



# SoftOx Solutions AS

Medtech and pharmaceutical company listed on Euronext Growth

Presentation Q3 2022

26 October 2022



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## Presenters



**Highlights, SoftOx in brief & Commercial development**  
CEO Geir Almås



**SoftOx technology development**  
CMO Dr Christopher Burton



**Financial review**  
CFO Kristine Rød



01

Third quarter highlights and SoftOx in brief

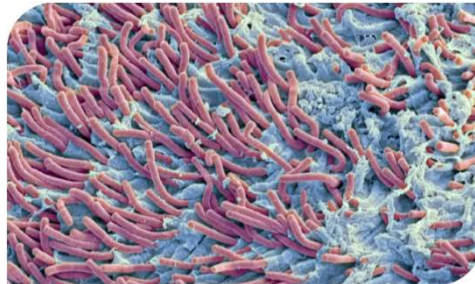
## Helping the world fighting infections

### VIRUSES



Respiratory infectious diseases are among the **leading causes of death** <sup>[1]</sup>

### BIOFILM RESISTANCE



**1-2% of the population** are projected to experience a chronic wound during their lifetime in developed countries <sup>[2]</sup>

### ANTIMICROBIAL RESISTANCE



AMR is regarded as one of the **biggest threats** to global health <sup>[3]</sup>

**Our vision is to become a world-leading developer of antimicrobial technology**

- 1) Forum of International Respiratory Societies (2019). The Global Impact of Respiratory Disease – Second Edition. Sheffield, European Respiratory Society.
- 2) Sen, C.K. et al. (2009) Human Skin Wounds, *Wound Repair Regen*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2810192/>
- 3) IACG (2019). No Time to Wait, WHO. [https://www.who.int/antimicrobial-resistance/interagency-coordination-group/IACG\\_final\\_report\\_EN.pdf?ua=1](https://www.who.int/antimicrobial-resistance/interagency-coordination-group/IACG_final_report_EN.pdf?ua=1)

## Third quarter highlights and subsequent events

### RESEARCH & DEVELOPMENT

Early completion of **SBE-01** study evaluating the SoftOx Biofilm Eradicator (SBE) in treating chronic wounds

**Positive top line results of SBE-01** showed SBE was safe and well tolerated

Selected as **one of three main technologies** that form the basis for the European Defence Fund (EDF) grant

### COMMERCIAL DEVELOPMENT

Received **final approval on SoftOx disinfectant family in Sweden** (KemI) which allows SoftOx to sell disinfection products in Sweden and proceed with partner opportunities to bring products to market






### FINANCE

Q3 result of NOK -23.7 million (LY: NOK -22 million)

Secured a convertible loan from existing shareholders for NOK 25 million and refinanced NOK 15 million convertible loan reported in June 2022



## Product pipeline – Good progress in clinical development programs

Product classification	Project	Indication	Pre-clinical/ EN studies	Phase I/ Pilot studies	Phase II/ Confirmative studies	Pending regulatory approval
BIOCIDE	Disinfection (SafeDes & EffectDes)	Surface disinfectant Hand disinfectant				
MEDICAL DEVICE	Wound irrigation solution (SWIS)	Wounds				
DRUG	Infection treatment (SBE)	Chronic leg wounds				
	Inhalation solution (SIS)	Respiratory tract infections				
	Military medical countermeasure	CBRN threats				

This table presents a simplified version of the development phases as processes vary for biocide, medical device and drug development



