Report 1st half year of 2020 with operational update for Q3





SoftOx Solutions AS is a medtech company listed on the Merkur Market, Oslo Stock Exchange, with the ticker 'SOFTOX-ME'. SoftOx was founded in 2012 and is headquartered in Oslo with subsidiaries in Malmö and Copenhagen.

SoftOx has developed a highly effective antimicrobial solution which eradicates and prevents biofilm, viral and antimicrobial 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 30.6.2020

Key figures (NOK 1,000)

	Q2 2020	Q2 2019	YTD 2020	YTD 2019	FY 2019	
SoftOx Solutions Group						
Total operating revenue	6 2 6 6	1 267	7 505	2 557	4 0 9 9	
Total operating expenses	16 160	6 161	24 653	11728	25 969	
Operating result	-9 894	-4 893	-17 148	-9 171	-21 870	
Net result before taxes	-9 801	-4 882	-17 046	-9134	-22 178	
Net proceeds from equity issues	1010	17 894	1010	17 894	88 194	
Net change in cash and cash equivalents	-18 934	7 454	-40 565	1624	70 246	
Cash and cash equivalents at end of period	35 430	2 861	35 430	2 861	75 995	
Outstanding shares, beginning of the period (1, 2)	7 751 000	3 758 650	7751000	3 778 650	3 778 650	
Outstanding shares, end of the period (1, 2)	7 829 900	4 626 000	7 829 900	4 626 000	7 751 000	
Employees, end of the period	13	11	13	11	12	

Highlights – first half 2020, including selected information for Q3

(figures in brackets apply to 2019)

- Pre-tax results ended with a loss of NOK 17 million (minus NOK 9 million). Profits have been affected by costs related to increased production capacity in Norway and several parallel development projects
- As a result of the COVID-19 epidemic, SoftOx has accelerated its launch of disinfection agents. In the first quarter of sales (Q2) we sold for impressive nearly NOK 5 million. Sales in Q3 have been affected by the restructuring of distribution and we experienced that a number of potential customers had already filled up their stocks in Q2. We expect lower sale in Q3, compared to Q2
- Throughout the year, the company has completed additional clinical studies that document that *AntiVir[™]* hand disinfectant is just as skin-friendly as salt water and more skin-friendly than alcohol
- The company has completed accredited (EN) virus tests that have showed very strong virucidal (anti-virus) effects of *AntiVir*[™]

- The Danish Medicines Agency approved SoftOx's clinical study for its SWIS-02 wound irrigation product
- In Q1 The University of Copenhagen started inhalation studies on pigs where the animals inhaled different concentrations of SoftOx. A prerequisite for the inhalation studies was that the studies could be performed without serious side effects for the pigs. The company has previously proved that the SoftOx solution deactivates all known viruses, including enveloped coronavirus
- In Q3, the company announced the results of inhalation studies on pigs. The results were very promising and SoftOx is excited about the potential for developing the company's technology into a treatment for respiratory infections, including COVID-19 patients. The results indicate that we have found 'safe' concentrations that do not damage the airways, while simultaneously showing a sufficient antimicrobial effect to deactivate viruses
- The company has decided to apply for accelerated development of an inhalation drug for the treatment of COVID-19. An initial meeting with the Danish Medicines Agency in Denmark has been agreed in the beginning of October
- Received a tentative grant of USD 2 million from a US government institution for the development of SoftOx's infection remover (SBE), a treatment of chronic wound infections
- Completed GLP studies on the SoftOx's infection remover (SBE). The study showed good results on tolerance and toxicity for what the company regards as sufficient doses to eradicate difficult infections in chronic wounds

A statement from CEO Geir Almås



Our vision is clear:

Preventing and treating infection – the world needs new solutions

SoftOx's technological solution has the potential for being important in the way that we prevent and treat infections. We will be an important contribution to reducing the use of antibiotics and the development of resistance to antibiotics. Our technology is designed to form the basis of a number of products that both prevent and treat infection.

"To develop new ways of eradicating infections and fighting antimicrobial resistance".

SoftOx shall become an important contributor to solve the world's major challenges presented by viral infections and antibiotic-resistant-bacteria. The world is in need for an effective treatment of infections in wounds and mucous membranes and to counteract the development of new resistance to antibiotics. Our products have the potential to become a supplement and alternative to existing antibiotics.

Hand disinfection

We aim to help millions of healthcare professionals who suffer from dry and broken skin every day.

Clinical trials on both healthy and damaged skin show that SoftOx is gentler on the skin than currently available solutions. Tests further show that SoftOx has a broader effect and works faster than alcohol.

