Helping the world fighting infections

SoftOx Solutions AS

Norwegian medtech and pharmaceutical company

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A breakthrough fighting infections

Next Generation SoftOx

Stable solutions at higher concentrations

Results achieved:

- Developing second generation SoftOx
  - Market leader on efficacy
  - Unique environmental profile
  - Efficient business model
- Abstract presented US Military Health System Research Symposium Aug 23

Respiratory Care

Next step:
Proof of Concept in humans

Results achieved

- Human safety proved
- Repeated studies in mice documented
- Prophylactic and curative effects towards virucidal infections
- Lead partner in EDF/Counteract*
- Partnership with University of Copenhagen

Wound Care

Next step:
Establish separate company

Results achieved

- Proof of concept (PoC) in humans
- Reduction in bacterial load
- Decreased wound size

*EDF/Counteract (European Defense Fund)

Overview development of SoftOx the next 2 – 3 years

Wound and skin care

Today

Proof of concept on both treatment and prophylactic use in human

2024-25

Approval Medical device EU/US

★ Phase 2 SBE Infection remover

Outsource production First- and Next- Generation Technology

Distribution Animal Health in EU

2026

Distribution of SoftOx wound cleanser in EU and US

Sale or listing as separate unit

Respiratory

Today

Phase 1 human safety and proof of concept in animals

2024

Bridging the civil data into military application

2025/2026

Phase 1 Maximum Tolerated Dose finding study

★ Start Phase 2

★ Separate Funding

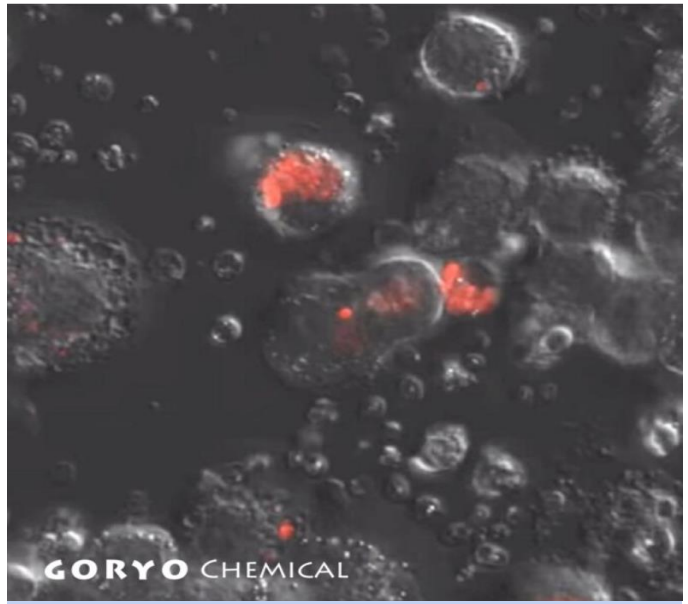
01

Platform technology

Reinforcing nature's own ability to eradicate unwanted microbes

HYPOCHLOROUS ACID

Documented broad antimicrobial effect



Picture of HOCl in action within human immune cells

- Disrupts microbial replication, budding & host cell entry
- Disrupts microbial integrity & repair
- Disrupts nucleic acid synthesis & metabolism
- Increases microbial immunogenicity

The chemical solution: Reinforcing nature's own ability to eradicate unwanted microbes

HYPOCHLOROUS ACID
Documented broad antimicrobial effect

+

ORGANIC ACID
Antimicrobial stabilizer & biofilm eradicator

→

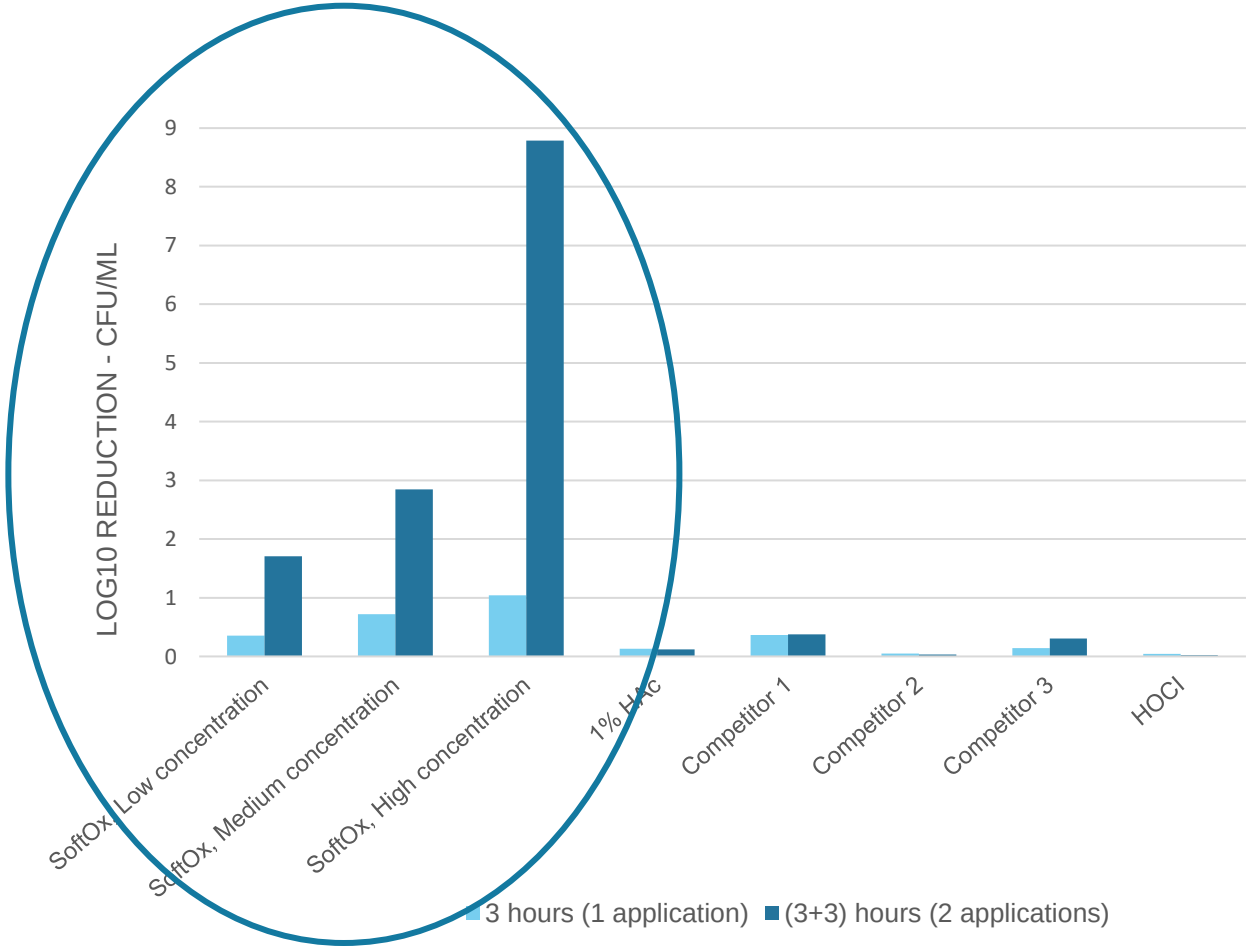
SOFTOX TECHNOLOGY

- **Strong pan-spectrum antimicrobial (virucidal/bactericidal) effects**
- **Not shown to induce antimicrobial resistance**
- **Good safety and tolerability profile – no systemic side effects**
- **Stabilized formulation**

