

# Helping the world fighting infections





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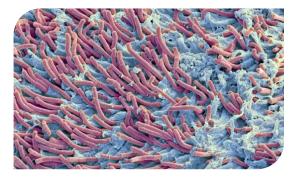
# Helping the world fighting infections

#### **VIRUSES**



Respiratory infectious diseases are among the **leading causes of death** [1]

#### **BIOFILM RESISTANCE**



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

#### **ANTIMICROBIAL RESISTANCE**



AMR is regarded as one of the **largest threats** to global health [3]

## Our goal is to become a world-leading developer of antimicrobial technology

- World Health Organization. https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death.
- 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



# New ways of eradicating infections and fighting antimicrobial resistance



#### Team of top scientists and supported by an international KOL network

- Experienced R&D team with the top biofilm researchers and several medical professionals
- Support from US Naval Medical Research Center, European Defence Fund and leading European universities and medical centres
- Global network of influential researchers and key opinion leaders



#### **Excellent clinical results**

- · All completed clinical studies have confirmed safety and tolerability
- Accumulated in vitro, in vivo and clinical evidence of broad spectrum antiviral and antimicrobial effects.
- Patented technology platform based on hypochlorous acid, a critical component of the human innate immune defence



### Pathway to market

- Targeting market opportunities to address unmet needs for millions worldwide
- · Versatile technology platform with many possibilities for further development
- Products designed with input from payers, patients and healthcare professionals to minimize risk for market adoption



## SoftOx overview

Public company dedicated to developing a new class of antimicrobials restructuring into two companies to secure focus and answer on different investor needs



## **Wound Care**

Anti- infective Technology

#### **Opportunity:**

Leveraging exciting clinical data to accelerate development of wound care products in a standalone entity providing unique partnering and investment opportunities.

# Respiratory Care

Anti-infective Technology

#### **Opportunity:**

Leveraging exciting clinical and preclinical data to accelerate development of respiratory care products in a stand-alone entity providing unique partnering and investment opportunities.



# Technology co-developed with key players in wound care

#### SCIENTIFIC & RESEARCH TEAM

#### Chief Medical Officer Dr Christopher Burton, MD, PhD

MA (Cambridge University); MD (Imperial College London)
PhD (University of Copenhagen)
MRCP (Royal College of Physicians London)
15+ years' Pharmaceutical & Clinical Development Experience



#### Chief Scientific Officer Prof Thomas Bjarnsholt, PhD, Dr. Med.

MSc (Danish Technical University); PhD (Danish Technical University)
Doctor of Medical Science (University of Copenhagen)

Professor of Microbiology

245+ peer reviewed publications



## Director of Research Development Mustafa Fazli, PhD

MSc (Technical University of Denmark)

MSc (Copenhagen Business School)

PhD (University of Copenhagen)

15+ years' experience in biofilm research



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

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



#### **COLLABORATION PARTNERS**

#### EDF funds research and development of state-of-the-art defence technology

December 2022 – Granted approx. **€4.1 million** to SoftOx and **€4.2 million** to consortium partners develop a military medical inhalation countermeasure. The Norwegian Ministry of Defence has pledged approx.**€1** million in co-financing







#### MTEC collaborating with the U.S. Naval Medical Research Center

November 2020 - Awarded **\$1.97 million** from the Naval Medical Research Center (NMRC) under the Medical Technology Enterprise Consortium (MTEC) for phase 1 & 2 development of a chronic wound treatment



#### Collaborations with leading universities and medical centers in Europe















# Patented and well protected technology

#### SoftOx

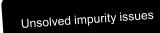
Competitors

SoftOx's broad and extensive patent protections (first on file and pending applications)

A unique and protected technology for achieving an acceptable regulatory profile

Unique antimicrobial properties and shelf life

Focus on development of medicinal purpose products and applications



Unsolved stability

Ineffective against biofilms

#### Broad and extensive patent portfolio covering:

- formulation
- production
- storage
- route of administration
- antimicrobial indications

# A unique and protected technology for achieving an acceptable regulatory profile

- Two years shelf life in active substance
- Avoid building up non-acceptable impurities

72 granted and 77 pending patents worldwide and addressing formulations, uses, methods and devices



