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# Report 4<sup>th</sup> quarter of 2019

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## Biofilm eradication

Fighting Chronic Wounds and Antimicrobial Resistance

*SoftOx Solutions AS (“SoftOx”) is a medtech company listed on the Merkur list, Oslo Stock Exchange with the ticker “SOFTOX-ME”. SoftOx was founded in 2012 and is headquartered in Oslo, Norway, with subsidiaries in Malmö and Copenhagen.*

*SoftOx develops a well-tolerated and highly efficient antimicrobial technology, which eradicates and prevents biofilm infections, based on years of research and product development with leading Nordic research institutes.*

## Highlights for the 4th quarter of 2019

- The first- in-human clinical trial of the wound rinsing product, SWIS, was completed and the results were reported.
- Signed distribution agreement with VESO, Norway's leading supplier of vaccines and medicines for animal health, as a part of the animal health line, in November of 2019.
- The company raised NOK 75 million (information regarding the placement has been published). The share issue was approved by the General Assembly the 20<sup>th</sup> of December of 2019.
- SoftOx was granted the tax incentive provision “Skattefunn” for its research projects, for the upcoming three years.

## Key figures

Key figures (NOK 1,000)

	2019	2018
<b>SoftOx Solutions Group</b>		
Total revenue and other income	4 216	4 323
Total operating expenses	24 387	21 609
<b>Operating result</b>	<b>-20 171</b>	<b>-17 286</b>
<b>Net result before taxes</b>	<b>-20 279</b>	<b>-17 466</b>
Net proceeds from equity issues	88 194	600
Net cash flow	70 246	-15 862
<b>Cash and cash equivalents at end of period</b>	<b>71 483</b>	<b>1 237</b>
Outstanding shares, beginning of the period	3 778 650	2 488 500
Outstanding shares, end of the period	7 751 000	3 778 650
Employees, end of the period	11	11

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## Operational review

### Product development

#### SWIS & BE wound care products

The development of SoftOx Wound Irrigation Solution (SWIS) and SoftOx Biofilm Eradicator (BE) is progressing according to plan. The intended use of SWIS is mechanical rinsing of acute wounds with ancillary antimicrobial action to prevent infections in wounds, while for BE it is to fight established biofilm infections. Both products are intended to be an alternative to antibiotic treatment in skin-related infections, specifically targeting chronic infections.

#### SafeDes™ - alcohol-free hand disinfectant

Offering health care workers as well as those with normal and sensitive skin a superior antimicrobial hand disinfectant. The formulation has shown no signs of inducing antimicrobial resistance and has recently been clinically tested in acute human wounds – showing excellent safety and tolerability, without impeding natural wound healing.

#### Effect Vet - animal products

SoftOx has two products in development targeting specific needs in animals:

*Wound Irrigation for small pets* is a mild, but effective solution to use on wounds and scratches to clean the wounds and prevent infections.

*Wound Irrigation in infected wounds* is the most effective solution in the product range. This product is intended for wounds that are hard to heal and/or infected.

SoftOx has established collaborations with commercial and scientific organizations and universities in the Scandinavian region including Copenhagen, Malmö, Lund, Trondheim and Oslo for the continued development of SoftOx' technology. This research is led by world leading experts on biofilm and antibiotic resistance specializing in both animal as well as human health. SoftOx has also continued its ongoing clinical collaboration with Excite International Toronto, Canada. The company is a member of the World Health Organization (WHO) in a division intended to fight Hospital Acquired Infections (HAI), known as POP's group.

## Major milestones in 4<sup>th</sup> quarter

#### Completed first clinical trial

First trial in humans shows positive effects in acute wounds. SoftOx Solutions' (SoftOx) first-in-man clinical trial (SWIS-01), its wound rinsing product, abbreviated SWIS, has been successfully completed. The pilot study which was conducted at the Department of Dermatology and Copenhagen Wound Healing Center at Bispebjerg University Hospital, was designed to explore safety and performance properties of SWIS in patients with split skin transplant donor sites, serving as a model for surgically inflicted acute wounds. Overall results show that SWIS has a very good safety profile, which was the primary endpoint of the study. Performance-wise, the SWIS irrigation procedure documents bacterial reduction, without impeding the epithelialization rate (wound closure). More information on this study can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT03742284).