Synergistic properties give unique ability to eradicate biofilm infections in wounds

Unrivalled combination effect on bacterial biofilms

SoftOx with increased amount of Acetic Acid

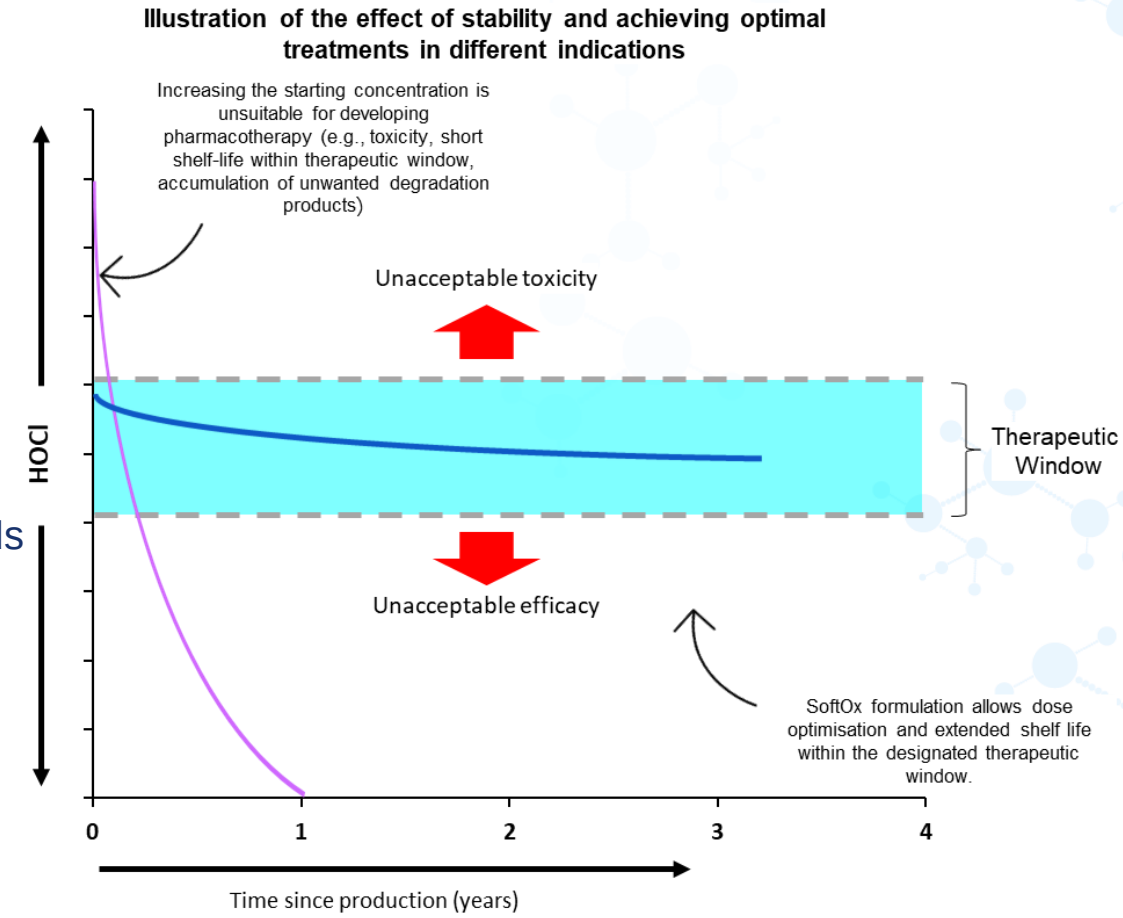


Outperforming market leading competitors

SoftOx Antimicrobial Technology

Next Generation SoftOx technology even better

- Final product is the same as todays SoftOx
- Stability, less than 5% degradation over 2 years
- Different acids to different needs
  - Including possibility to remove scent of acetic acid
  - Concentrations up to 1.000 ppm tested in human wounds
- Remain time for patents pending 19 years
- When double the amount of active substance
  - Increase the effect with 100 times (>log 5 vs >log 3)
  - Half the time required for disinfection



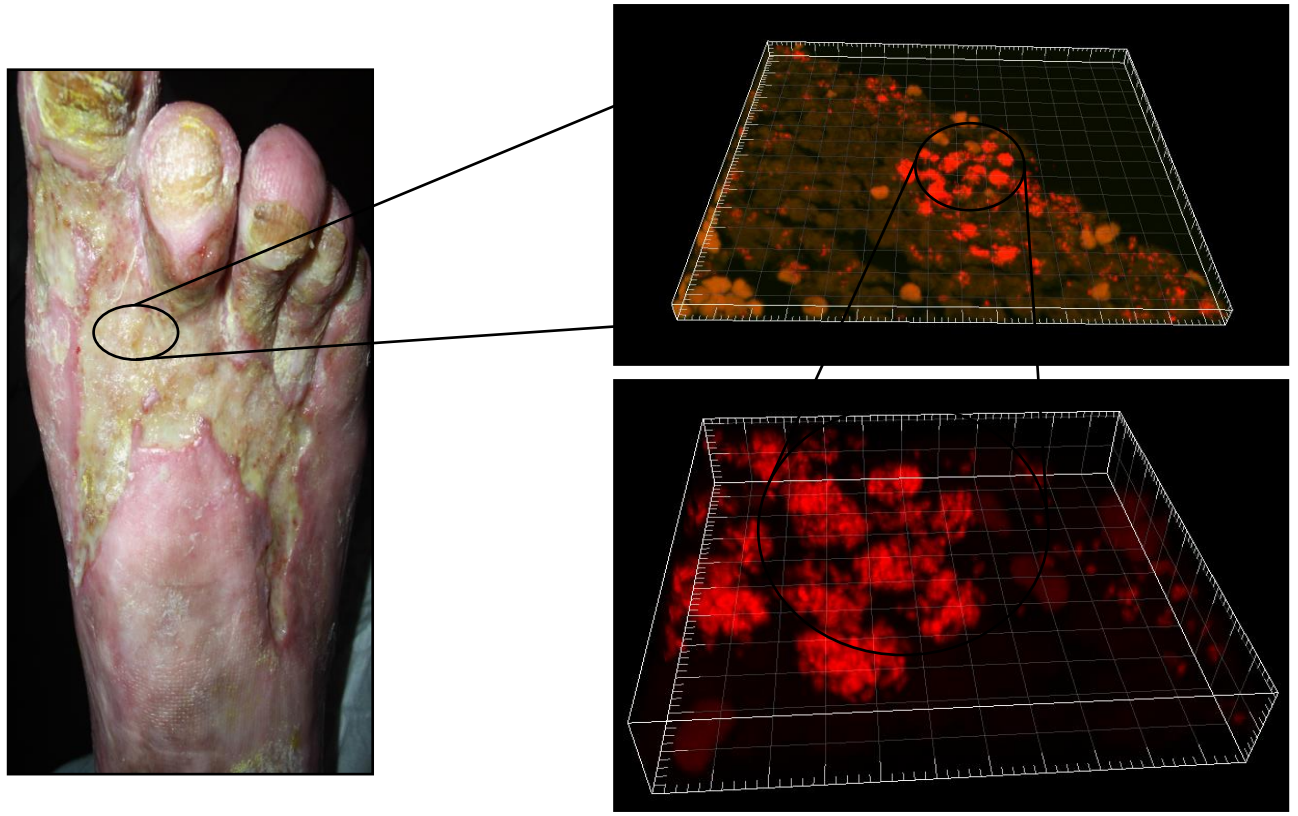
The Combination effect together with Second generation gives SoftOx a unique position