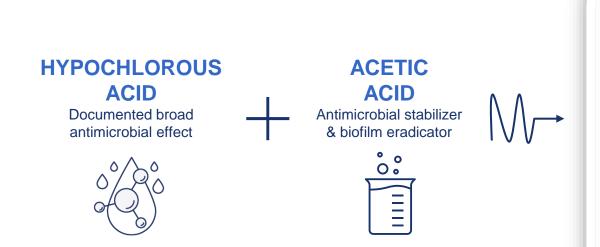
# 

Platform technology





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



#### **SOFTOX TECHNOLOGY**

Strong pan-spectrum antimicrobial (virucidal/bactericidal) effects

Not shown to induce antimicrobial resistance

Good safety and tolerability profile – no systemic side effects

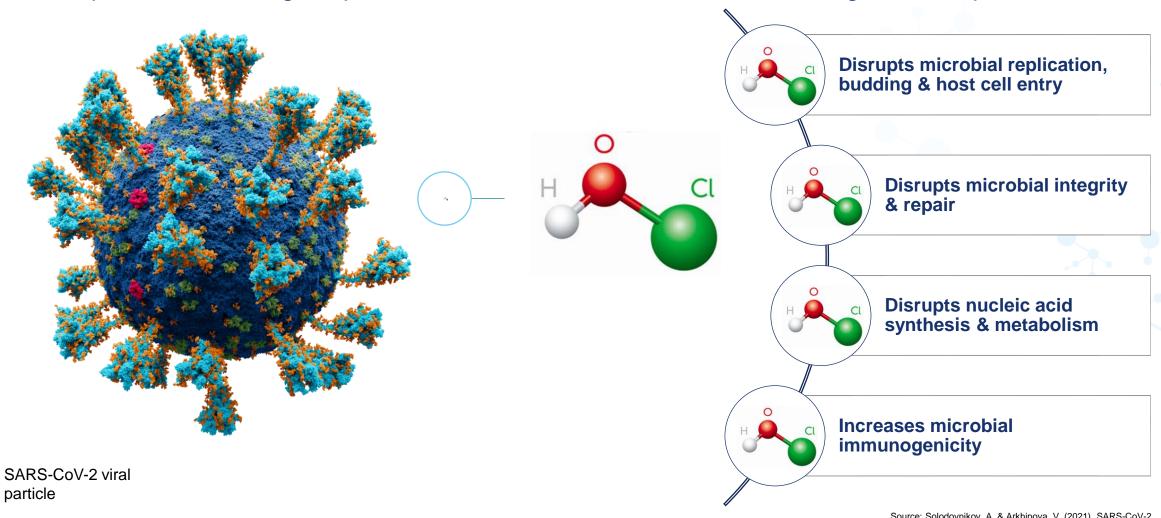
Stabilized formulation

Synergistic properties give unique ability to eradicate biofilm infections in wounds



## **HOCI** has direct and indirect antimicrobial MoA:

independent of biological processes and unreliant on a metabolic target or receptor

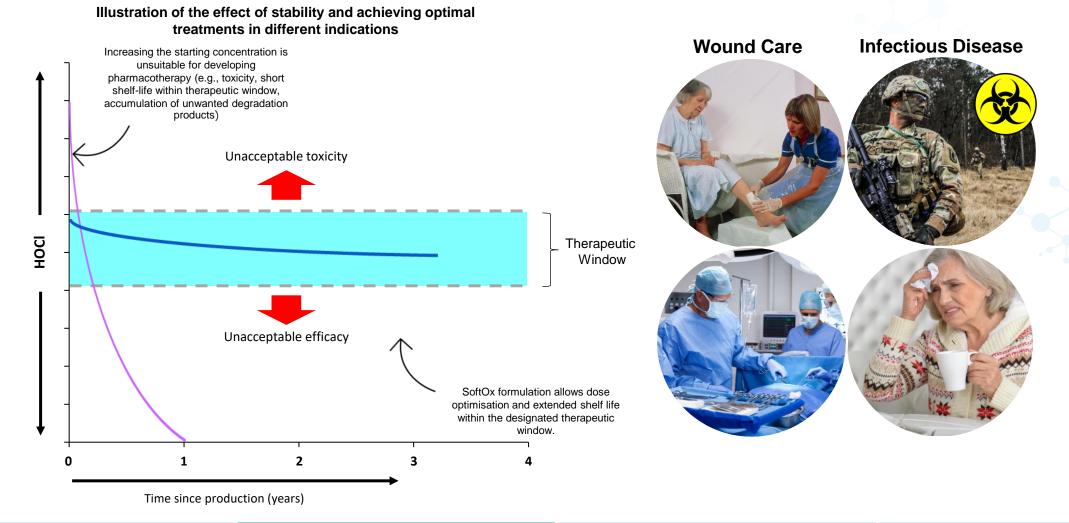


Source: Solodovnikov, A, & Arkhipova, V. (2021). SARS-CoV-2. https://commons.wikimedia.org/wiki/File:Coronavirus.\_SARS-CoV-2.png#file



# Stabilised formulations of hypochlorous acid (HOCI)

are pre-requisite for developing HOCI based pharmacotherapeutics and enhancing commercial viability