02

SoftOx technology development



## SoftOx technology – successfully developed a stable and long-lasting product with unique combination effects

### HYPOCHLOROUS ACID

Documented broad  
antimicrobial effect



### ORGANIC ACID

Antimicrobial  
stabilizer



### SOFTOX TECHNOLOGY

Strong pan-spectrum antimicrobial  
(virucidal/bactericidal) effects

Not shown to induce antimicrobial resistance

Good safety and tolerability profile –  
no systemic side effects

Stabilized molecule

A base technology tailored for different indications and uses

## Business segments



### Wounds

Infection prevention and treatment for acute and chronic wounds



### Respiratory

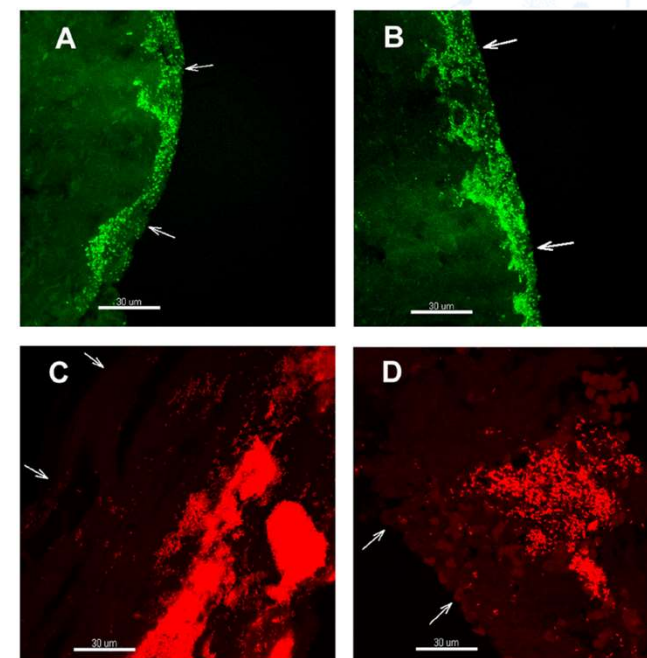
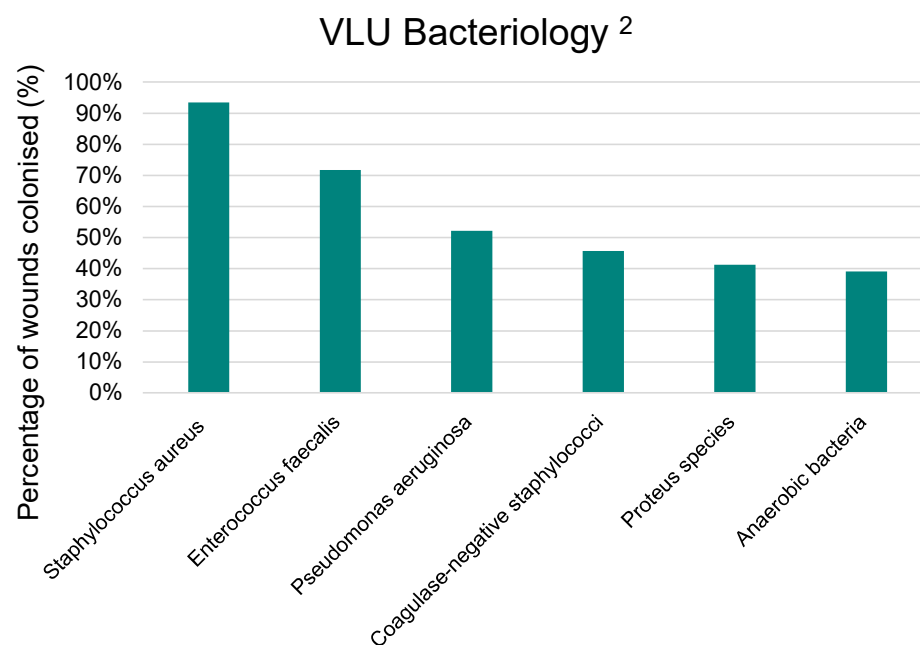
Treatment of viral infections



### Disinfection

Infection prevention solutions for hands and surfaces

# Infection is one of the most frequent factors associated with delayed wound healing<sup>1</sup>



Representative CLSM images of *S. aureus* (A and B), *P. aeruginosa* (C and D). Arrows point to the wound surfaces.

40-70% of venous leg ulcers are colonized by multiple (~5 to 6) bacterial species<sup>2</sup> which often cluster in biofilms with variable distance to the wound surface

1. EWMA (2022). Antimicrobials and Non-healing Wounds: An Update. *Journal of Wound Management*. <https://viewer.ipaper.io/jowm/1035279jowm20222303/sup01/>

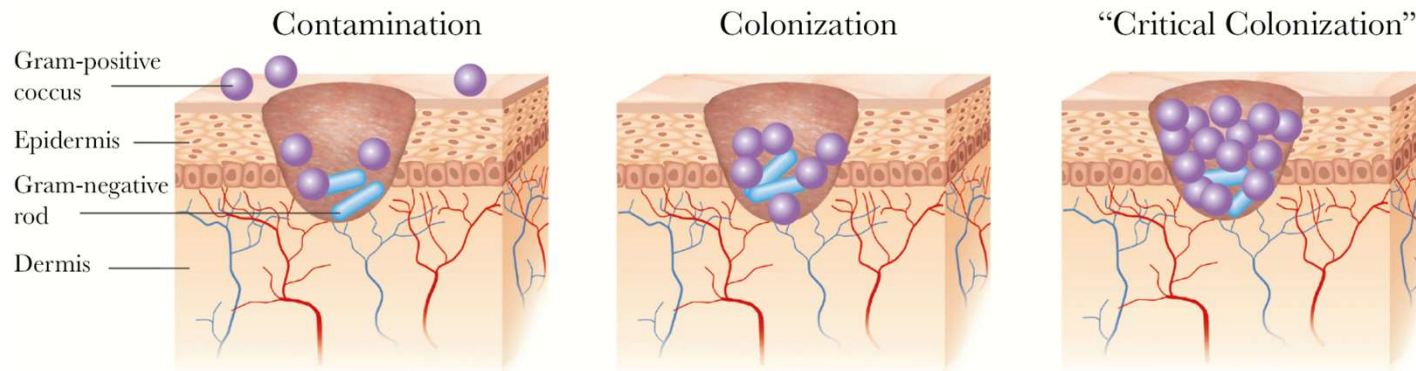
2. Gødsbøl et al, Copenhagen Wound Healing Center; 2. Fazli et al. J Clin Microbiol 2009 Dec;47(12):4084-9

# First line prevention and treatment of locally infected wounds (i.e. no evidence of systemic infection)



## PREVENTION

### Pathogenesis of Open Wound Infections



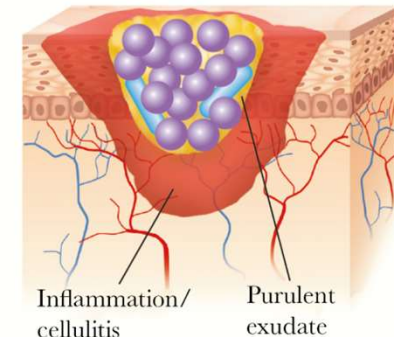
**Figure.** The typical evolution of a superficial wound infection.