The company's hand disinfectant has already been launched in the Nordic countries, and we are awaiting our European certification so the company can launch the hand disinfection product in other selected countries in Europe. Our aim is to become the leading supplier of hand disinfectant to healthcare workers in Europe. To launch a new product in an established market requires both effort and resources. We want to be a serious player over the long term in a professional and regulated market in which establishing new technology takes time.

Wound products and resistance to antibiotics

We aim to establish a new standard for the treatment of wound infections and thereby eradicate one of the most important sources of the formation of new antibiotic-resistant bacteria.

Many leading research environments believe that the fight against resistance to antibiotics assumes that you must develop an effective remover of biofilm infections in chronic wounds (biofilm is 'mucus' produced by bacteria for protection). Highly renowned researchers in the field Professor Thomas Bjarnsholt, PhD, University of Copenhagen, and Dr Klaus Kirketerp Møller, PhD, at Bispebjerg University Hospital, lead our work in this area.

SoftOx has received a tentative support of USD 2 million from the US authorities to clinically document that the company's solution effectively removes biofilm infections in chronic wounds. This is a recognition of our work and potential. This in combination with good results from animal studies that show the safety of presumed clinically effective doses, means that we are now able to start work on making Proof of Concept (PoC) in humans.

The Research Council of Norway (NFR) and the US authorities will together cover more than 80% of the expected costs of clinical development up to PoC for this wound product.

The effect of SoftOx technology on the respiratory tract?

"This technology is unique, simple and exceptionally effective. I am convinced that we are facing a breakthrough in the treatment of severe infections. We have examined the effect of the SoftOx solution in the airways, and this may be the solution that the world has been waiting for, a solution that can play an important role in the treatment of current and future epidemics and pandemics," says Professor Thomas Bjarnsholt ¹, University of Copenhagen.

¹ Professor Bjarnsholt is one of the inventors of the SoftOx technology, and he is a member of the SoftOx Solutions AS' advisory board. He owns options (20 000) to acquire shares in the company, and he is being paid for his work for SoftOx Solutions AS.

When the COVID-19 pandemic hit the world with full force, SoftOx and Professor Bjarnsholt and his team at the University of Copenhagen decided to try to develop an inhalation solution that is sufficiently broad-spectrum to heal people from respiratory infections. Respiratory infections have always been the Achilles' heel of mankind. Before we got antibiotics, respiratory infections were life-threatening. With the COVID-19 virus, the world has once again been reminded of the risk of viruses and bacteria for which we have no treatment and of the consequences of the world community not having effective antimicrobial agents.

If we succeed, the SoftOx technology could represent a paradigm shift in the treatment of respiratory 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 effective against viruses. Enveloped viruses (e.g. corona, influenza etc.) in particular can be destroyed relatively easily by chemical modification of surface molecules on the virus (proteins and lipids). This will be able to 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 airways. Studies in animal models have shown that the inhaled solution reaches the lung tissue and has good tolerability within a given concentration range. Future studies will focus on examining optimised dosage and efficiency. SoftOx has requested a preconference with the Danish health authorities (Danish Medicines Agency) with the aim of applying to accelerate the development time according to special rules for the development of COVID-19 treatments. Our aim is to be able to treat COVID-19 patients as quickly as possible. The company will later look into the possibilities of using SIS towards other respiratory infections like influenza virus, antibiotic resistant infections and other microbial infections in the respiratory system.

SoftOx Biofilm Eradicator (SBE):

A toxicity study (GLP standard) over 28 days has been performed at the European Research Biology Center (ERBC) in Pomeza, Italy, to examine the company's SBE product candidates with regards to tolerance and toxicity in mini pigs (which is the chosen animal model for toxicological studies of damaged skin for drugs testing and which is also recommended by the regulatory authorities). Even at the highest concentrations, no adverse local or systemic effects of the test solutions were observed, and the product candidates can therefore be regarded as safe. This is a very important milestone, and the results must be said to be better than expected. The study facilitates further development of SBE in human patients with infected chronic wounds. 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 research that has already been completed. In addition, SoftOx has received a tentative grant of USD 2 million from a US government institution. Together, these grants will take the project forward to PoC in humans where 80% of costs are expected to be covered by the stated contributors. Further studies will then be based on the results reached and financed in cooperation with future partners.

SoftOx is already working on the further development of new technology which is designed to give the product new and enhanced attributes. This also includes parts of a doctoral dissertation, partially financed by the Research Council of Norway and in partnership with the Department of Pharmacy at the University of Oslo.