**SoftOx signs a distribution agreement with VESO, one of Norway's leading companies for Animal Health.**

SoftOx signs distribution agreement with VESO one of Norway's leading companies for animal health, with 30 years of experience. The agreement opens a new and exciting market for SoftOx. VESO, is Norway's leading supplier of vaccines and medicines for animal health. In accordance with this agreement VESO will distribute SoftOx's new product line within disinfection and wound care in the animal health market. The total market for these types of products is approximately NOK 100 million in Norway. Distribution agreement including development opportunities. At this stage, SoftOx and VESO have entered into a distribution agreement for new, ready for market, products, however the agreement will also cover products which are currently under development at SoftOx. The new collaboration with Veso is a good indication that the company's cooperation with scientific institutions at the University of Copenhagen and University of University of Oslo paves the way for new and exciting opportunities within the treatment of bacterial infections in the wound space. The business area "animal products" opens a new market for SoftOx with a total value of NOK 6 billion globally. The agreement with VESO is the first commercial agreement within the segment and is a significant milestone for the company.

#### **Private placement completed and accepted by the General Assembly**

The General Assembly approved a share issue amounting to NOK 75 million, based on TNOK 62,5 in new share capital with a total of 3,125,000 issued shares, at a price per share of NOK 24.

The General Assembly has authorized the board of directors to issue shares with a nominal value of up to TNOK 16.

## **Major milestones in 1<sup>st</sup> quarter 2020**

### **Establish production facilities**

Production facilities for SoftOx hand disinfection are established, and test runs have been successfully completed.

### **Notified Body gained approval**

The European Union's new regulations for approval of medical devices (MDR) will be implemented in May 2020 and will require the appointed Notified Bodies to comply with the new MDR guidelines. SoftOx' selected Notified Body (Presafe) gained approval in February 2020.

### **Skattefunn**

SoftOx was granted the tax incentive provision "Skattefunn" for research projects, for the upcoming three years.

### **SoftOx Hand disinfection shows full viricidal effect on all types of viruses**

SoftOx hand disinfection has a fully viricidal effect on all types of viruses. SoftOx has received positive confirmatory study results from a well-recognized German Laboratory, Institute for Hygiene and Microbiology, led by Dr. Brill + Dr. Steinmann. The test, according to International standard EN 14476, shows that the company's hand disinfectant has full viricidal effects, as opposed to alcohol-based hand disinfection. This means that it inactivates and fights all kinds of viruses. It is also effective on Norovirus, - a virus that causes nausea and vomiting.

### **Proposed research at University of Copenhagen to explore possible effects on infections in the respiratory tract.**

By request from the University of Copenhagen, SoftOx Solutions AS has decided to co-finance a research team at the University of Copenhagen to start work on the effect of SoftOx when used for inhalation to combat viral and bacterial infections of the respiratory tract and lungs. SoftOx has allocated NOK 3.5 million to the project. Studies in animal models are expected to take 6 months. Starting March 30, SoftOx will begin searching for additional external funding to support further research .

### **Organizational information**

The company (including daughter companies) had a total of eleven employees at the end of the year.

### **Upcoming risk next three months**

#### **Covid 19, Corona Pandemic**

The Covid 19 virus pandemic has increased the risk level in the market and will potentially create delays around:

- Clinical trials for the hand disinfectant at Bispebjerg Hospital in Copenhagen
- Planned animal studies in Italy, which will in turn delay the product development of the company's infection remover BE

## **Financial review**

*Financial figures in this report are unaudited figures for the SoftOx Solution Group.*

“Other operating revenues in 2019 attribute mostly to accrued grants from the Norwegian Research Council under the BIA program and

“Skattefunn”. Total grants in 2019 were TNOK 4.216, compared with TNOK 4.323 last year.

Personnel expenses increased to TNOK 11.289 in 2019, compared to TNOK 8.183 in 2018, due to planned staff increases, both in the parent company and the Danish subsidiary.

“Other operating expenses decreased to TNOK 11.415 compared to TNOK 12.311 in 2018.