*A Proposed New Classification of Skin and Soft Tissue Infections Modeled on the Subset of Diabetic Foot Infection, Open Forum Infect Dis. 2016*

## TREATMENT



### Infection Local/Systemic

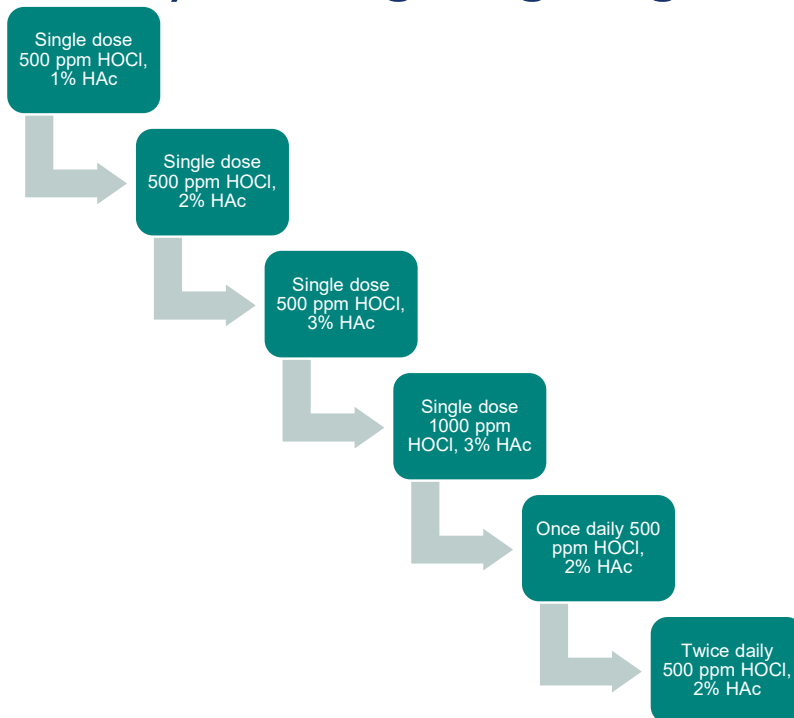


**By definition, VLUs are most likely beyond critical colonization at presentation.**

Dose dependent response answers on different wound needs, depending on colonization



## Positive results from Phase 1 in treatment of chronic wounds (SBE-01) investigating single- and multiple ascending doses SBE



### Topline results

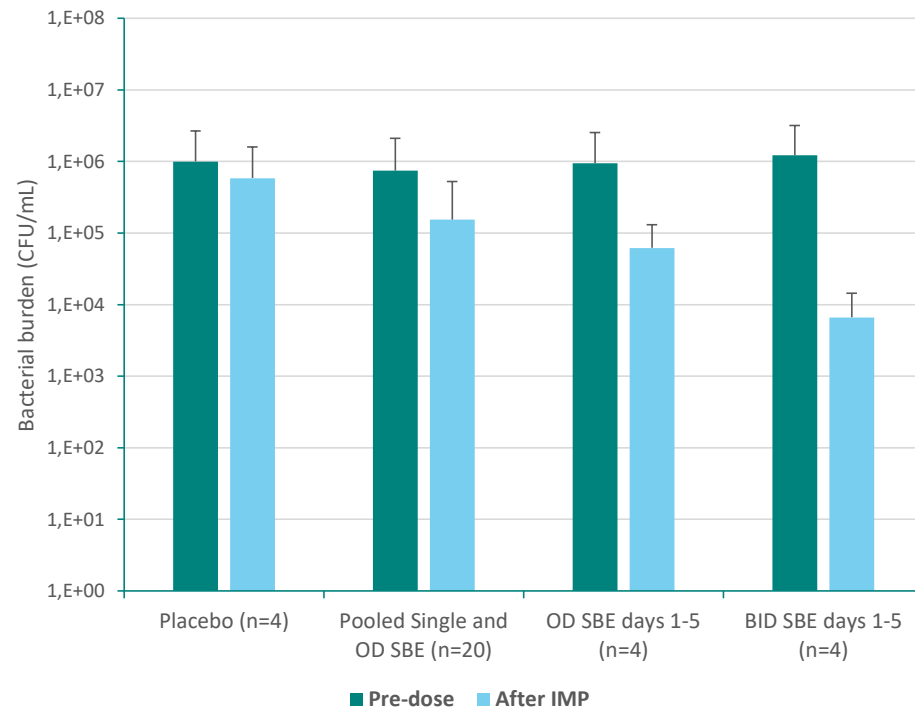
- Safe and well tolerated
- SBE formulations reduced the absolute number of bacteria (bacterial burden) in the wound compared with pre-treatment (baseline).
- A dose dependent reduction in wound size was observed in multiple dose treatment groups.