# 

Wound care





# Targeting the chronic wound market in the US

#### UNMET NEED1:

6.5 million

chronic wound patients in the US annually<sup>1</sup>

#### Patient population drivers:

- Obesity
- Diabetes
- Population over 65 years of age

\$25 billion

Annual treatment costs of chronic wounds in US<sup>1</sup>

#### WANTED PRODUCT PROFILE

According to FDA Wound Care Conference 2022<sup>2</sup> and EXCITE International

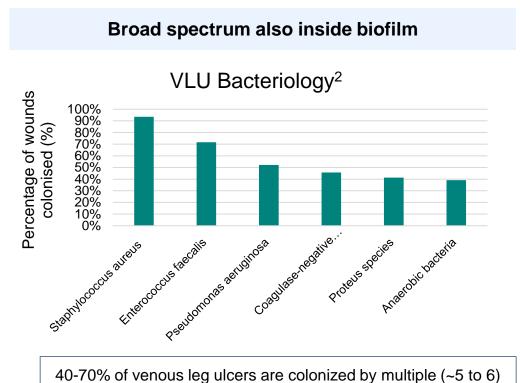
- ☑ A small molecule drugs for treatment of chronic wounds
- ☑ An effective antimicrobial enhancing wound closure
- ☑ Easy to use in outpatient and inpatient facilities
- ☑ Does not induce antimicrobial resistance
- ☐ Large RCT study proofing clinical efficacy in chronic wounds
- ☐ Regulatory approval

Verma, K. D, et al. (2022). Food and Drug Administration perspective... Wound repair and regeneration, 30(3), 299–302. https://doi.org/10.1111/wrr.13008

FDA Healing Workshop (2022). <a href="https://carolinefifemd.com/2022/05/16/watch-the-excellent-fda-wound-healing-workshop-for-free/">https://carolinefifemd.com/2022/05/16/watch-the-excellent-fda-wound-healing-workshop-for-free/</a>

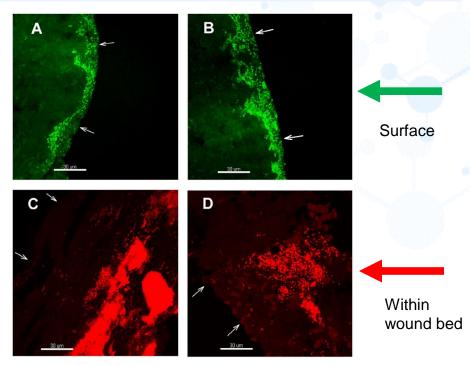


## The unmet need for treatment of chronic wounds



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

#### Reaching microbes where they are



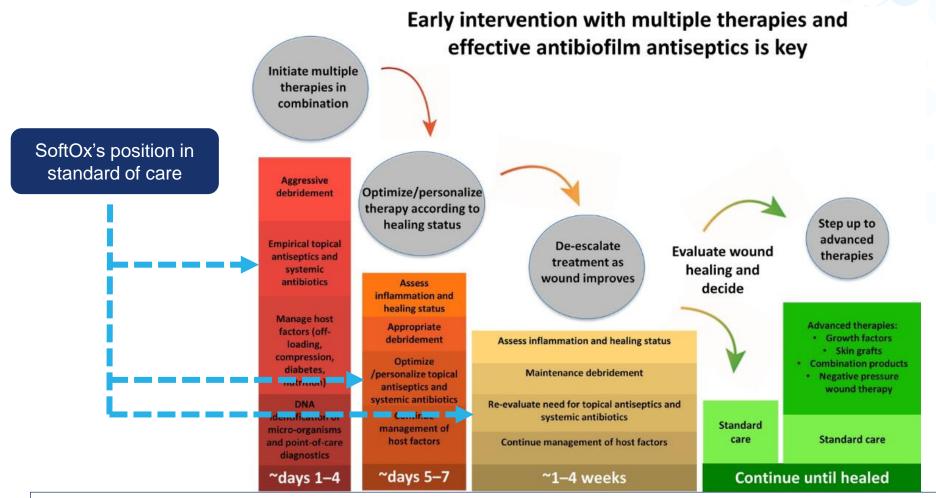
Representative CLSM images of *S. aureus* (A and B), *P. aeruginosa* (C and D). Arrows point to the wound surfaces<sup>-1</sup>

## Today's antibiotics and antiseptics does not answer on this need

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



# SoftOx target positioning fits well with current consensus guidelines



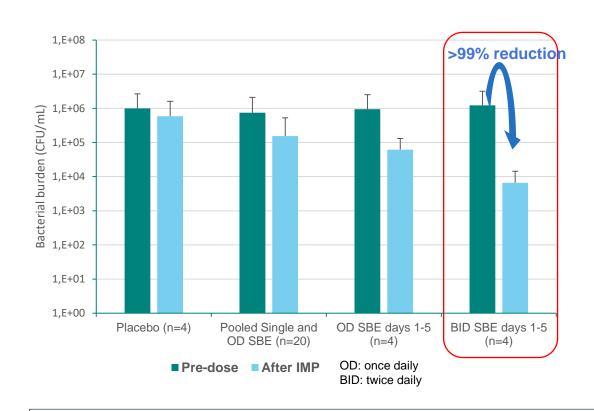
Topical antiseptics are recommended as first-line therapy in wounds

Consensus guidelines for the identification and treatment of biofilms in chronic nonhealing wounds. Schultz G, Bjarnsholt T, et al., 2017.