02

Wound and Skin care

Chronic wounds, biofilms and antibiotic resistance – a major treath

- Chronic wounds impact the quality of life (QoL) of nearly 2.5% of the total population in the United States
- Diabetic foot ulcers (DFUs) (30.5%) have a comparable 5-year mortality rate to cancer (31%)
- Induces tolerant biofilms to induce new resistances
- Due to poor blood circulation, antibiotics often do not even reach the infection
- Due to dormant bacteria, the doses with antibiotics needed to be a to high to be safe

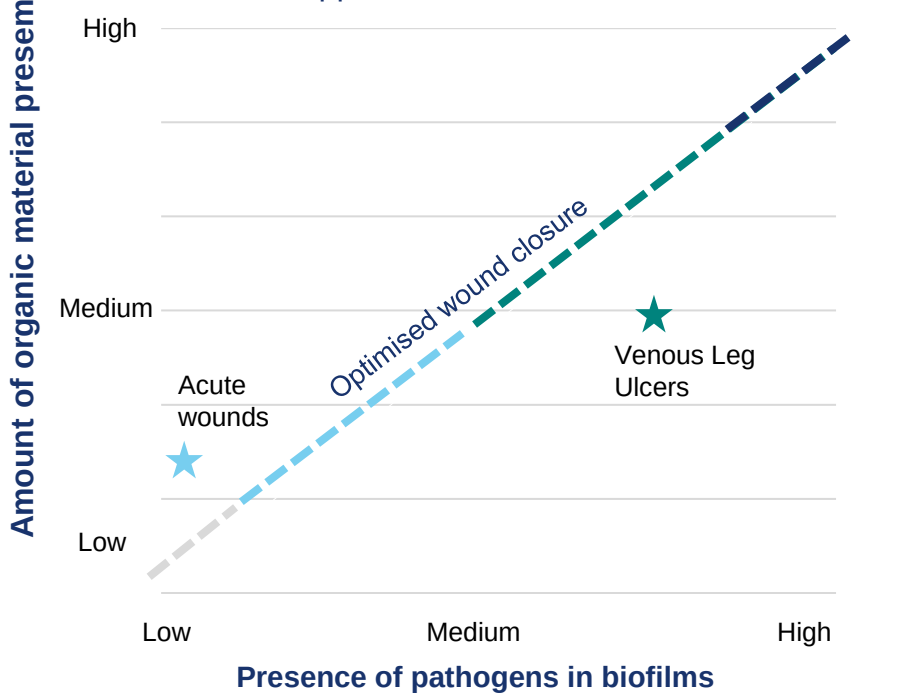


The global advanced wound care market is projected to reach $18.7 billion by 2027

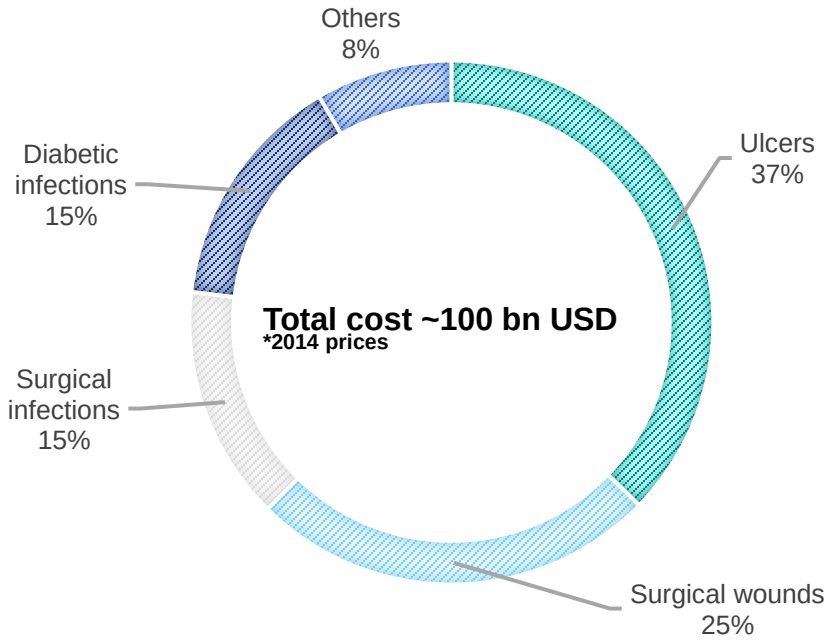
The cost drivers in wound care – infections and lack of wound healing

SoftOx's synergistic antimicrobial effect

Creates opportunities to treat different wounds

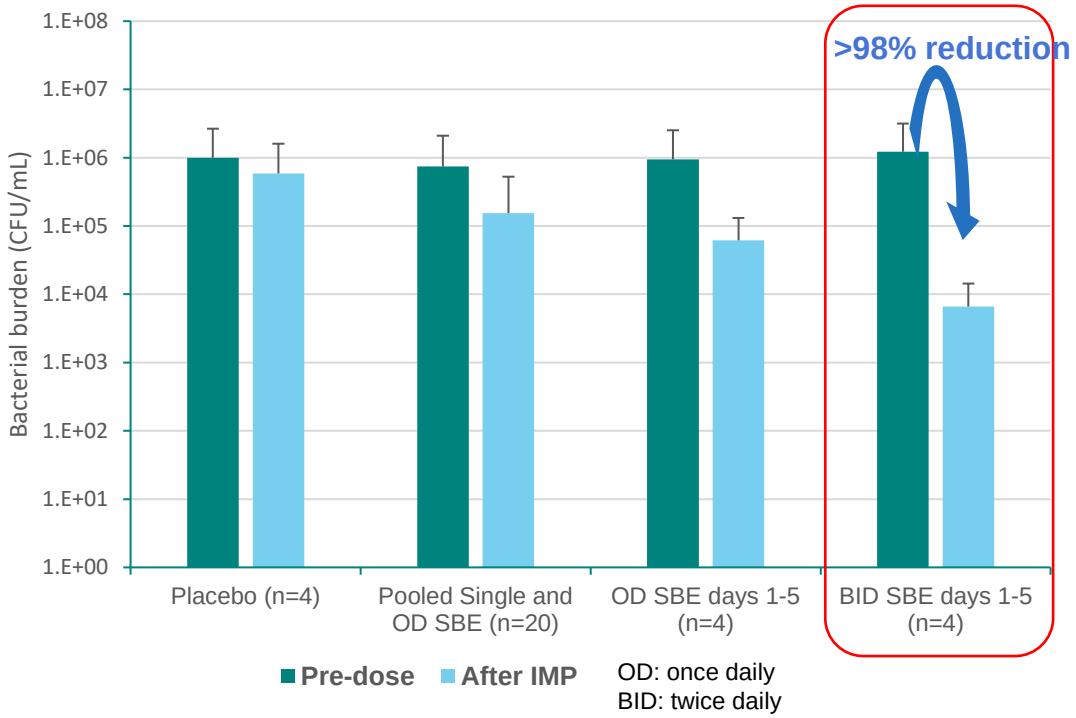


Cost of wound care – Medicare[2]