Safe and well tolerated





## Positive results from Phase 1 in treatment of chronic wounds (SBE-01) investigating single- and multiple ascending doses SBE



### Topline results

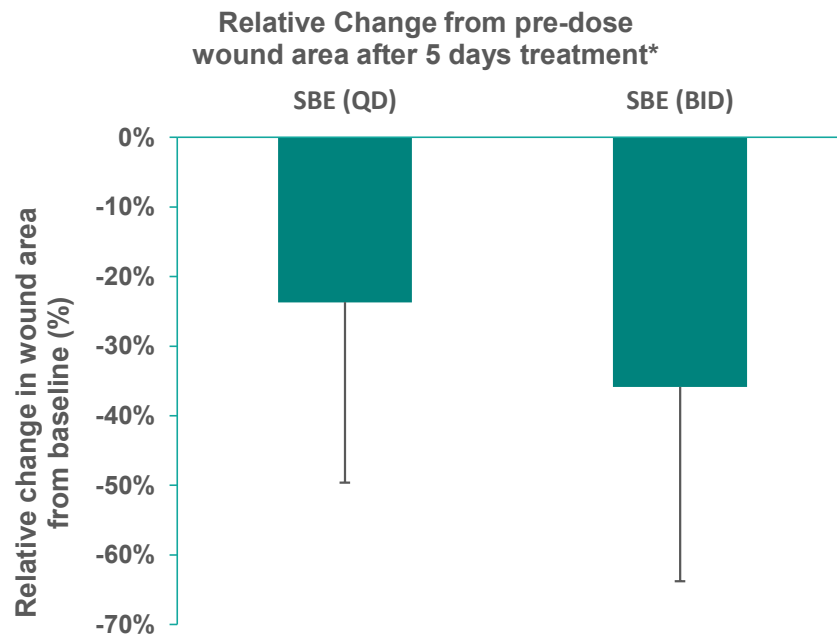
- Safe and well tolerated
- SBE formulations reduced the absolute number of bacteria (bacterial burden) in the wound compared with pre-dose (baseline).
- A dose dependent reduction in wound size was observed in multiple dose treatment groups.

Observed reductions in bioburden\*

\*) SBE-01 trial pooled & multiple dosing groups.  
Data on file. Means  $\pm$  standard deviation



## Positive results from Phase 1 in treatment of chronic wounds (SBE-01) investigating single- and multiple ascending doses SBE



### Topline results

- Safe and well tolerated
- SBE formulations reduced the absolute number of bacteria (bacterial burden) in the wound compared with pre-treatment (baseline).
- A dose dependent reduction in wound size was observed in multiple dose treatment groups.

Observed dose dependent trend in reduction of wound size\*

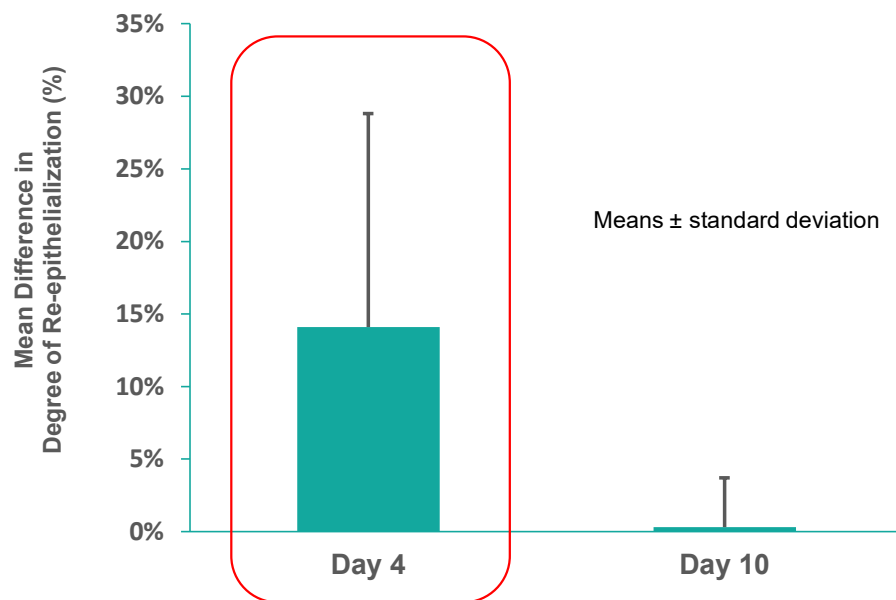
\*) SBE-01 trial multiple dosing groups.  
Data on file. Means  $\pm$  standard deviation



