



SoftOx Solutions AS

Unique antimicrobial platform technology with application to Wound Care & Infectious Disease treatment and prevention

DNB HEALTHCARE CONFERENCE 2022

15 December 2022

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Today's presenters from SoftOx management



Geir Hermod Almås
Chief Executive Officer

MSc (Norwegian Business School - BI)
Chartered Accountant (Norwegian School of
Economics, NHH)
15+ years' experience in business
development



Dr Christopher Burton
Chief Medical Officer

MA (Cambridge University)
MD (Imperial College London)
PhD (University of Copenhagen)
15+ years' pharmaceutical & clinical
development experience

SoftOx – Key takeaways



Clinical studies of wound technology – showing consistent reduction in wound bacterial burden and dose-dependent reduction in wound size after just 5 days' treatment



Clinical study of respiratory technology - showing favourable tolerability and safety with preclinical proof of concept in animals



Wide-ranging platform technology with extended patent family – over 70 patents issued worldwide

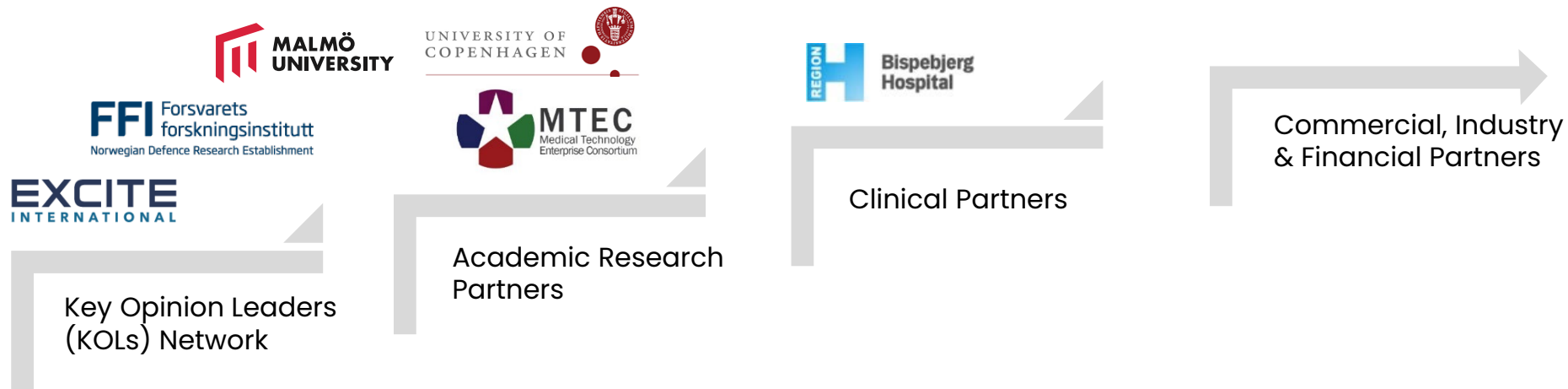
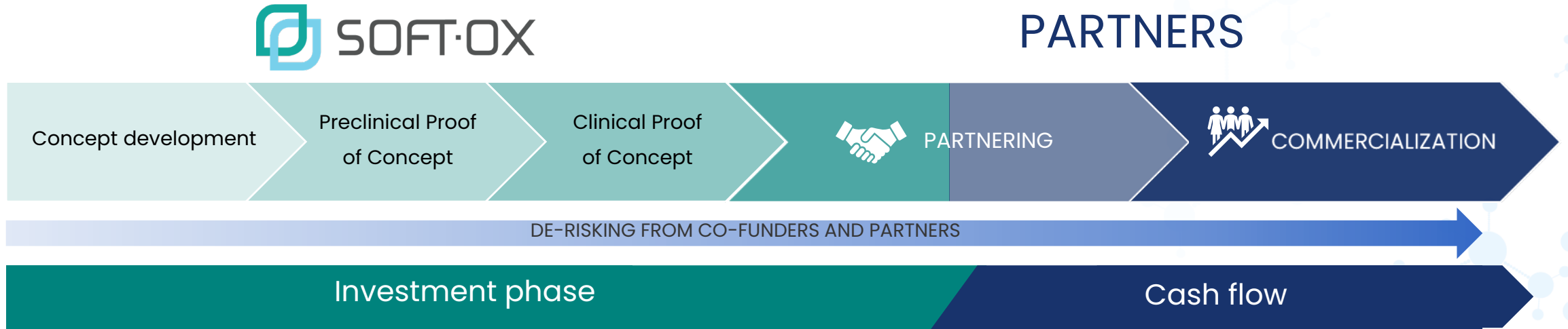


Today's projects address significant unmet needs identified by the FDA, US DoD and the EU











Ongoing defence collaborations in the US and EU providing non-dilutive funding

Network-based product development



Product pipeline – Good progress in clinical development programs

Business segments	Projects	Pre-clinical	Phase I	Phase II	Regulatory approval	Collaborations
Disinfection	Hand and surface disinfectants (SafeDes & EffectDes)				Keml (Sweden) granted 10-2022	
Wound Care	Wound irrigation solution					
	Chronic wound treatment					
Infectious disease	Inhalation solution					

This table presents a simplified version of the development phases as processes vary for biocide, medical device and drug development
 The Company's negotiations with distributors and partners are in different phases and some are in the early stages of the dialogue. No assurance can be made as to whether final agreements are concluded.