1. Effects of stabilized hypochlorous acid on re-epithelialization and bacterial bioburden in acute wounds, Ewa A Burian et al. Acta Derm Venereaol 5/2022
2. An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds, Samuel R. Nussbaum, MD et al. 2018

Results in treatment of leg ulcers (SBE-01) show >98% reduction in bacterial bioburden



Topline results

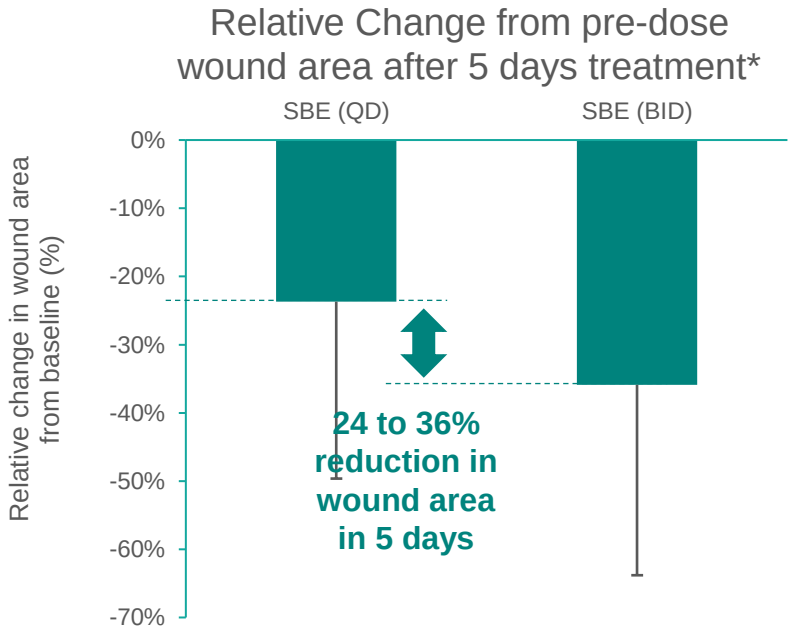
- Safe and well tolerated
- SBE formulations reduced the absolute number of bacteria (bacterial burden) in the wound compared with pre-dose (baseline)
- A dose dependent reduction in wound size was observed in multiple dose treatment groups

SoftOx answers on the unmet need for reduction in bioburden to promote wound healing*

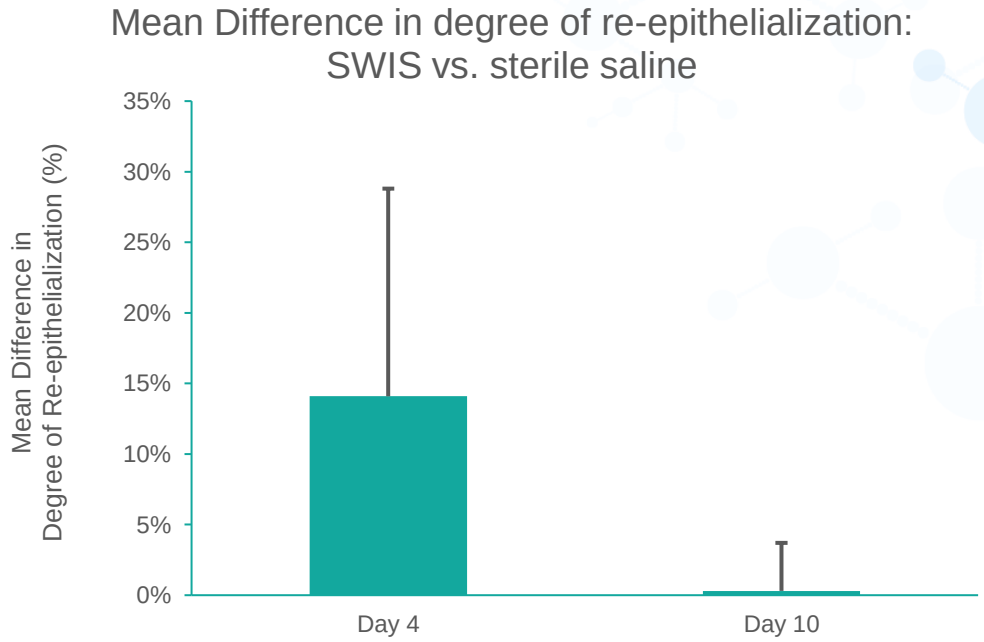
*) SBE-01 trial pooled & multiple dosing groups.
Data on file. Means ± standard deviation

Wound healing observed in several clinical studies

Wound Healing SBE Phase 1b)



Wound Healing SWIS Confirmative Study



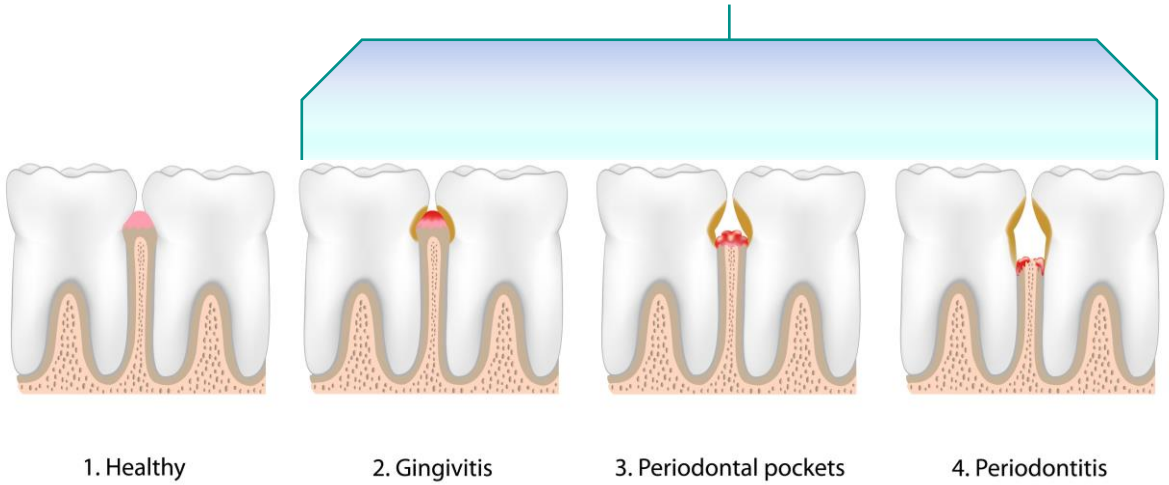
Observed dose dependent trend in reduction of wound size*

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

SoftOx Dental:
Unique ability to remove oral biofilm and treat periodontitis

SoftOx Mouthwash

Aiding in the preventing disease development steps 2-4



A new penetrative mouthwash against sub-gingival biofilms in the fight against periodontitis

Goal: To replace/remove cosmetic competitors through dental professional market sales