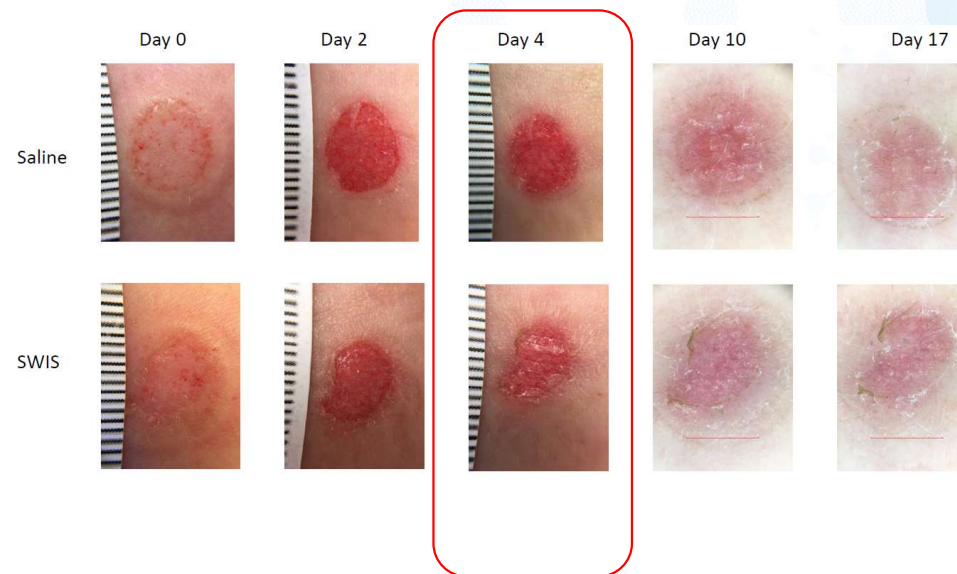
# Clinical effect of re-epithelialization in acute wounds supports finding in chronic wounds



Mean Difference in degree of re-epithelialization:  
SWIS vs. sterile saline



Picture of re-epithelialization in acute wounds:  
SWIS vs. sterile saline



Evidence of faster re-epithelialization in acute wounds

## SBE-02 - US Phase 2 follow up study

- Blinded, randomised, PC, 2 arm: **SBE vs. Normal Sterile Saline (NSS)**
- Patients with chronic ulcers of lower extremities (VLU)
- Treatment regimen: Once daily, 3 times per week for 4 weeks
- **End points:**
  - Clinical evaluation of wound
  - Microbial determination, reduction of bacterial burden
  - Percentage wound closure
  - Re-epithelialisation
  - Safety (AEs)



*Co-funded by US Medical Technology Enterprise Consortium (MTEC)*

USA icon by Alexander Skowalsky from [Noun Project](#)

## Business segments



### Wounds

Infection prevention and treatment for acute and chronic wounds



### Respiratory

Treatment of viral infections



### Disinfection

Infection prevention solutions for hands and surfaces

## SoftOx Inhaled Solution (SIS): Summary of development within civilian indication



Civilian treatment  
of endemic  
disease

Non-clinical  
proof of  
concept

Clinical safety  
and tolerability

Clinical proof of  
concept

Confirmatory  
clinical studies

# SoftOx Inhaled Solution (SIS): Exploring potential military applications as a countermeasure to biologic threats



Civilian treatment  
of endemic  
disease

Non-clinical  
proof of  
concept

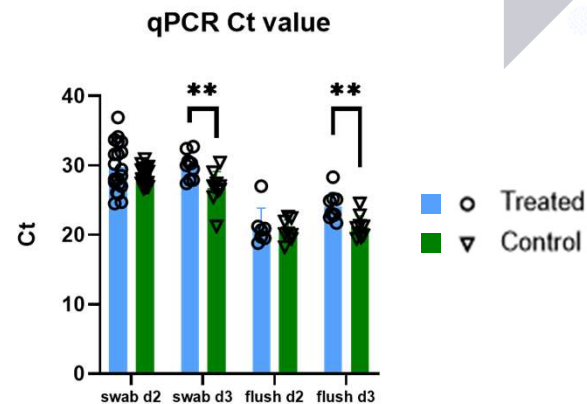
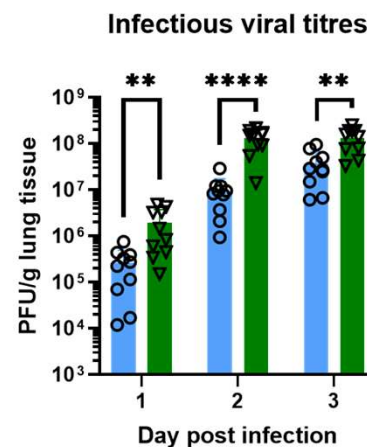
Clinical safety  
and tolerability

Clinical proof of  
concept

Confirmatory  
clinical studies

## SIS non-clinical in vivo Proof of Concept

Reproducible, dose dependent treatment effects of SIS in mice infected at day 0 with Influenza A virus strain A/Puerto Rico/8/1934 (H1N1)



Data on file. Mann-Whitney test, \*\*( $P < 0.01$ ), \*\*\*\* ( $P < 0.0001$ ).