At the end of 2019 the group had cash in the amount of TNOK 71.483.

Net results before taxes, at the end of 2019 showed a net loss of TNOK -20,279 compared to TNOK -17,466 in 2018, mainly due to increased cost of personnel. Deferred taxes showed an increase of TNOK 5.126 in 2019 compared to TNOK 4.534 in 2018. Total of deferred taxes at end of 2019 was TNOK 17.390 compared to TNOK 12.305 at end of year 2018.

At the end of year 2019 the Group had other intangible assets of TNOK 4.775 compared with TNOK 3.343, primarily attributable to capitalized patent expenses in the Swedish subsidiary.

It must be noted, that pending an official audit for 2019, and an official financial statement, all numbers may be subject to change.

## **Outlook**

The company's plans for the upcoming twelve months include:

- Preparation and commencement of the confirmatory clinical investigation of SWIS medical device
- Commercialization and distribution of SoftOx-hand-disinfectant, following the signed agreement with KiiltoClean AS (previously Antibac)
- Completion of the preclinical repeated dose toxicity studies on BE drug candidates
- Preparation of first-in-human drug study (phase I) for BE
- Continued dialogue with European players for establishing a distribution partnership for SoftOx hand disinfectant products outside the Nordic and Baltic countries

SoftOx will offer three variants of wound cleanser (see product development for details) The EU animal wound-treatment market is valued at NOK 2 billion, with a CAGR of 6,5 %. The total market for disinfection and wound care in animals is NOK 100 million, in Norway.

In partnership with VESO, a market leader in the Norwegian market, SoftOx will distribute its wound cleansers for animals to the Norwegian market, in addition to seeking strong strategic partnerships for entry to the rest of Europe and the US.

### **SoftOx wound products**

The market for Biofilm Eradicator (BE) for treatment of chronic infections in leg ulcers is estimated at USD 7,2 billion in Europe and the US and USD 4 billion R.O.W. To secure market adoption the company will continue to cooperate closely with EXCITE International on clinical development.

The market for SoftOx Wound Irrigation Solution for prevention of chronic infections is estimated at USD 2 billion in Europe and the US.

## **The opportunity**

### **SafeDes hand disinfectant**

The market for SafeDes, SoftOx' premium non-alcoholic antimicrobial hand disinfection is valued at USD 20 bn in Europe and the US. Out of 18.8 million health care workers in the EU and the US, 13.3 million report irritated skin and eczema creating a large market opportunity.

In partnership with Kiiltoclean (Antibac), market leader in the region (est. >50% market share), SoftOx will distribute its hand disinfection products to Nordics/Baltics in addition to seeking strong strategic partnerships for entry in the rest of Europe and the US.

### **Effect Vet**

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## Declaration

*We declare that to the best of our knowledge the accounts for 2019 have been prepared in accordance with current accounting standards for the Group and that the disclosures in the accounts provide a true and fair view of the company's and the Group's assets, liabilities, financial position and results as a whole and that the quarterly report, including a description of the most important risk and uncertainty factors facing the Group, gives a true and fair view of the development, results and position of the entity and the Group.*

Oslo, 30<sup>th</sup> of March 2020

*SIGN*

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*Lars Johan Frigstad, Chairman*

*SIGN*

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*Kristian Almås, Director*

*SIGN*

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*Olav Trygve Jarlsby, Director*

*SIGN*

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*Kari Grønås, Director*

*SIGN*

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*Geir Hermod Almås, CEO*

<b>Profit and loss statement</b>		
<b>SoftOx Solutions Group</b>		
<i>NOK 1,000</i>	<b>2019</b>	<b>2018</b>
Other operating revenues	4 216	4 323
<b>Total operating revenues</b>	<b>4 216</b>	<b>4 323</b>
Personnel expenses	11 289	8 183
Other operating expenses	11 415	12 311
Depreciation	1 683	1 115
Depreciation, goodwill	0	0
<b>Total operating expenses</b>	<b>24 387</b>	<b>21 609</b>
<b>Operating result</b>	<b>-20 171</b>	<b>-17 286</b>
<b>Net financial items</b>	<b>-107</b>	<b>-179</b>
<b>Net result before taxes</b>	<b>-20 279</b>	<b>-17 466</b>
Tax	5 126	4 534
<b>Net result after tax</b>	<b>-15 153</b>	<b>-12 932</b>