- **Clinical significance of periodontitis:**
  - Over 538 million affected globally
  - 276 million afflicted with tooth loss[1]
  - Affects 46% of US adults over the age of 30
  - 8 of 10 Europeans over 30 show signs of gum disease[3]

- **The Oral Healthcare Market:**
  - Global market valued at $30 – 50 billion
  - Cosmetic mouthwash valued at $1,5 bn

SoftOx Mouthwash can help ensure the complete removal of plaque*

**in conjunction with daily toothbrushing*

Animal care – very similar to a human product portfolio

Pets – ~220 million household dogs and cats in US and Europe

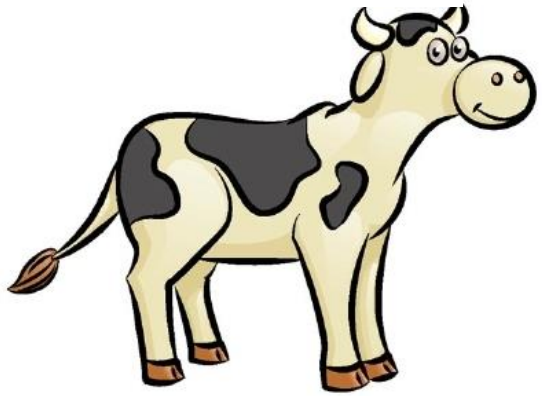
Veterinarian pet market

Wound care, ears wash, eye cleansers and tooth wash
SoftOx disinfectant will improve indoor climate

Production animals – ~31 billion animals worldwide

Surface disinfectant

Unique on decontamination of facilities, specially under disease outbreak; swine fever, mad cow decease and others



Other potential products

- Mastitis treatment and udder disinfectant with color
- Claw treatment and claw bath with color
- Disinfection of drinking- and milk systems
- Disinfectant of carcass in US

Regulatory fast track to market – large potential with the right partner

The Wound and skin care drop down 2–3 years plan

- Finance the new company with a separate funding of Euro 10 million.
- Achieve regulatory approval of Medical Device wound cleanser in Europe and US.
- Perform Phase 2 for SoftOx Biofilm Eradicator (SBE):
  - The estimated probability of success is statistically over 80%.
  - According to the external valuation report the value will increase up to NOK 4 billion after successful phase 2 (see attachments).
- Establish an outsourced production for both first- and second-generation technology.
- Through partners and distributors, bring products to market within animal health care, human wound health care, oral health care and skin disinfection.
- Within two to three years list/sell the Wound and Skin care company on a relevant international market. If successful, Wound and Skin care can finance further development of SIS or be used to pay dividends to shareholders.

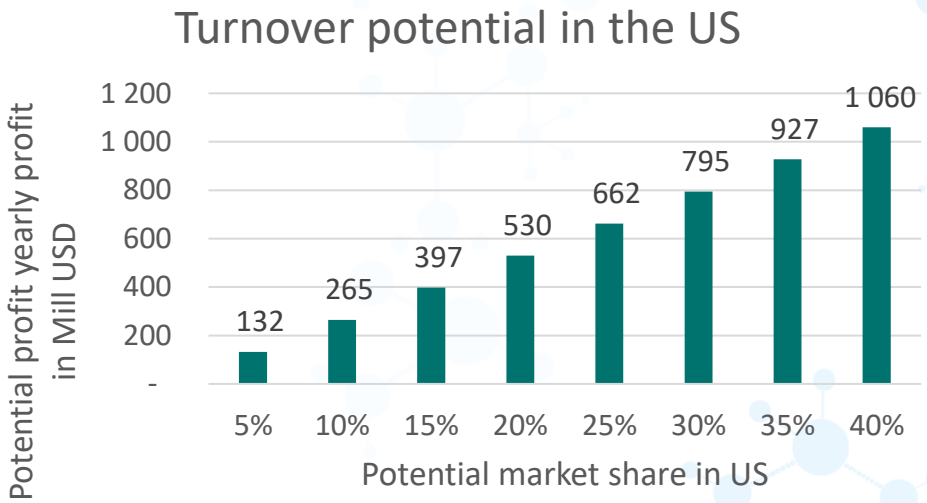
Exit strategy wound care

Valuation and market trends

- KWC, fair market value Wound Care MUSD 200
  PE 13 on yearly expected net licence fee
- KWC, fair market value will increase up to approx. NOK 4 billion after successful phase 2
- Summer 2023 – Coloplast acquire Kerecis for USDbn 1,3, Turnover USDM 75, EBITA <30%, only US market, PEG 36

Why haven't we sold wound care already

- International advisers, market value is too small
- Venture Capital – lack of plan for commercialization
- Industry – too little data
- Merger with NY listed company – Board too early
  - Valuation wound care fair market value – USD 200
  - 85% ownership in the merge company



Assumptions Turnover Potential US

- Avg price per patient is $2,280, which equates to 35% of est. saving per patient in MedValue model
- Distributors are responsible for sale and take 50% of end user price
- Estimated EBITA 35%/COGS 20%

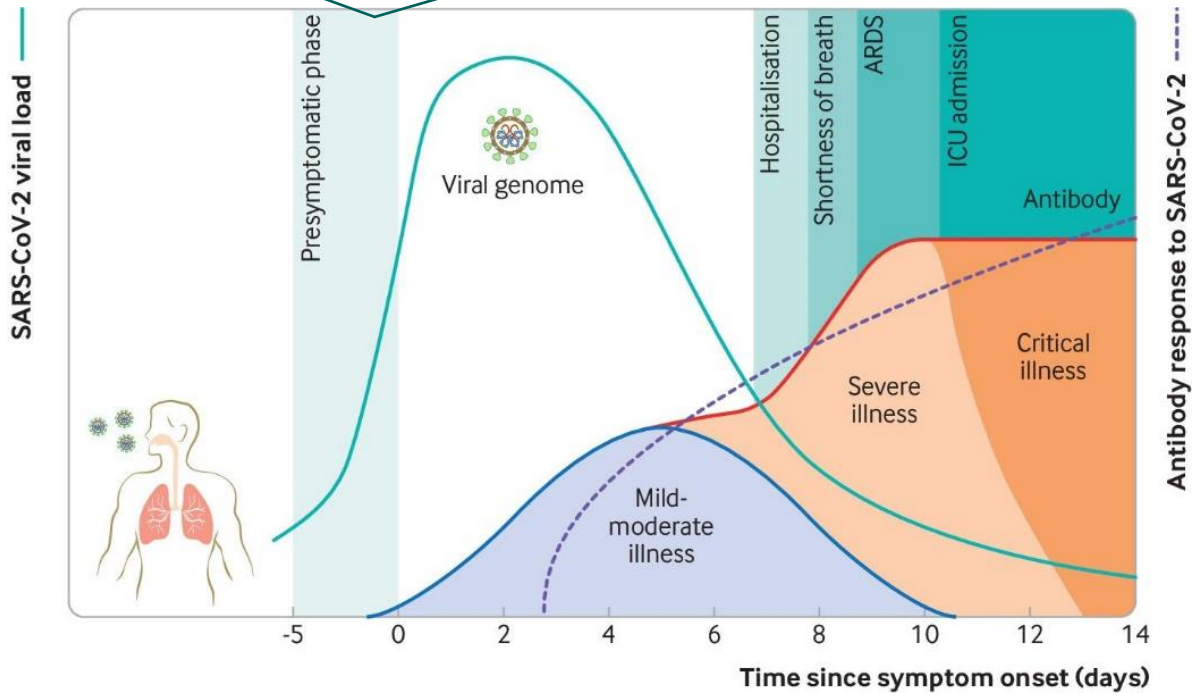
Exit - Sale of applications or technology platform or separate listing