Wound Repair Regeneration. 2017. Vol. 25 (5), p.744-757



# Phase 1 results in treatment of leg ulcers (SBE-01) show >99% 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

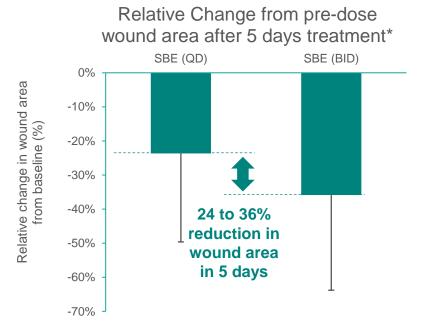
SoftOx answers on the unmet need for reduction in bioburden to promote wound healing\*

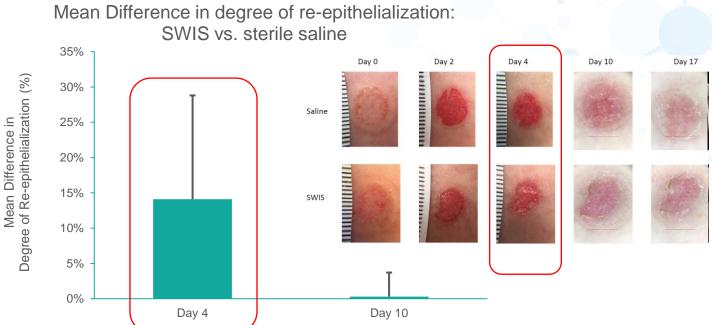
\*) SBE-01 trial pooled & multiple dosing groups.

Data on file. Means ± standard deviation



# Wound healing observed in three clinical studies



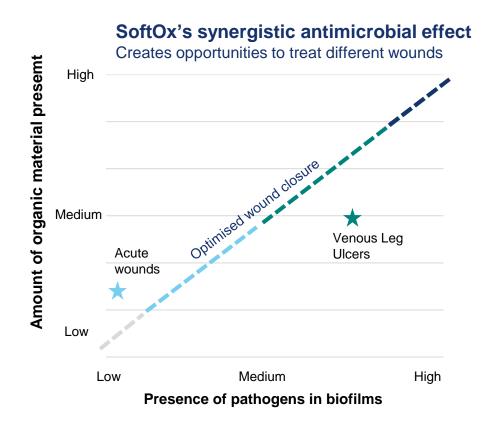


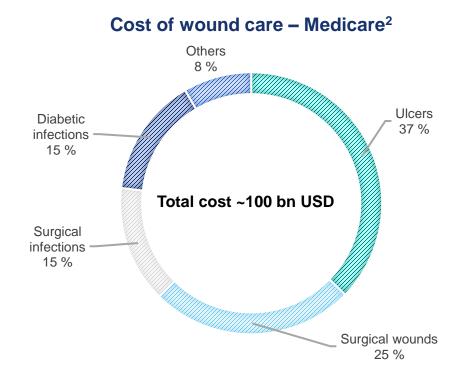
Observed dose dependent trend in reduction of wound size\*

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



# Technology platform: Different concentrations offers possibility to designing products for different indications and wounds



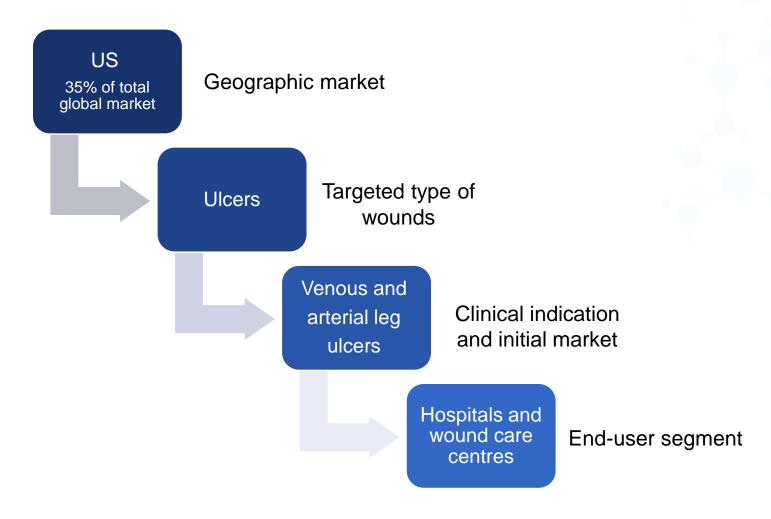


<sup>.</sup> Effects of stabilized hypochlorous acid on re-epithelialization and bacterial bioburden in acute wounds, Ewa A Burian et al. Acta Derm Venereaol 5/2022

An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds, Samuel R. Nussbaum, MD et al. 2018



