease compared to Q2 is due to reduced activity at the production facility as well as holiday closures. The increase compared to last year is due to two factors as in the Q2 reporting:

- The construction and facilitation of the company's own production that is expected to provide both short-term and long-term value creation
- Increased activity for research and development projects that are expected to provide long-term value creation. This applies to the SIS and SBE projects.

SoftOx continues to build up its organisation for future growth and development, and pre-tax results ended with a loss of NOK 29 million (loss of NOK 15 million).

Cash flow and consolidated balance sheet

Of the capitalised assets, the company has patents worth NOK 5.2 million. These are capitalised patent costs in the Swedish subsidiary. Deferred tax assets stand at NOK 18.5 million, corresponding to the end of 2019, 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 5.8 million have been capitalised. This mainly applies to production facilities that have been put into operation. Due

to low sales in Q3, stocks have been built up to a value of approx. NOK 2.8 million at the same time as trade receivables have been reduced by approx. NOK 2 million.

So far this year, the company has had a negative cash flow of NOK 50.6 million, of which NOK 11 million has been spent on repayment of short-term debt from 2019. As of 30 September 2020, capital holdings are NOK 25 million.

Outlook

The company's plans for the next 12 months include:

- Progressing work on the development of each individual project
 - SWIS – complete the clinical study (SWIS-02) and quality system for medical devices. Establish GMP production and submit an application to the *Notified Body* for CE certification
 - SBE – establish a partnership with the US Naval Medical Research Center, achieve regulatory certification and launch a Phase I study of patients with chronic wounds
 - SIS – progress the efficient development according to the advice of the regulatory authorities
- The company's work to build up sales to be able to achieve a positive cash flow
- Submission of tenders for HINAS announcement, where the tender will for the first time include a separate category for alcohol-free hand disinfection
- Get disinfectants approved outside the Nordic region to launch the products in selected markets
 - Selecting European markets in Northern Europe, incl. Germany, but also in Asia, is considered high priority
- Resume activities in animal health
- Establishment of a network of partners and distributors in Norway, Sweden, Denmark and Germany will be an important activity for the next 6-12 months - experience can be utilized at launches in other countries

Declaration by the Board

We confirm, to the best of our knowledge, that the unaudited, summarised Q3 accounts for the period 1 January to 30 September 2020 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 Q3 report provides a true and fair view of the information specified in Section 5-6, fourth paragraph, of the Norwegian Securities Trading Act.

Oslo, December 13th 2020

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 third quarter and year to date 2020					
SoftOx Solutions Group					
<i>NOK 1,000</i>	Q3 2020	Q3 2019	YTD 2020	YTD 2019	FY 2019
Other operating revenues	1 738	1 309	9 243	3 866	4 099
Total operating revenues	1 738	1 309	9 243	3 866	4 099
Personnel expenses	4 269	3 088	10 929	8 044	11 197
Other operating expenses	9 114	3 953	26 207	10 169	13 071
Depreciation	579	273	1 480	828	1 701
Depreciation, goodwill					
Total operating expenses	13 962	7 314	38 615	19 041	25 969
Operating result	-12 224	-6 005	-29 372	-15 175	-21 870
Net financial items	25	1	127	38	-308
Net result before taxes	-12 199	-6 004	-29 245	-15 137	-22 178
Tax					5 842
Net result after tax					-16 336

Statement of financial position	30.09.2020	30.09.2019	31.12.2019
SoftOx Solutions Group			
<i>NOK 1,000</i>			
Other intangible assets	5 248	2 432	4 928
Deferred tax asset	18 501	12 264	18 135
Goodwill from acquisition of subsidiary			
Total intangible assets	23 748	14 696	23 063
Production equipment	5 751	246	242
Total fixed assets	5 751	246	242
Non-current assets	29 499	14 942	23 304
Inventory	2 807		
Total inventory	2 807		
Other receivables	10 722	8 672	5 664
Total receivables	10 722	8 672	5 664
Cash and cash equivalents	25 370	1 299	75 996
Current assets	38 899	9 971	81 660
Total assets	68 398	24 913	104 965

Share capital	157	93	155
Other paid in equity	90 620	35 647	89 713
Total paid in equity	90 777	35 740	89 868
Other equity	-32 412	-18 502	-3 399
Total equity	58 365	17 238	86 469
Other long term debts	0	0	114
Other non-current liabilities			
Public duties payable	526	995	659
Shareholder loans	0	21	3 101
Other current liabilities	1 734	5 342	3 622
Accounts payable	7 773	1 317	10 999
Total current liabilities	10 033	7 675	18 382
Total liabilities	10 033	7 675	18 496
Total equity and liabilities	68 398	24 913	104 965

Cash flow statement	Q3 2020	Q3 2019	YTD 2020	YTD 2019	FY 2019
SoftOx Solutions Group					
<i>NOK 1,000</i>					
Cash flow from operating activities					
Net result before taxes	-12 199	-6 004	-29 245	-15 137	-22 178
Tax paid			0	0	
Depreciation	579	273	1 480	828	1 701
Change in current assets	-879	-598	-7 865	-2 490	518
Change in current liabilities	2 566	4 450	-8 349	690	9 397
Net cash flow from operating activities	-9 932	-1 879	-43 978	-16 109	-10 562
Cash flow from investment activities					
Investments in non-current assets	-213		-7 674	0	-3 201
Net cash flow from investment activities	-213	0	-7 674	0	-3 201
Cash flow from financing activities					
Proceeds from equity issues	0	0	1 010	17 894	88 394
Other financing activities	0	300	-114	-1 700	114
Translation differences	85	17	131	-22	14
Net cash flow from financing activities	85	317	1 027	16 172	88 521
Net change in cash and cash equivalents	-10 061	-1 562	-50 625	63	74 759
Cash and cash equivalents at beginning of per	35 431	2 861	75 995	1 237	1 237
Cash and cash equivalents at end of period	25 370	1 300	25 370	1 300	75 995

Statement of changes in equity					
SoftOx Solutions Group					
<i>NOK 1,000</i>					
	Q3 2020	Q3 2019	YTD 2020	YTD 2019	FY 2019
Equity at end of prior period	70 478	22 926	86 468	14 409	14 409
Share issues	0	0	1 010	17 894	88 393
Loss for the period	-12 199	-6 003	-29 245	-15 137	-16 336
Other changes in equity	85	315	131	72	2
Equity at end of period	58 365	17 238	58 365	17 238	86 468

Notes to the financial 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.