SoftOx Wound Irrigation Solution (SWIS):

The development of SoftOx Wound Irrigation Solution (SWIS), the company's first wound irrigation solution, has seen good progress. The clinical study (SWIS-02) which is to confirm the results of the first pilot study (SWIS-01), has been approved by the Danish Medicines Agency. The study can therefore be commenced as soon as it has been cleared by the Danish Research Ethics Committees (VEK). This is expected to take place in October 2020. The study will be performed at the recognised wound treatment centre at Bispebjerg University Hospital in Copenhagen.

In parallel with the completion of the clinical study, the company's quality system is being developed to satisfy the requirements for CE marking.

The company has furthermore investigated the possibility of an optimal approach to entering the US market. After a so-called 'pre-submission' meeting with the Food and Drug Administration (FDA) in June 2020, it seems possible to use a '510(k) clearance' for SWIS in the US market. This will be strategically assessed against the option of launching a product with a documented medical effect.

Animal health

Extensive use of antibiotics in the treatment of animals is one of the main reasons for the development of resistance. The company has a long-term goal of contributing to a reduction in the use of antibiotics in animals. Due to the COVID-19 situation, work on the development of animal health products has been delayed.

The original plan was to commence studies in Norway in the spring of 2020, but these studies have been postponed until the spring of 2021. The studies will be conducted on wounds on dogs.

Market trends, sales and distribution

Launches and production

As a result of the COVID-19 pandemic, SoftOx decided to accelerate its production of disinfectants which was launched five months ahead of the original schedule. The first production line was established at the end of Q1, and in the first half of the year, the company built up significant production capacity to meet potential future demand. In Q2 and the first part of Q3, the company has established a new laboratory and its own production facilities in Oslo.

Sales and distribution

SoftOx Hand and Surface Disinfectant was introduced to the market both in Norway and Sweden in Q2. The first products were launched and distributed through Kiiltoclean/Antibac under the Antibac Alkoholfri hånddesinfeksjon (Antibac Alcohol-free Hand Disinfectant) and Powered by SafeDes brands in Norway and DAX ALKOFRI (DAX ALCOFREE) and Powered by SafeDes in Sweden. For SoftOx, this meant that the company went from being a purely research-based organisation to being a combined research/commercial organisation. Total sales of hand and surface disinfectant from April to end of June was just under NOK 5 million. At the end of June, the company received its first order of hand disinfectant from the Southern and Eastern Norway Regional Health Authority (the largest healthcare company in Norway).

The company has also launched two of its own brands: AntiVir Hånddesinfeksjon (AntiVir Hand Disinfectant) – Patent by Soft-Ox and EffectDes Overflatedesinfeksjon (EffectDes Surface Disinfectant) – Patent by Soft-Ox as part of establishing the SoftOx technology as its own brand to a wider target group.

The company's long-term aim is to establish a new category of highly effective and simultaneously skin-friendly hand disinfectant. We want to establish SoftOx's products as preferred disinfectants, especially in the segment of users who are experiencing that currently available hand disinfectant products dry out and damage their skin. High demand for disinfectant products in combination with the authorities' temporary relaxation of biocide regulations have meant that many new products have come on the market in Q2. However, we are not aware of any competing technology that challenges SoftOx's position as the leading solution for effectiveness and skin friendliness

National guidelines currently prefer alcohol disinfectant products. SoftOx is working to ensure that new products, like ours, with a documented effect are at least as preferable as products with alcohol. The COVID-19 pandemic has led the authorities to reconsider existing guidelines, but the process takes time.

SoftOx wants to build a category for disinfectant aimed at everyone with sensitive and damaged skin. A great unmet need exists in this segment as the current alternative of alcoholdisinfectant is considered to have adverse effects on this type of skin. In addition to the healthcare segment, there is a large customer group in schools and nurseries who have skin that is dehydrated, sensitive and/or may be damaged due to frequent hand washing. SoftOx has therefore signed letters of intent with several leading segment distributors in Norway to reach out to these customer groups, including Milas and Bonaventura Scandza. The distribution agreement with Milas covers the sale and distribution of hand and surface disinfectants in schools and nurseries, while the distribution agreement entered into with Bonaventura Scandza covers the consumer market for disinfectants.

The HINAS tender, a framework agreement for hospital procurement, is expected to be announced shortly. This tender will for the first time include a separate category for alcoholfree hand disinfectant.

The company is also very actively working to raise the profile of its SoftOx technology and *AntiVir* brand in the marketplace, especially among end users. An updated website with renewed content and design has been launched. It is now possible for end users to order products directly.