03

Respiratory care

Early intervention treatment: potential to impact peak viral load, time of viral peak and infection duration[1]

Because SS0330/1 is directly virucidal, it is delivered directly to upper respiratory tract mucosal surfaces (sites of viral replication), and has the potential to reduce further disease transmission, the **target population are pre-symptomatic and early symptomatic patients**



Early intervention and direct virucidal activity is expected to:

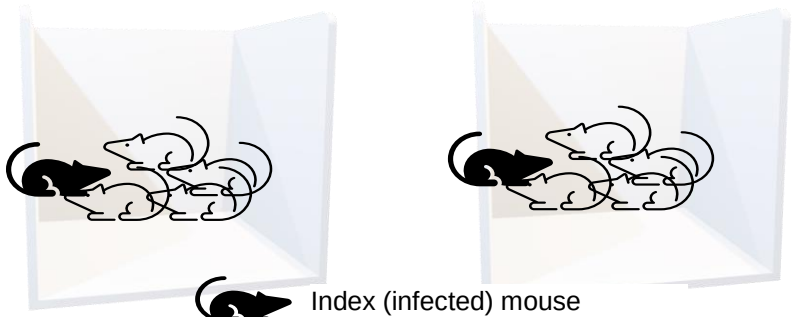
- reduce peak viral load
- reduce time of viral peak
- reduce infection duration
- improve symptoms and/or avert severe illness as a result of a reduced viral AUC [1,2]

1. Epidemiologia 2020, 1(1), 5-15; https://doi.org/10.3390/epidemiologia1010003
2. BMJ 2020; 371 doi: https://doi.org/10.1136/bmj.m3862

Respiratory care – Treatment and prevention

In vivo Proof of Concept – Post-exposure prophylaxis

Co-housing with infected mice & post-exposure prophylaxis with saline or SoftOx



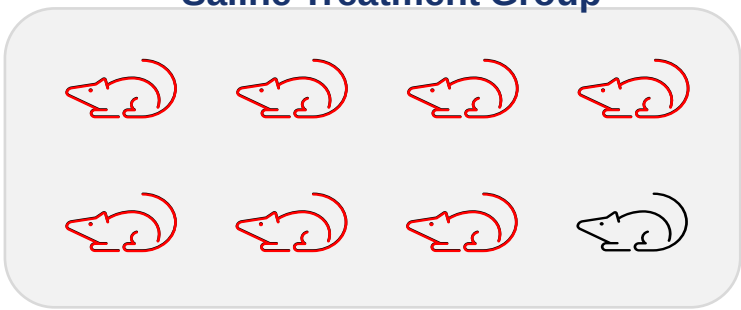
Index (infected) mouse removed from cohousing on day 3

Uninfected mouse

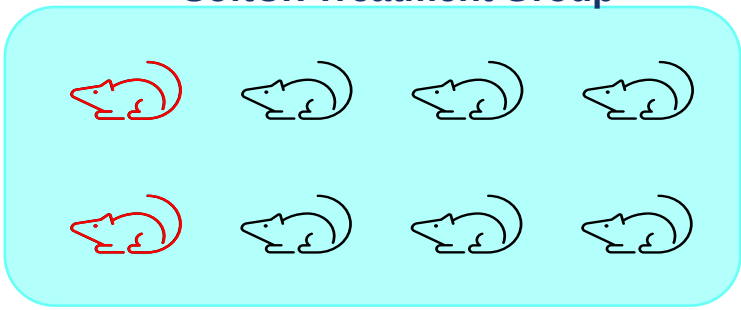
Infected mouse (determined by IVIS [average radiance ≥ 10^3 p/s/cm^2/sr])