# Target market selection in advanced wound care





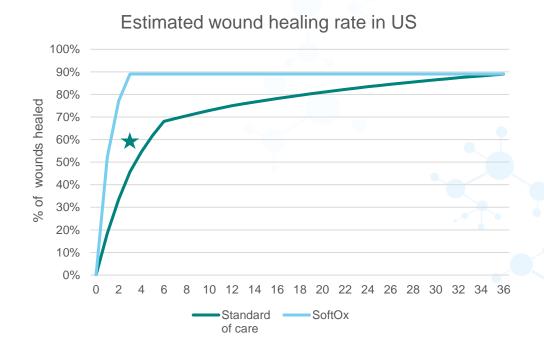
# High cost-saving potential for leg ulcer treatment

Independent health market analyses Excite International and University of Radboud

- Cost of care based on literature and interview with KOL/Payers
- Median age of patients: 72 years
- Focus on the US market
- Estimate value of faster wound closure and prophylactic treatment of infections in VLU
- Based on value-based prescription drug pricing



\* Assumed wound healing rate in third party valuation model



MedValue & Radboud University (2019).

Decision Modeling Assessment.



# Potential profit in US – given assumptions<sup>1)</sup>

#### **Assumptions**

- Number of patients in the US: 2,323,804
- Avg price per patient is \$2,280, which equates to 50% of est. saving per patient in MedValue model
- Distributors are responsible for sale and take 50% of end user price
- Treatment according to standard of care<sup>2)</sup> and set up planned for phase 2 (slide 19)
- COGS \$10 per unit, according to estimated price per unit from CMO
- Replacing many of todays advanced wound care products – representing a USD 7 bn market in the US with CAGR of 5.4%<sup>3)</sup>

#### POTENTIAL PROFIT SBE



- 1) See attached slide no. 39 for further details
- 2) Consensus guidelines for the identification and treatment of biofilms in chronic nonhealing wounds. Schultz G, Bjarnsholt T, et al., 2017.
- https://www.researchandmarkets.com



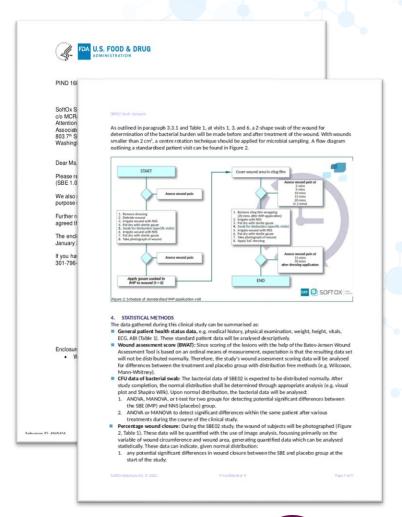
# SBE-02 - US Phase 2 follow-up study

Blinded, randomised, placebo-controlled, study comparing **SBE vs. Normal Sterile Saline (NSS)** in patients with venous leg ulcers (VLU)

#### End points:

- Change in bacterial burden
- Percentage wound closure
- Clinical evaluation of wound
- Safety and tolerability

Co-funded by US Medical Technology Enterprise Consortium







# Timeline development of SoftOx wound care technology

2018

Preclinical Wound Irrigation 2019

Pilot study Wound Irrigation

Pre-clinical SBE drug

2020

2021

Pivotal study Wound Irrigation 2022

Phase 1a/1b

Early PoC
wound closure

2023/24

Phase 2 Wound antimicrobial effect 2025/26

Phase 3 study Wound closure 2026/27

Market
approval
Wound
antimicrobial
effect &
closure

PoC: Proof of concept

# 

Respiratory infections

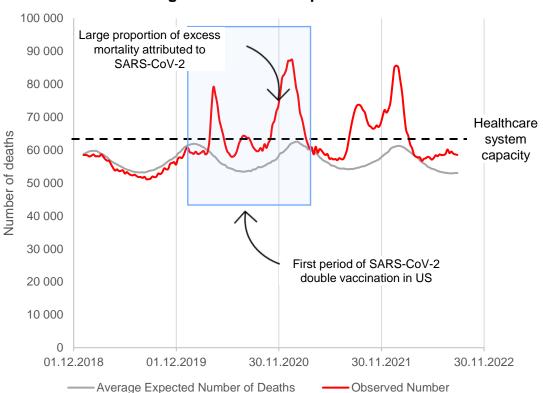




# **SARS-CoV-2** pandemic & preparedness for Disease X:

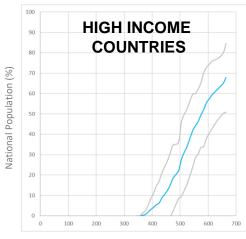
Consequences of exceeding healthcare system capacity

# US observed vs. expected weekly deaths<sup>1</sup> during the SARS-CoV-2 pandemic



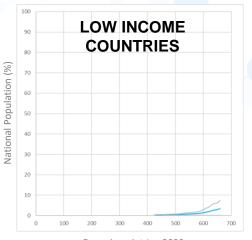
# Vaccines are virus species/strain specific and require repeated inoculation

#### SARS-CoV-2 Vaccination Rates<sup>2</sup>



Days since 1st Jan 2020

Mass population testing and vaccine roll out required significant healthcare restructuring, and is a strategy limited to High Income Countries.