SoftOx expects that the market will continue to demand large volumes of disinfectants in the future, and products with documented effect (such as SoftOx's) will gradually increase their market share. An updated survey from Norsk's COVID-19 monitor conducted by Opinion shows that 8 out of 10 respondents want infection control measures related to disinfection to continue even when the situation normalises.

SoftOx has therefore decided to follow its long-term strategy of building the basis for the 'highly effective and skin-friendly disinfectant' category in combination with establishing its own category of skin-friendly hand disinfectant with *AntiVir*, as the preferred brand, rather than maximising its short-term sales of *AntiVir* in a saturated alcoholic disinfectant market.



Organisational information

At the end of Q3, the company (including its subsidiaries) has a total of 16 employees. Several new recruitments have been done, in both operations and in the development department, in the past six months. Kristine Rød is the new finance manager and will take the main responsibility for investor relations. Kristine has an MSc in Economics from NHH Norwegian School of Economics and is a state authorized public accountant with several years' experience as an auditor, consultant, and controller. Hanne C. Grøgaard is a new CMC scientist. She is a biotechnologist from the Norwegian University of Science and Technology and has experience in pharmaceuticals, dietary supplements and start-ups as well as product development, production and research. Julia Robertson has been appointed as clinical research manager. She has a PhD in Molecular Biology from the University of Oslo and has several years' experience of clinical studies.

A new board was elected at the Annual General Meeting on 30 June 2020. The Board now comprises:

- Melvin Teigen (chairman of the board, new)
- Kari Myren (board member, new)
- Claus Seeberg (board member, new)
- Olav Jarlsby (board member, re-elected)

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 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
- > The company worked to build up sales to achieve a positive cash flow

Financial review

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

Profit and loss statement

In the first half of 2020, the company sold hand and surface disinfectant worth approx. NOK 5 million. Sales were mainly to KiiltoClean AS, Milas and Veso. In addition, about NOK 3 million has been recognised as income in connection with funding from the BIA programme with the Research Council of Norway. Compared to 2019, revenue has increased by approx. 200% due to the sale of disinfectants.

Salary costs were NOK 6.7 million (NOK 5 million), an increase of 34%. The increase is mainly due to the launch and development of operating facilities, as well as consolidated expertise in quality requirements in connection with production and distribution.

Other operating costs have increased to NOK 17.1 million (NOK 6.2 million). Additionally, investments of approx. NOK 5.5 million have been made in production capacity (NOK 0 mill).

2020 has been a year characterised by significantly higher activity than previous years, and the increase in operating costs is mainly added value associated with long-term value creation:

- Other operating costs include just below NOK 8 million, including investment, relating to the construction and start-up of future-oriented production capacity. The construction and development of the facilities took place in record time, and the company built up strong expertise in the area and is equipped for further expansion. By undertaking some of these costs, the company has built up a solid foundation for significant growth in future production and revenue.
- Several major development projects are being completed in parallel in Norway, Sweden, and Denmark. Projects such as SWIS, SBE and SIS have in the past six months involved significant costs related to research and development. Total costs for the period are just over NOK 8 million. Activities in research and development form the basis for added value in the projects that will be realized in the coming years.

In summary, the company is in a build-up phase to prepare for long-term growth and development. Pre-tax results ended with a loss of NOK 17 million (minus NOK 9 million).

Cash flow and consolidated balance sheet

Of the capitalised assets, the company has patents worth NOK 5.7 million. These are capitalised patent costs in the Swedish subsidiary. Deferred tax assets stand at NOK 18.4 million, corresponding to the end of 2019, adjusted for Sweden. Tax calculations will be performed at the end of the year on revised figures.

Production has been initiated and investments of approximately NOK 5.8 million have been capitalised. This mainly applies to production facilities that have been put into operation.

Accounts receivable has increased significantly from last year and at the end of the year and apply to increased activity as well as SkatteFUNN funds.

During the first half of 2020, the company had a negative cash flow of NOK 40.6 million, of which NOK 11 million was due to repayment of short-term debt. As of 30 June 2020, capital holdings were NOK 35 million.