DAY 3

Saline Treatment Group



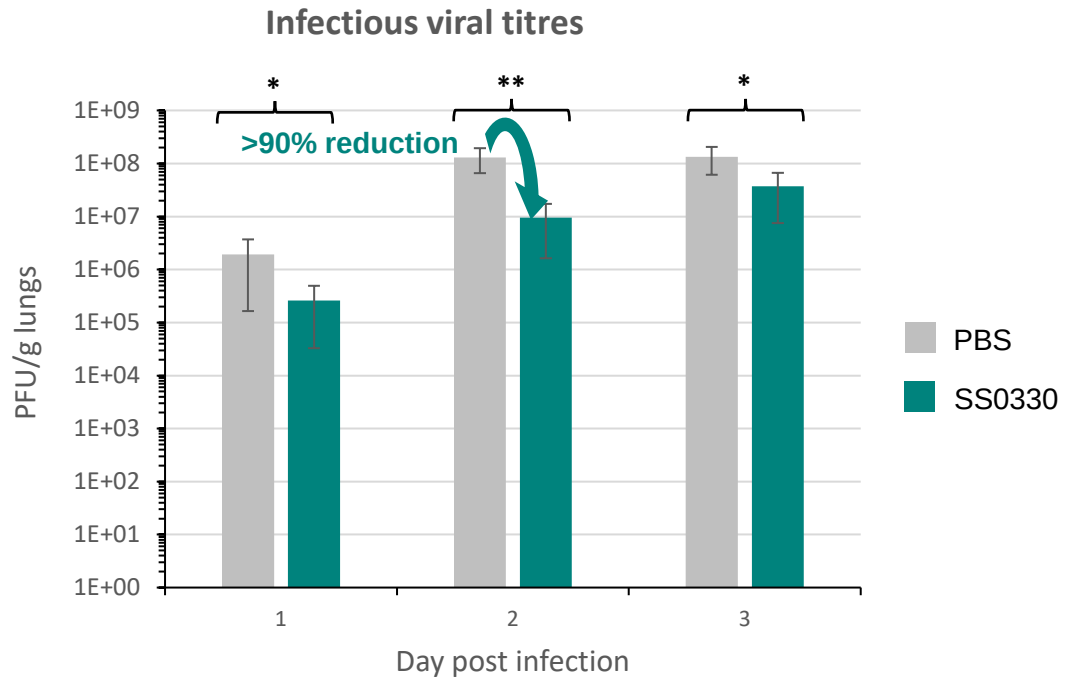
SoftOx Treatment Group



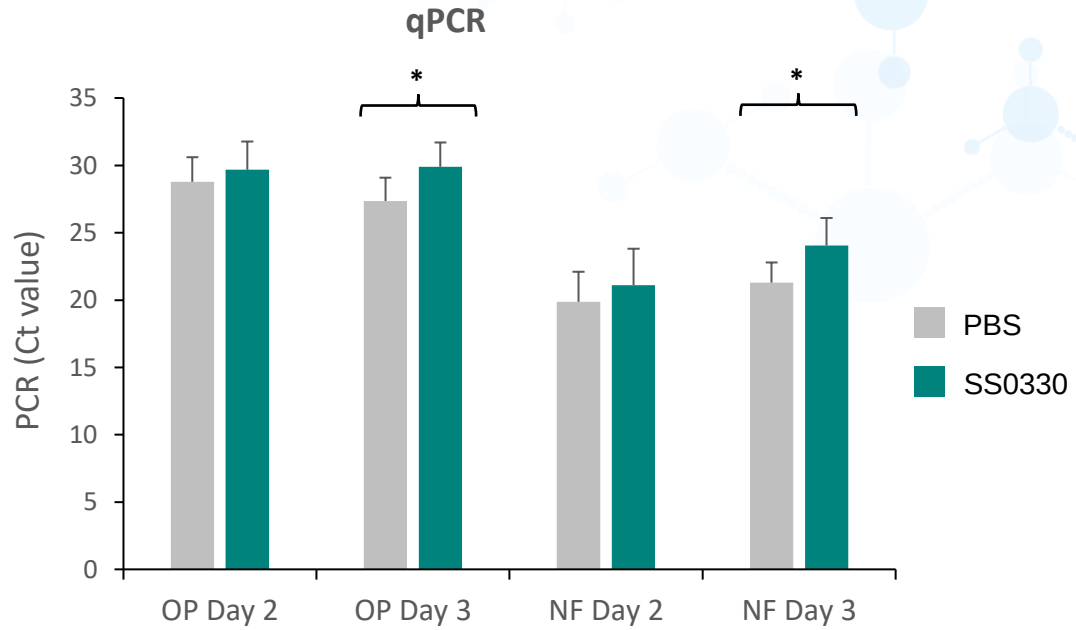
Data on file.

Respiratory care – dose dependent treatment effect in mice infected at day 0 with Influenza A virus

Twice daily treatment resulted in lower viral titres on post-infections days 1 to 3



… and correspondingly higher qPCR cycle threshold values (day 3)



OP: Oropharyngeal swob, NF: Nasal flush
Data on file. Mann-Whitney test, *($p < 0.01$), ** ($p < 0.0001$).

SIS-01: Nebulized formulation safe and well tolerated at all dose levels

Randomized, placebo controlled, first in human trial in healthy volunteers

Abstract presented to ERS 2022

36474

SOFT·OX

Safety of ascending single and multiple doses of inhaled SIS, an isotonic aqueous solution of sodium hypochlorite, in healthy subjects

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[1]SoftOx Solutions A/S - Copenhagen (Denmark), [2]DanTrials ApS - Copenhagen (Denmark), [3]SDS Life Science - Stockholm (Sweden), [4]Department of Immunology and Microbiology, University of Copenhagen & Department of Clinical Microbiology, Copenhagen University Hospital, Rigshospitalet - Copenhagen (Denmark), [5]Department of Immunology and Microbiology, University of Copenhagen - Copenhagen (Denmark), [6]Department of Clinical Pharmacology, Bispebjerg and Frederiksberg Hospital, University of Copenhagen - Copenhagen (Denmark) & Dept of Clinical Medicine, Faculty of Health and Medical Sciences, University of Copenhagen, Copenhagen, Denmark

Background:

SIS is a novel aqueous formulation of sodium hypochlorite (NaOCl), which is present as hypochlorous acid (HOCl), a biological oxidant with broad spectrum antimicrobial activity in vitro.

Objectives & Methods:

This single-centre, first-in-human, randomised, double-blind, placebo-controlled study was designed to explore the safety and tolerability of ascending single and multiple doses of inhaled SIS. Subjects were randomised 3:1 to receive SIS formulations (HOCl concentrations 25 – 100 µg/mL) in single or multiple daily administrations (once to four times daily) for 5 days, or a matching placebo regimen.

Results:

A total of n = 57 healthy subjects (age 27 ± 6 years, BMI 23.9 ± 2.9 kg/m² (*mean* ± *SD*), 60% male, 84% Caucasian, 98% not Hispanic or Latino,) were randomised to receive SIS (n = 43) or placebo (n = 14) (**Table 1**). One subject withdrew voluntarily from the study due to personal choice, unrelated to study treatment. There were no reported serious adverse events. A total of 18 adverse events were reported in 15 subjects (27.9% subjects receiving SIS and 21.4% subjects receiving placebo). Adverse events were predominantly mild (**Figure 1**). Solicited reporting of primarily mild local tolerability showed a dose-response relationship in SIS treated groups (e.g., solicited reporting of "burning" was recorded in 0% assessments in the single dose 25 µg/mL formulation group and 14.2% assessments in the four times daily 100 µg/mL formulation group over 5 days) (**Figure 2**). No dose-response effects on spirometry were observed (**Figure 3**).

Conclusions:

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.

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Table 1: Summary statistics of demographic characteristics

Variable	Single dose			OD day 1-5		BID	QID			
	SIS 25 ppm (n=6)	SIS 50 ppm (n=6)	SIS 100 ppm (n=6)	SIS 50 ppm (n=6)	SIS 100 ppm (n=6)	SIS 100 ppm (n=6)	SIS 100 ppm (n=7)	Placebo (n=14)	Total SIS (n=43)	Total (n=57)
Age (years)	32 ± 10	26 ± 6	27 ± 5	28 ± 7	24 ± 6	28 ± 3	25 ± 6	27 ± 7	27 ± 6	27 ± 6
Sex (% male)	1 (16.7%)	3 (50.0%)	4 (66.7%)	3 (50.0%)	3 (50.0%)	3 (50.0%)	5 (71.4%)	12 (85.7%)	22 (51.2%)	34 (59.6%)
Race										
Asian				1 (16.7%)					1 (2.3%)	1 (1.8%)
Black								1 (7.1%)		1 (1.8%)
Caucasian	5 (83.3%)	6 (100.0%)	3 (50.0%)	4 (66.7%)	6 (100.0%)	6 (100.0%)	7 (100.0%)	11 (78.6%)	37 (86.0%)	48 (84.2%)
Other	1 (16.7%)		3 (50.0%)	1 (16.7%)				2 (14.3%)	5 (11.6%)	7 (12.3%)
Ethnicity (% not Hispanic or Latino)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	7 (100.0%)	13 (92.9%)	43 (100.0%)	56 (98.2%)
Height (cm)	169 ± 9	177 ± 10	180 ± 5	176 ± 11	174 ± 13	177 ± 9	186 ± 13	183 ± 9	177 ± 11	179 ± 11
Weight (kg)	66.7 ± 11.1	74.7 ± 9.2	81.2 ± 14.1	73.3 ± 12.5	71.3 ± 17.7	73.2 ± 15.4	80.9 ± 18.5	83.1 ± 11.8	74.6 ± 14.3	76.7 ± 14.1
Body Mass Index (kg/m²)	23.3 ± 3.0	23.8 ± 2.8	24.9 ± 3.4	23.7 ± 3.5	23.3 ± 3.2	23.3 ± 3.5	23.2 ± 2.9	24.8 ± 2.6	23.6 ± 3.0	23.9 ± 2.9

Data are mean ± SD

Figure 1: Number of adverse events by preferred term and dose

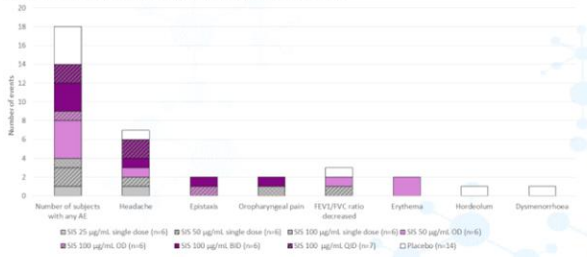


Figure 2: Solicited local tolerability (% of administrations) in relation to last dose (summary over days/dose)