## SoftOx Inhaled Solution (SIS): Exploring potential military applications as a countermeasure to biologic threats



## Civilian treatment of endemic disease

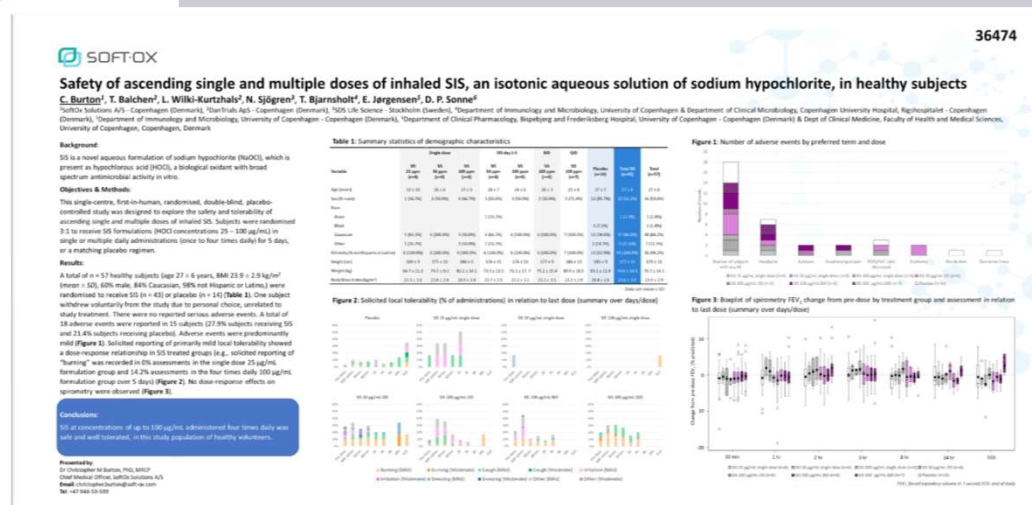
## Non-clinical proof of concept

## Clinical safety and tolerability

## Clinical proof of concept

## Confirmatory clinical studies

**SIS clinical safety and tolerability**  
SIS at concentrations of up to 100 µg/mL administered four times daily was safe and well tolerated, in this study population of healthy volunteers



## SoftOx Inhaled Solution (SIS): Exploring potential military applications as a countermeasure to biologic threats



Civilian treatment  
of endemic  
disease

Non-clinical  
proof of  
concept

Clinical safety  
and tolerability

Clinical proof of  
concept

Confirmatory  
clinical studies



Bridging



Bridging



Military  
countermeasure  
to biologic  
threats

Non-clinical  
proof of  
concept

Clinical safety  
and tolerability

Clinical proof of  
concept

Confirmatory  
clinical studies



## Business segments



### Wounds

Infection prevention and treatment for acute and chronic wounds



### Respiratory

Treatment of viral infections



### Disinfection

Infection prevention solutions for hands and surfaces

## Regulatory approval in Sweden

### Swedish Chemicals Agency final approval – October 2022

- Received final approval on application for SoftOx biocidal product family for hand and surface disinfection
- Approval allows SoftOx to sell its disinfection products in Sweden
- Can be used as basis for new applications (mutual recognition in sequence) to enter other European markets
- Proof that products are a safe and effective alternative to alcohol-based disinfectants



Major milestone achieved: SoftOx's first regulatory approval



# 03

Markets & commercial development

## Market potential in disinfection

### Cost-saving and life-improving

75%

of HCWs with hand eczema have Staphylococcus aureus biofilm infection <sup>[1]</sup>

25–55%

of health care workers (HCWs) have irritated skin and eczema <sup>[1]</sup>



#### Major cost driver of HAIs

Direct relationship between hand hygiene compliance and HAIs<sup>[2]</sup>



#### 31 million HCWs in the EU & the US <sup>[3] [4]</sup>

Whereof 10 million have irritated skin and eczema<sup>[5]</sup>



### Clinically proven skin friendliness

*“The skin barrier function of the healthy skin is **unaffected** by the repetitive exposure to SafeDes solution as compared to alcohol-based hand rubs. SoftOx’s hand disinfectant is subjectively well-tolerated when applied on both healthy and irritated skin.” <sup>[6]</sup>*

Department of Dermatology, Bispebjerg Hospital,  
University of Copenhagen

- 1) Tomczak, H. et al. (2019). The role of Staph aureus in atopic dermatitis. Adv Dermatol Allergol; XXXVI (4): 485–491
- 2) MedValue+, Radboud University Medical Center and Exite International's Panel of 11 KOL/experts – “2019 Health Technology Assessment; SoftOx Hand-wash for Health Care Workers with Eczema”
- 3) Eurostat- Majority of Health Jobs Held by Women (2020)
- 4) Kaiser Family Foundation – Total Health Care Employment (2020)
- 5) National Eczema Association – Hand Eczema Common Among Health Care Workers
- 6) Yasemin Topal Yüksel, Mie Sonne, Line Brok Nørreslet, Glenn Gundersen, Magnus Mustafa Fazli, Tove Agner. Skin Research and Technology 2021; DOI: 10.1111/srt.13096

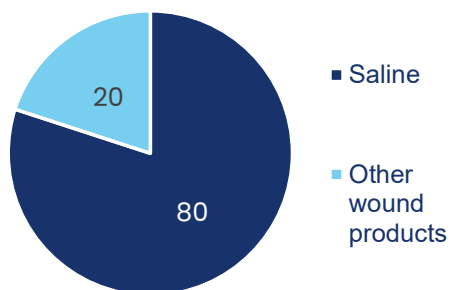
## Market potential in wound care

### ACUTE WOUNDS

180 million

Individuals have skin wounds worldwide each year<sup>1</sup>

Today's wound rinse market is **dominated by saline**



Replacing today's wound rinse products with a better or equal risk profile and profound antimicrobial effect