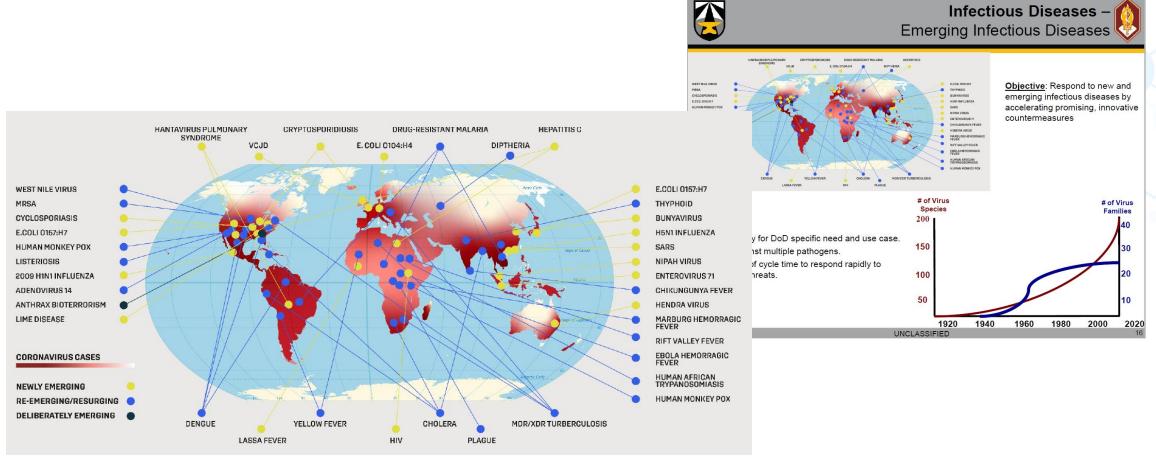
Days since 1st Jan 2020

Under-reporting, and limited vaccination programs in Low Income Countries provides protection to selected individuals rather than achieving herd immunity.

- . https://www.cdc.gov/nchs/nvss/vsrr/covid19/excess\_deaths.htm#dashboard
- 2. COVID-19 Map Johns Hopkins Coronavirus Resource Center (jhu.edu)



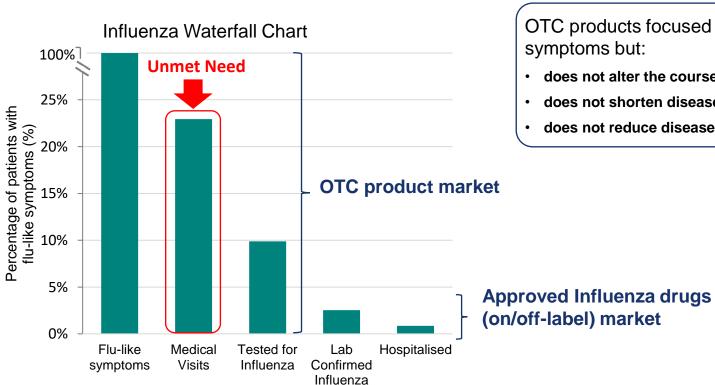
# US and EU military priority: Medical readiness for emerging infectious diseases and bioterrorism



Military Infectious Diseases Research Program Portfolio Overview and Strategy. COL Stuart D. Tyner, PhD. 07 November 2022



# 12% of the EU/US population experiences flu-like symptoms annually



OTC products focused on reducing symptoms but:

- does not alter the course of disease
- does not shorten disease duration
- does not reduce disease transmission

demonstrated specific antiviral activity but:

- limited clinical efficacy in uncomplicated influenza within 48 hrs of symptom onset
- documented cross-resistance
- ineffective for other viral causes of respiratory tract infection

Approved influenza drugs have

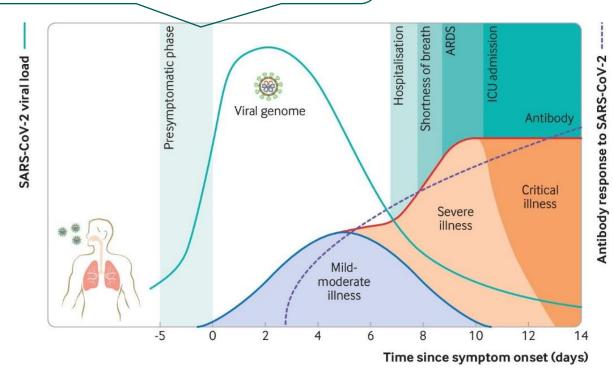
Currently available treatment options provide **limited clinical efficacy** in uncomplicated influenza OR **do not** address the underlying microbial cause at all

Respiratory infections



# Early intervention treatment: potential to impact peak viral load, time of viral peak and infection duration<sup>1</sup>

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
- and improve symptoms and/or avert severe illness as a result of a reduced viral AUC 1,2