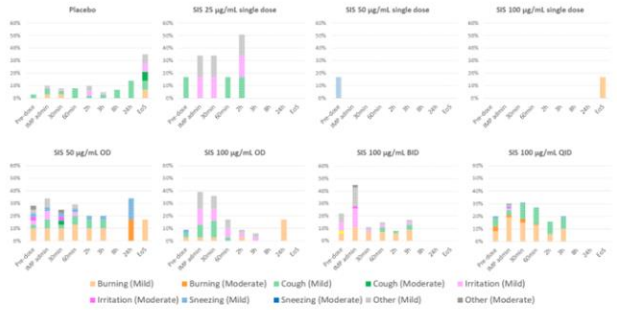
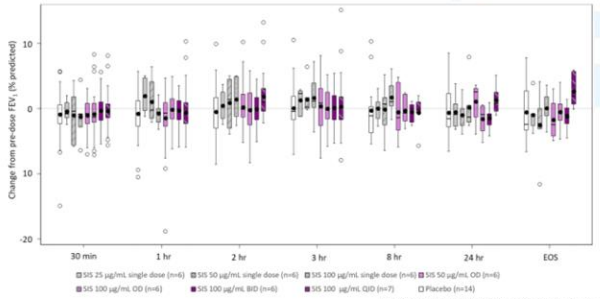


Figure 3: Boxplot of spirometry FEV_1 change from pre-dose by treatment group and assessment in relation to last dose (summary over days/dose)



FEV_1: forced expiratory volume in 1 second; EOS: end of study

SIS-01 trial (NCT05188638). Burton et al. ERS Congress 2022. Abstract #36474.

EDF/COUNTERACT project (*)
Financed Phase I study (EDF/MOD)
Progressing according to plan (2023-2025)

Key deliveries:

- **Optimization of Next generation API (Active Pharmaceutical Ingredient)**
  - Main partner: CR Competence
- **Testing SIS 2.0 in vitro, in vivo and through different nebulizers and fogging systems**
  - Main partners: University of Tous, University of Galway, University of Copenhagen, FFI (Forsvarets Forskningsinstitutt)
- **Regulatory toxicology studies**
  - Main partners: University of Tous, University of Galway, University of Copenhagen
- **Phase Ib in healthy volunteers – Maximum Tolerated Dose Study (Phase I)**
  - Main Partner: University of Galway
- **CMO production of SIS 2.0**
  - Main Partner: CMO and CR Competence

(*) European agile network for medical COUNTERmeasures Against CBRN Threats

The COUNTERACT project will also benefit the civilian development of SIS

Pathway to exit

Acute Exacerbation of COPD prevention
Volume: 💧💧💧
Price: €€

Influenza like-illness** treatment +/- prevention
Volume: 💧💧
Price: €€

Hospital acquired,* ventilator associated pneumonia prevention
Volume: 💧
Price: €€€

EUA biologic countermeasure with 3-year stockpiling
Volume: 💧💧💧
Price: €

Price erosion compensated by larger increase in volumes – opportunity to go OTC

Price increase justified by full regulatory approval within a high-cost care space

Lower price due to shared development and different drug (efficacy : safety) profile

MNOK 80 - Expected total cost of Proof of Concept in phase 2

MNOK 40 - Expected total cost of Proof of Concept in phase 2

Civil phase 2 expected to create first incomes sale to preparedness

Exit - Sale of applications or technology platform after phase 2 or separate listing

04

Summary

SOFT·OX

Key takeaways

Targeting a $40bn+ market

High profitability

Proven effect
Successful clinical trial in humans

Strong platform
with great potential for many products/segments

Strong patents protecting IP

Commercial Phase

Collaboration
outsourced product development

Huge unmet medical need
and no antimicrobial resistance

SOFT-OX

Unique solution for eradicating infections and fighting antimicrobial resistance

Contact Information: ir@soft-ox.com

Euronext Growth ticker: SOFTX

Appendix

Board of directors

Board of Directors

Geir H. Almås
Executive Chairman

- Extensive experience from business development in Norway and Poland
- Previously PwC and KLP Asset Management
- MSc in business administration (BI) and Chartered Accountant (NHH)

Olav Jarlsby
Non-Executive Director

- Former Counsel & Attorney-at-law, Elopak AS
- LL.M. law (UiO)

Henrik Nielsen
Non-Executive Director

- Founder & CEO at CAP Partner
- Director of the European Wound Management Association
- Advisory Council Member for EXCITE International
- Expertise in association management, advocacy, fundraising and organization as well as many years of experience in the medical device industry

Jørgen Berggrav
Non-Executive Director

- Many diverse roles in Armed Forces as submarine commanding officer, Defence attaché, Director General in the Ministry of Defence, representative to the Supreme Allied Commander Transformation and¨NATO's operational command, SHAPE.
- Royal Norwegian Naval Academy; German Command and General Staff Academy; Norwegian Defence University College

Adrian Bignami
Non-Executive Director

- Early co-inventor of the SoftOx technology
- Vice President of Finance, Business Planning and Analysis at C4 Therapeutics, Inc
- Over 20 years of experience in management consulting, investment banking, entrepreneurship, business development and corporate finance across pharmaceutical and biotechnology sectors
- SM, Biomedical Enterprise Program, Harvard-MIT Health Sciences and Technology & MBA, (MIT Sloan School of Management)

Management and financial team

Organization Leadership

Johan Christian Harstad
Chief Executive Officer

- Former submarine commander and deputy leader in the Norwegian Special Operation Forces with rank of Commodore
- Experience with US Special Operations Command, Norwegian Armed Forces central staff, and Ministry of Defence
- Security policy and foreign relations studies at the US Naval War College

Harald Saetvedt
Chief Financial Officer

- Extensive experience as senior executive, capital market advisor and board director with more than 20 years of experience
- Previously Clarksons Platou Securities and Pareto Securities
- MSc in financial economics (BI)

Ingrid Juven
Chief Operating Officer

- 25+ years of consulting and management expertise within a variety of industries
- Previously Director at EY and Partner at Frost Nordic
- MBA in management and marketing (BI)

Elin Jørgensen, DVM, PhD
International Senior Project Manager

- DVM with broad clinical experience and profound research experience with infection models, especially wound models, including biofilm infected wounds
- Lead on SoftOx' commitment in the EDF project COUNTERACT (9 WPs) with development of SoftOx inhalation solution
- SoftOx R&D expert and veterinary advisor

Klaus Kirketerp Møller, MD, PhD
Co-inventor/ Scientific Advisory Board Member

- Medical Doctor, PhD at Copenhagen Wound Healing Center,
- Bispebjerg Hospital Denmark
- Co-inventor of the SoftOx technology
- 15+ years' research focus on chronic wounds and bacterial biofilms

Dr Thomas Bjarnsholt
Chief Scientific Officer

- Expert in the role of bacterial and fungal biofilms in chronic infections with over 245 peer-reviewed publications
- Co-inventor of the technology with financial rights
- Professor at the Costerton Biofilm Center, Department of Immunology and Microbiology (University of Copenhagen)
- Member of the Global Wound Biofilm Expert Panel