### CHRONIC WOUNDS

40 million

Chronic wounds worldwide<sup>1</sup>

1-2%

of population are projected to have a chronic wound in developed countries<sup>2</sup>

Venous leg ulcers (VLUs)

Target US patient population (2018)

2,323,804

Prevention of infections (costs) / patient

-\$643

Estimated **\$1.5 billion potential cost savings** in prevention of infections in VLUs<sup>3</sup>

Improving today's chronic wound treatment with more effective removal of infections protected by biofilm



1) MedMarket Diligence (2011). Wound prevalence and wound management: 2012-2020

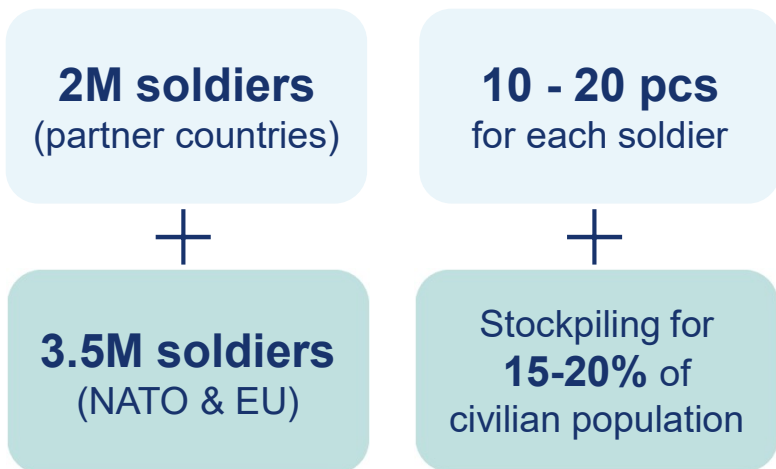
2) Sen, C.K. et al. (2009) Human Skin Wounds, Wound Repair Regen, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2810192/>

3) MedValue & Radboud University (2019). Decision Modeling Assessment.

## Market potential of inhalation solutions

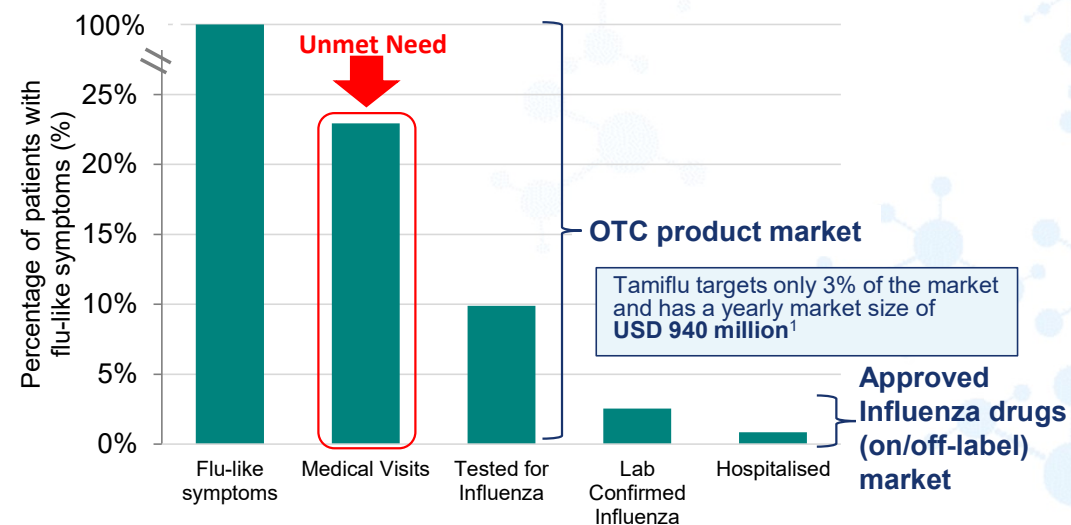
### Defence

Expected 3-year stock 250 million units within NATO & partners<sup>2</sup>



### Civil

12% experiences flu-like symptoms annually



EDF cooperation on SIS represents huge income potential to SoftOx

1) Transparency Market Research - Tamiflu (Oseltamivir Phosphate) Market (2019)  
2) Company estimate



04

Financial review



## Financial review

### Profit and loss statement Accounts for Q3 and FY 2021

#### SoftOx Solutions Group NOK 1,000

	Q3 2022	Q3 2021	Change	FY 2021
Operating revenue	0	-382		1 752
Grants	2 037	1 895		6 150
<b>Total operating revenues</b>	<b>2 037</b>	<b>1 513</b>	<b>35%</b>	<b>7 901</b>
Personnel expenses	6 931	5 959	<b>16%</b>	21 113
Other operating expenses	17 437	16 748		69 107
Depreciation	928	721		3 784
<b>Total operating expenses</b>	<b>25 296</b>	<b>23 428</b>	<b>8 %</b>	<b>94 004</b>
<b>Operating result</b>	<b>-23 259</b>	<b>-21 915</b>	<b>6 %</b>	<b>-86 102</b>
<b>Net financial items</b>	<b>-461</b>	<b>-121</b>		<b>-189</b>
<b>Net result before taxes</b>	<b>-23 720</b>	<b>-22 036</b>	<b>8 %</b>	<b>-86 291</b>
Tax				20 888
<b>Net result after tax</b>				<b>-65 403</b>

### Operating revenue

Low operating income due to low sales

### Operating expenses

R&D expenses accounted for approx. 64% of operating expenses year to date 2022.