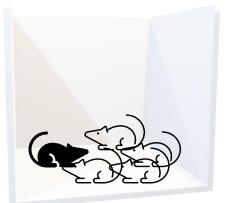
Epidemiologia 2020, 1(1), 5-15; https://doi.org/10.3390/epidemiologia1010003
 BMJ 2020; 371 doi: <a href="https://doi.org/10.1136/bmj.m3862/">https://doi.org/10.1136/bmj.m3862/</a>

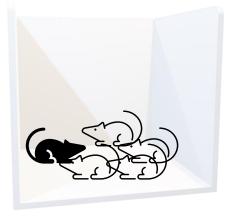


# Pre-clinical proof of concept in infectious disease:

Mice exposed to index mouse infected with Sendai virus at day 0

# Cohousing with infected mice & 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<sup>3</sup> p/s/cm<sup>2</sup>/sr])

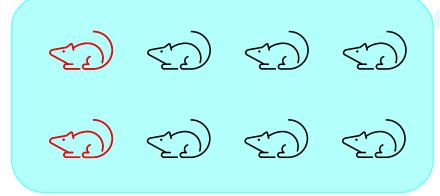


#### **Saline Treatment Group**





#### **SoftOx Treatment Group**



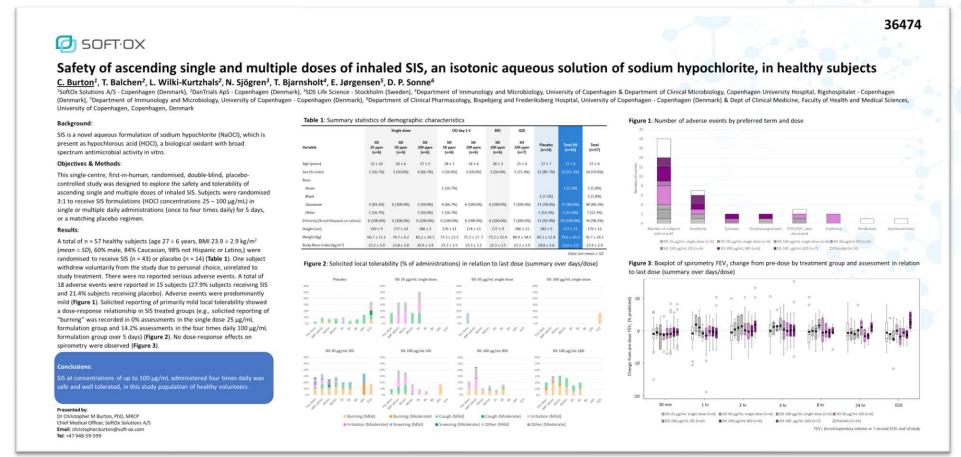
Data on file.



## 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



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



# Ongoing clinical development plans (CDP) addresses feedback received from European and US Regulatory Authorities

**EMA** 

FDA



In context of clinical ILI indication



In context of SARS-CoV-2 indication



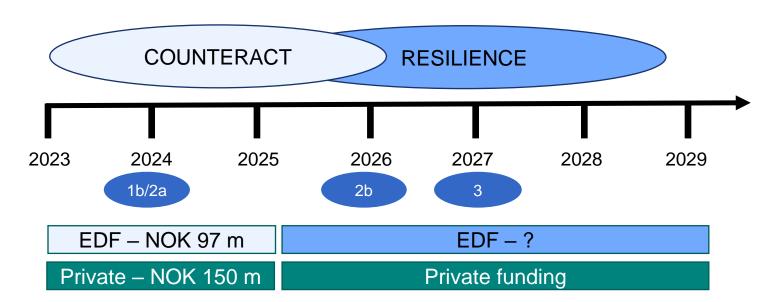


# Protecting the soldier and the population from respiratory infectious disease & biological threats

#### **European Defence Fund (EDF)**

COUNTERACT aims to develop and deploy medical countermeasures against major Chemical, **Biological**, Radiological, and Nuclear (CBRN) threats such as terror plots, nuclear accidents, weapon developments and **epidemics** caused by emerging or reemerging high-consequence pathogens.

COUNTERACT will increase EU preparedness for immediate response to such threats.





Biological Warfare Agents



Influenza-like Illness (Pandemics)





# **SoftOx summary**

#### SoftOx Solutions AS

Non-toxic and highly effective anti-infective technology

## **Wound Care**

Anti- infective Technology

#### **Opportunity:**

- Aim to cover a large unmet need
- Well tolerated in humans
- Achieved early clinical proof of concept
- High demand and willingness to pay identified
- Easy to use and fits well into standard of care
- Well protected IP
- Developed and supported by world leading scientists