Outlook

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

- > Progressing work on the development of each individual project
 - SWIS complete clinical studies and quality system for medical device and submit application to *Notified Body* for CE marking
 - o SBE progress development towards PoC in humans
 - SIS progress the efficient development according to the advice of the medical authorities
- In the autumn of 2020, Sykehusinnkjøp HF will be inviting bids for the HINAS tender which includes the procurement of hygiene and patient care products for all Norwegian hospitals in the period 2021-2022 with the option of a two-year extension to 2024. For the first time, a separate category for non-alcoholic hand disinfectant has been opened up in this tender process
- Get disinfection products approved outside the Nordic region, including EU to launch the products in selected markets
 - Selection of European markets, where Germany is a high priority
- Resume activities in animal health
- In terms of marketing and sales, penetrating the Nordic healthcare market and establishing AntiVir Hånddesinfeksjon (AntiVir Hand Disinfectant) as a leading authority and brand in effective and skin-friendly disinfection will be the top priority. The establishment of a network of partners and distributors in Norway, Sweden and Denmark will be an important activity over the next 6-12 months

Declaration by the Board

We confirm, to the best of our knowledge, that the unaudited, summarised interim half-year accounts for the period 1 January to 30 June 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 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, 30 September 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 second quart	er and first l	half year 2	020		
SoftOx Solutions Group					
NOK 1,000	Q2 2020	Q2 2019	YTD 2020	YTD 2019	FY 2019
Other operating revenues	6 266	1 267	7 505	2 557	4 099
Total operating revenues	6 266	1 267	7 505	2 557	4 099
Personnel expenses	3 304	2 395	6 660	4 956	11 197
Other operating expenses	12 238	3 488	17 093	6 216	13 071
Depreciation	618	278	901	555	1 701
Depreciation, goodwill					
Total operating expenses	16 160	6 161	24 653	11 728	25 969
Operating result	-9 894	-4 893	-17 148	-9 171	-21 870
Net financial items	93	12	102	37	-308
Net result before taxes	-9 801	-4 882	-17 046	- <mark>9 13</mark> 4	-22 178
Тах					5 842
Net result after tax					-16 336

Statement of financial position	30.06.2020	30.06.2019	31.12.2019
SoftOx Solutions Group			
NOK 1,000			
Other intangible assets	5 675	2 711	4 928
Deferred tax asset	18 390	12 264	18 135
Goodwill from acquisition of subsidiary			
Total intangible assets	24 065	14 975	23 063
Production equipment	5 800	246	242
Total fixed assets Non-current assets	5 800	246	242 23 304
	29 865	15 221	
Other receivables	12 650	8 074	5 664
Total receivables	12 650	8 074	5 664
Cash and cash equivalents	35 431	2 856	75 996
Current assets	48 081	10 930	81 660
Total assets	77 946	26 151	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	-20 298	-12 814	-3 399
Total equity	70 478	22 926	86 469
Other long term debts	0	0	114
Other non-current liabilities			
Public duties payable	-544	831	659
Shareholder loans	0	0	3 101
Other current liabilities	1 742	819	3 622
Accounts payable	6 269	1 575	10 999
Total current liabilities	7 467	3 225	18 38
Total liabiities	7 467	3 225	18 49
Total equity and liabilities	77 946	26 151	104 965

	79 106				14 409
NOK 1,000	Q2 2020 Q	2 2019 Y	TD 2020 Y	TD 2019	FY 2019
Statement of changes in equity SoftOx Solutions Group					
cash and cash equivalents at end of period	33 431	2 801	33 431	2 001	75 99
Cash and cash equivalents at begining of Cash and cash equivalents at end of period	35 431	-4 595 2 861	35 431	2 861	
Net change in cash and cash equivalents Cash and cash equivalents at begining of	-18 934 54 365	7 454	-40 565 75 995	1 624 1 237	74 759 1 231
Net cash flow from financing activities	1 173	15 858	942	15 854	88 52
Translation differences	163	-36	46	-39	14
Other financing activities	0	-2 000	-114	-2 000	114
Proceeds from equity issues	1 010	17 894	1 010	17 894	88 394
Cash flow from financing activities					
Net cash flow from investment activities	-6 230	0	-7 461	0	-3 20:
Investments in non-current assets	-6 230		-7 461	0	-3 20:
Cash flow from investment activities					
Net cash flow from operating activities	-13 876	-8 404	-34 045	-14 230	-10 56
Change in current liabilities	306	-2 608	-10 915	-3 760	9 397
Change in current assets	-5 000	-1 192	-6 986	-1 892	518
Depreciation	618	278	901	555	1 70:
Tax paid					
Net result before taxes	-9 801	-4 882	-17 046	-9 134	-22 17
Cash flow from operating activities					
NOK 1,000					
SoftOx Solutions Group					
Cash flow statement	Q2 2020	Q2 2019	YTD 2020	YTD 2019	FY 2019

21879 quity at end of prior period 86 468 14 409 79 106 14 40 Share issues 1010 17 894 1010 17 894 88 393 Loss for the period -9801 -4 882 -17 046 -9 134 -16 336 163 46 -243 2 Other changes in equity 70 478 22 926 70 478 22 926 86 468 Equity at end of period

Notes to the half-year 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.