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

HYPOCHLOROUS ACID

Documented broad antimicrobial effect



ORGANIC ACID

Antimicrobial stabilizer



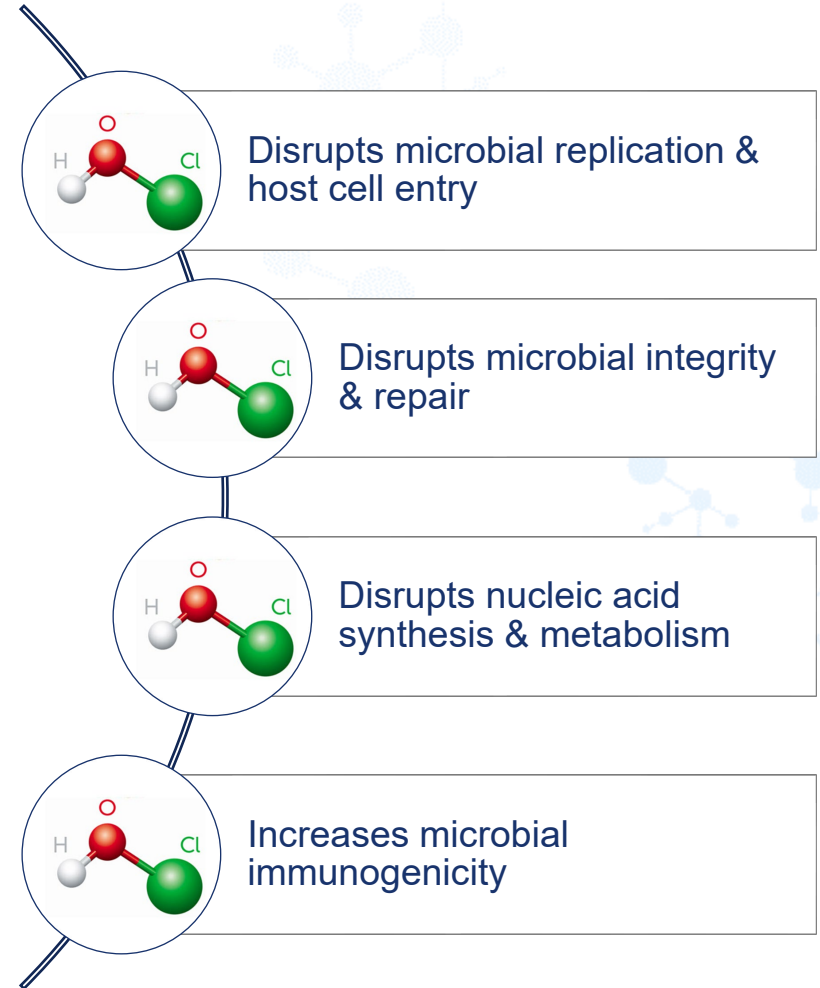
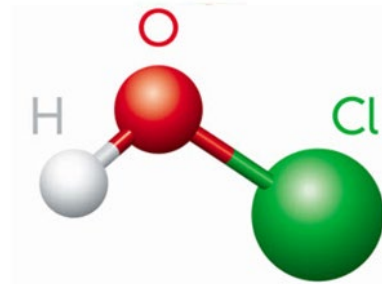
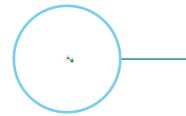
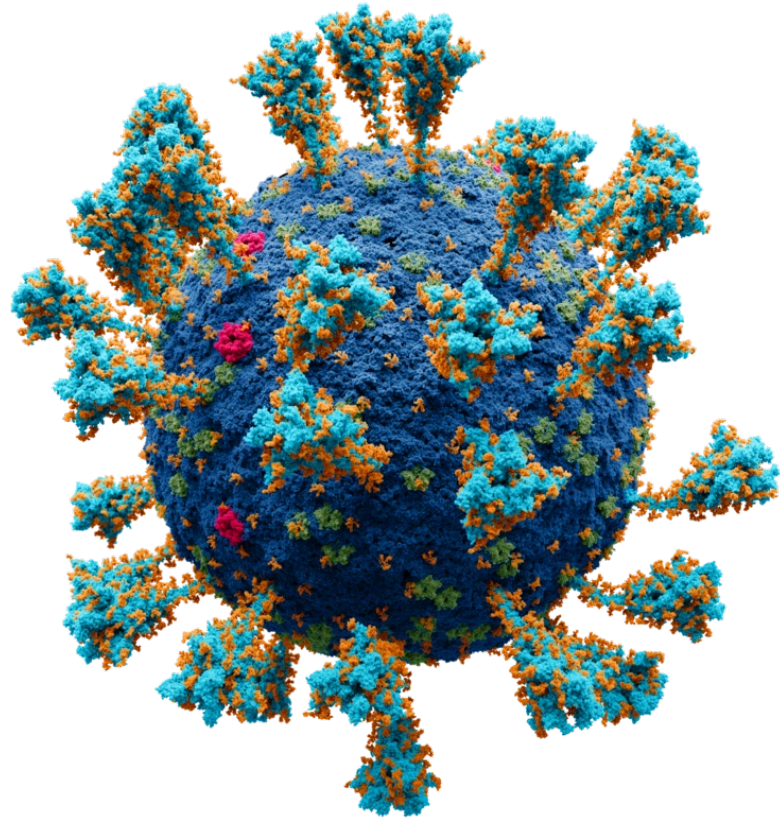
SOFTOX TECHNOLOGY