# Respiratory Care

Anti-infective Technology

#### **Opportunity:**

- Aim to cover a large unmet need
- Achieved early proof of concept in animals
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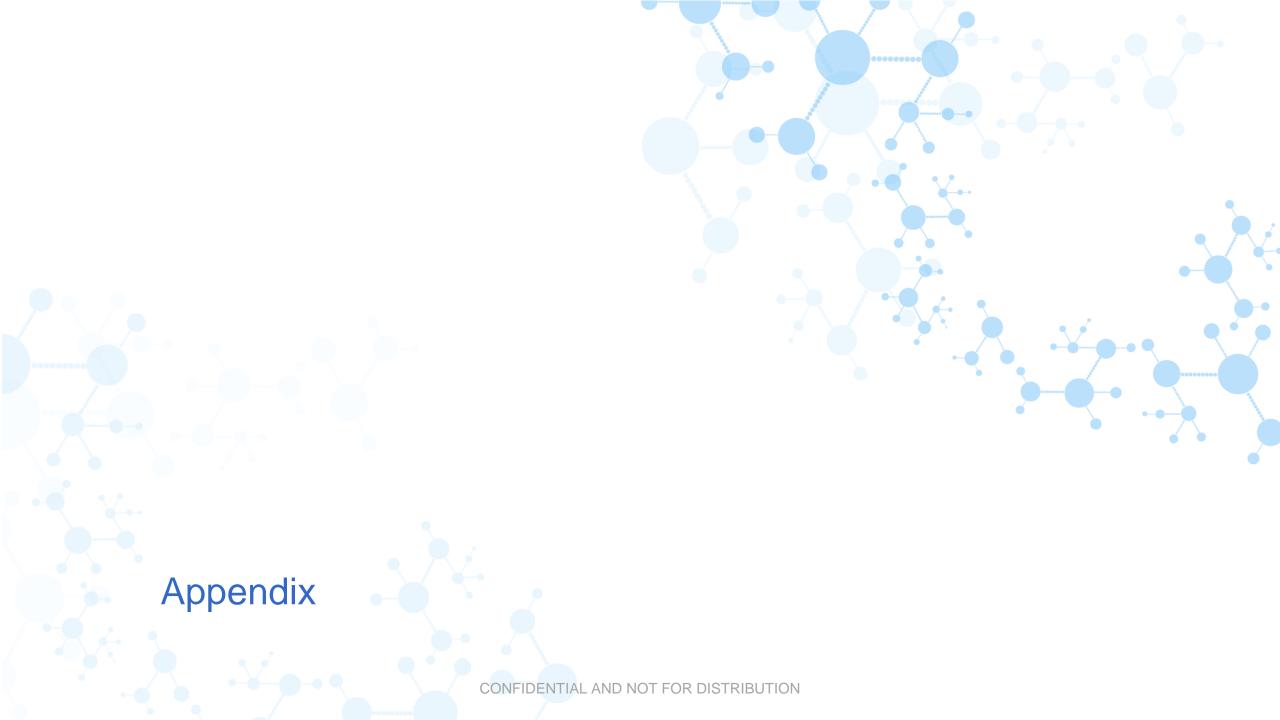




Unique solution for eradicating infections and fighting antimicrobial resistance

Contact Information: <u>ir@soft-ox.com</u>

**Euronext Growth ticker: SOFTX** 





### **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

- General Counsel & Attorneyat-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



Dr Kari Myren Non-Executive Director

- 10+ years in biotech & pharma industries
- Specialist in medical affairs management and drug development
- Cand.med. (UiO)



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)



## Dr Christopher Burton Chief Medical Officer

- Experienced pharmaceutical industry physician with 15+ years of work experience in pharmaceutical companies
- Previously Sr Clinical Director at Savara Pharmaceuticals and Medical Director at ALK
- MA in medicine (Cambridge University);
   MD in medicine (Imperial College); PhD (Copenhagen University)



#### 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



# **SoftOx Biofilm Eradicator background calculations**

SoftOx Biofilm Eradiactor backrground calculations		
Leg Ulcer Treatment (Annual US Revenues & Profitability)		Comments
Total Pts/Yr	2 323 804	
Peak Market Share	40 %	Market insight on which patients more likely to use -> According to standard of care it shall be a first line treatment on all stalled wounds
Pts with SoftOx	929 522	
Avg. Tx Duration (months)	1	Avg. duration and range with current therapies -> 4 weeks according to standard of care
Units/Pt (2unit = 1day)	24	Two treatments per day 3 days per week
Total Units	22 308 518	
\$/Unit (2unit=1day)	\$95	Competitors on a 510k ask for \$24 for similar unit
\$/Pt	\$2 280	Total treatment cost, treated according to standard of care as planed in phase 2
Product Revenues/ Yr (\$)	\$2 119 309 248	
Sales Parnership (% sales)	50 %	Expect 50%, Large US distributor ask for 67% on a private branded 510k wound cleanser. Branded drugs is expected to have 50/50
Net Revenues (\$)	\$1 059 654 624	
COGS (\$/unit)	\$10,0	According to production cost establised for sterile 510k production
COGS (% revenues)	11 %	
Total COGS (\$)	\$223 085 184	
Profit (\$)	\$836 569 440	