<b>Statement of financial position</b>	<b>2019</b>	<b>2018</b>
<b>SoftOx Solutions Group</b>		
<i>NOK 1,000</i>		
Other intangible assets	4 775	3 343
Deferred tax asset	17 390	12 305
<b>Total intangible assets</b>	<b>22 165</b>	<b>15 648</b>
Production equipment	234	327
<b>Total fixed assets</b>	<b>234</b>	<b>327</b>
<b>Non-current assets</b>	<b>22 399</b>	<b>15 975</b>
<b>Financial non-current assets</b>		
<b>Total non-current assets</b>	<b>22 399</b>	<b>15 975</b>
Other receivables	6 131	6 182
<b>Total receivables</b>	<b>6 131</b>	<b>6 182</b>
Cash and cash equivalents	71 483	1 237
<b>Current assets</b>	<b>77 614</b>	<b>7 419</b>
<b>Total assets</b>	<b>100 013</b>	<b>23 393</b>
Share capital	155	76
Other paid in equity	106 085	17 771
<b>Total paid in equity</b>	<b>106 240</b>	<b>17 846</b>
Other equity	-18 632	-3 438
<b>Total equity</b>	<b>87 607</b>	<b>14 409</b>
Public duties payable	1 420	706
Shareholder loans	3 101	2 000
Other current liabilities	3 835	1 868
Accounts payable	4 049	4 411
<b>Total current liabilities</b>	<b>12 406</b>	<b>8 985</b>
<b>Total liabilities</b>	<b>12 406</b>	<b>8 985</b>
<b>Total equity and liabilities</b>	<b>100 013</b>	<b>23 393</b>

<b>Cash flow statement</b>	<b>2019</b>	<b>2018</b>
<b>SoftOx Solutions Group</b>		
<i>NOK 1,000</i>		
<b>Cash flow from operating activities</b>		
Net result before taxes	-20 279	-17 466
Tax paid	0	0
Depreciation	1 683	1 115
Change in current assets	51	-3 386
Change in current liabilities	2 319	2 794
<b>Net cash flow from operating activities</b>	<b>-16 225</b>	<b>-16 943</b>
<b>Cash flow from investment activities</b>		
Investments in non-current assets	0	-1 444
<b>Net cash flow from investment activities</b>	<b>0</b>	<b>-1 444</b>
<b>Cash flow from financing activities</b>		
Proceeds from equity issues	88 194	600
Other financing activities	-1 700	2 000
Translation differences	-22	-75
<b>Net cash flow from financing activities</b>	<b>86 471</b>	<b>2 525</b>
<b>Net change in cash and cash equivalents</b>	<b>70 246</b>	<b>-15 862</b>
Cash and cash equivalents at beginning of period	1 237	17 098
<b>Cash and cash equivalents at end of period</b>	<b>71 483</b>	<b>1 237</b>

<b>Statement of changes in equity</b>			
<b>SoftOx Solutions Group</b>			
<i>NOK 1,000</i>	<b>Share capital</b>	<b>Other paid in equity</b>	<b>Total equity</b>
<b>Balance at 01.01.2018</b>	<b>50</b>	<b>30 263</b>	<b>26 846</b>
Loss for the period		-12 929	-12 932
Share issues	26	574	600
Other changes in equity		-137	-105
<b>Balance at 31.12.2018</b>	<b>76</b>	<b>17 770</b>	<b>14 409</b>
			<b>0</b>
<b>Balance at 01.01.2019</b>	<b>76</b>	<b>17 770</b>	<b>14 409</b>
Loss for the period			-15 153
Share issues	79	88 314	88 394
Other changes in equity	0		-42
<b>Balance at 31.12.2019</b>	<b>155</b>	<b>106 085</b>	<b>87 608</b>

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## **Notes to the Quarterly Financial Statement**

### Note 1 Accounting policies

The financial statements of SoftOx Solutions Group are presented in accordance with the Norwegian Accounting Act and generally accepted accounting principles for small-size companies.