1. Strong pan-spectrum antimicrobial (virucidal/bactericidal) effects
2. Not shown to induce antimicrobial resistance
3. Good safety and tolerability profile – no systemic side effects (including endogenous substances)
4. Stabilized formulations with 3-year shelf life

The base technology is applicable across different indications and uses

HOCl has direct and indirect antimicrobial MoA:

Independent of biological processes and unreliaint 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

Business segments



Infectious disease

Treatment of viral infections
and biological
countermeasure development



Wound care

Treatment for acute and
chronic wounds



Disinfection

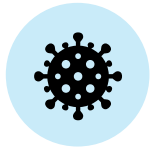
Infection prevention
solutions for hands and
surfaces

01

Business segment: Infectious disease



Respiratory infectious diseases are the third leading cause of death worldwide¹ and pose significant socioeconomic costs



Limitation of vaccines

Need for a novel, self-administered, product with broad-spectrum, antiviral and antibacterial effects



Morbidity & mortality

Need for early antimicrobial interventions that are unaffected by mutation, and do not induce antimicrobial resistance



Emergent microbial threats

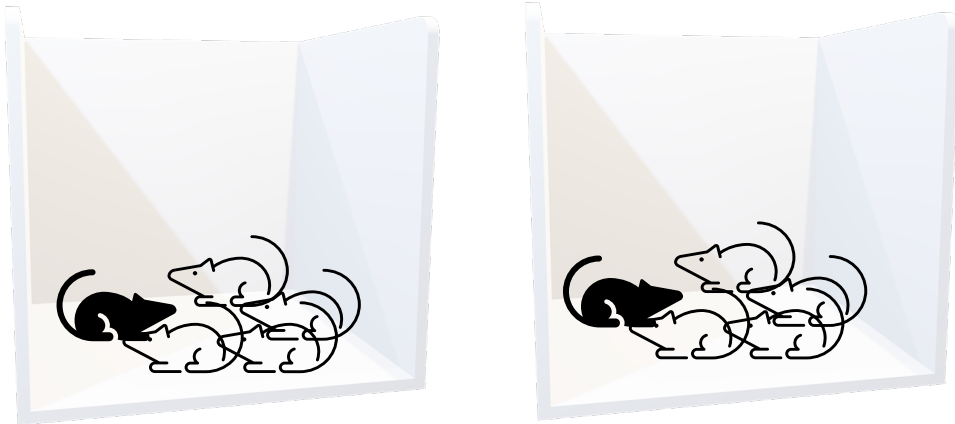
Need for a first-line defence product against disease X (the next pandemic) — a product that is both antibacterial and antiviral, and can be used immediately




1. Forum of International Respiratory Societies. (2017) *The Global Impact of Respiratory Disease – Second Edition*. European Respiratory Society.
https://www.who.int/gard/publications/The_Global_Impact_of_Respiratory_Disease.pdf
World Health Organization (WHO). (n.d.). *New report calls for urgent action to avert antimicrobial resistance crisis*. <https://www.who.int/news/item/29-04-2019-new-report-calls-for-urgent-action-to-avert-antimicrobial-resistance-crisis>

Pre-clinical proof of concept: Demonstration of infection prevention in a mouse model