## Financial review

Cash flow statement	Q3 2022	Q3 2021	FY 2021
SoftOx Solutions Group NOK 1,000			
<b>Cash flow from operating activities</b>	<b>-2 603</b>	<b>-13 713</b>	<b>-72 561</b>
Net result before taxes	-23 720	-22 036	-86 291
Depreciation	928	721	3 784
Change in current assets	12 772	4 287	3 061
Change in current liabilities	7 418	3 315	6 886
<b>Cash flow from investment activities</b>	<b>-1 934</b>	<b>-814</b>	<b>-4 596</b>
Investments in non-current assets	-1 934	-814	-4 596
<b>Cash flow from financing activities</b>	<b>701</b>	<b>-5</b>	<b>99 339</b>
Proceeds from equity issues	0	0	89 018
Other financing activities	0	0	10 355
Translation differences	701	-5	-34
<b>Net change in cash and cash equivalents</b>	<b>-3 836</b>	<b>-14 535</b>	<b>22 182</b>
<b>Cash and cash equivalents at end of period</b>	<b>3 278</b>	<b>16 596</b>	<b>56 984</b>

## Net change in cash and cash equivalents

- Strong focus on the product development and commercialisation processes while managing cash situation carefully
- Raised convertible loan from existing shareholders for NOK 25 million and refinanced the NOK 15 million convertible loan reported in June.
- Initiated a cost improvement plan to defer noncritical R&D activities, reduce future overhead and infrastructure expenditures



05

Summary

## Future SoftOx technology platform opportunities

### Platform products under development

☒ **Hand disinfection**

*Topical infection prevention for non-compromised skin*

☐ **Wound care for chronic and acute wounds**

*Topical infection prevention*

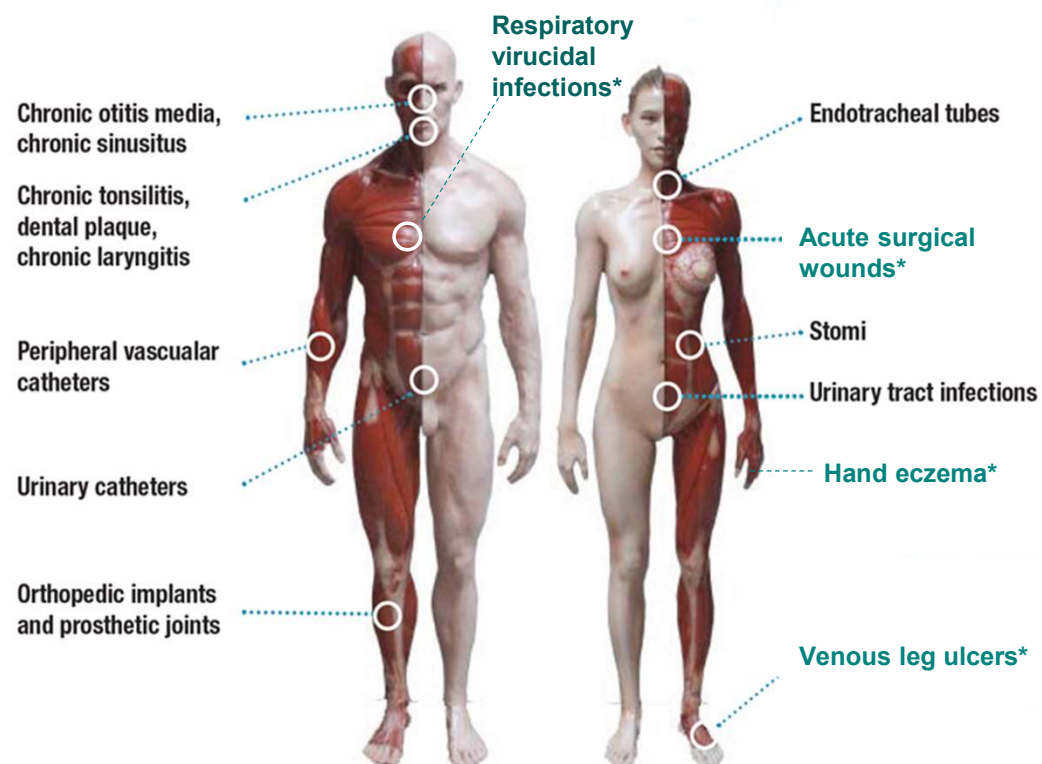
*Topical infection remover*

☐ **Respiratory**

*Topical infection remover in the respiratory track*

☐ **Military medical countermeasure**

*Inhalation treatment against CBRN threats*



\* Development projects already started



*Unique solution for eradicating infections and  
fighting antimicrobial resistance*

**Contact Information:** [ir@soft-ox.com](mailto:ir@soft-ox.com)

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