Co-housing with infected mice & exposure prophylaxis with Saline or SoftOx



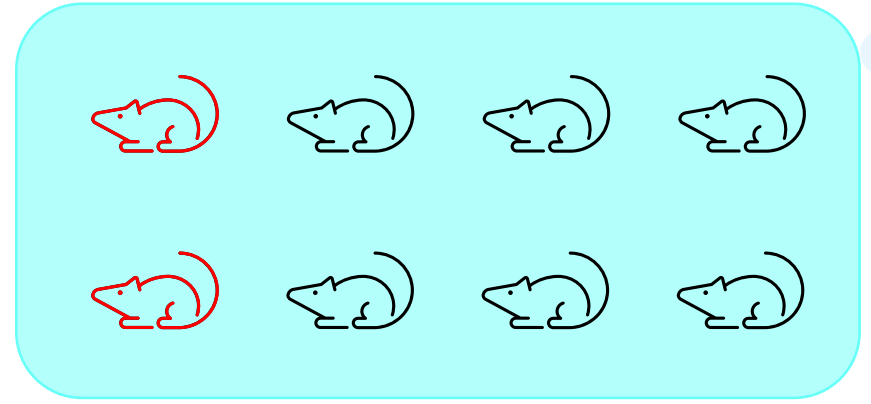
-  Index (infected) mouse removed from cohousing on day 3
-  Uninfected mouse
-  Infected mouse (determined by IVIS [average radiance $\geq 10^3$ p/s/cm²/sr])

DAY 5

Saline Treatment Group



SoftOx Treatment Group



Data on file.

Nebulised formulation safe and well tolerated

Abstract presented to ERS 2022



- No SAEs
- Mild, self-limiting AEs related/unrelated to drug administration
- Acceptable local tolerability
- No effect on spirometry, vital signs, ECG or safety laboratory values

At all dose levels

Regardless of dosing frequency

36474

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

C. Burton¹, T. Balchen², L. Wilki-Kurtzhals², N. Sjögren³, T. Bjarnsholt⁴, E. Jørgensen⁵, D. P. Sonne⁶

¹SoftOx Solutions A/S - Copenhagen (Denmark), ²DanTrials ApS - Copenhagen (Denmark), ³SIDS Life Science - Stockholm (Sweden), ⁴Department of Immunology and Microbiology, University of Copenhagen & Department of Clinical Microbiology, Copenhagen University Hospital, Rigshospitalet - Copenhagen (Denmark), ⁵Department of Immunology and Microbiology, University of Copenhagen - Copenhagen (Denmark), ⁶Department 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.

Presented by: Dr Christopher M Burton, PhD, MRCP, Chief Medical Officer, SoftOx Solutions A/S, Email: christopher.burton@soft-ox.com, Tel: +47 948 55 595

Variable	Single dose				4x daily 5 d				Placebo (n=14)	Total SIS (n=43)	Total (n=57)
	25 µg/mL (n=14)	50 µg/mL (n=14)	100 µg/mL (n=14)	100 µg/mL (n=14)	25 µg/mL (n=14)	50 µg/mL (n=14)	100 µg/mL (n=14)	100 µg/mL (n=14)			
Age (years)	32 ± 10	26 ± 6	27 ± 5	28 ± 7	28 ± 6	28 ± 3	25 ± 6	27 ± 7	27 ± 6	27 ± 6	
Sex (% male)	1 (0.07%)	3 (0.02%)	4 (0.02%)	3 (0.02%)	3 (0.02%)	3 (0.02%)	5 (0.04%)	12 (0.08%)	22 (0.16%)	34 (0.60%)	
Race									1 (0.01%)	1 (0.01%)	
Asian									1 (0.01%)	1 (0.01%)	
Black									1 (0.01%)	1 (0.01%)	
Other	1 (0.01%)	4 (0.03%)	3 (0.02%)	4 (0.03%)	4 (0.03%)	4 (0.03%)	7 (0.05%)	11 (0.08%)	19 (0.14%)	38 (0.67%)	
Ethnicity (% not Hispanic or Latino)	1 (0.01%)	4 (0.03%)	3 (0.02%)	4 (0.03%)	4 (0.03%)	4 (0.03%)	7 (0.05%)	11 (0.08%)	19 (0.14%)	38 (0.67%)	
Height (cm)	180 ± 11	174 ± 8	181 ± 5	176 ± 11	177 ± 10	180 ± 11	177 ± 10	181 ± 9	177 ± 11	179 ± 11	
Weight (kg)	68.7 ± 11.1	70.7 ± 8.2	69.2 ± 10.1	70.1 ± 10.1	70.1 ± 10.1	70.1 ± 10.1	66.9 ± 10.9	68.5 ± 11.0	70.1 ± 10.1	68.7 ± 10.3	
Body Mass Index (kg/m ²)	23.0 ± 1.0	23.8 ± 2.8	24.9 ± 1.4	23.7 ± 1.5	23.5 ± 1.2	23.5 ± 1.5	23.2 ± 2.8	24.9 ± 2.8	24.9 ± 1.9	23.9 ± 2.3	

Data are mean ± SD

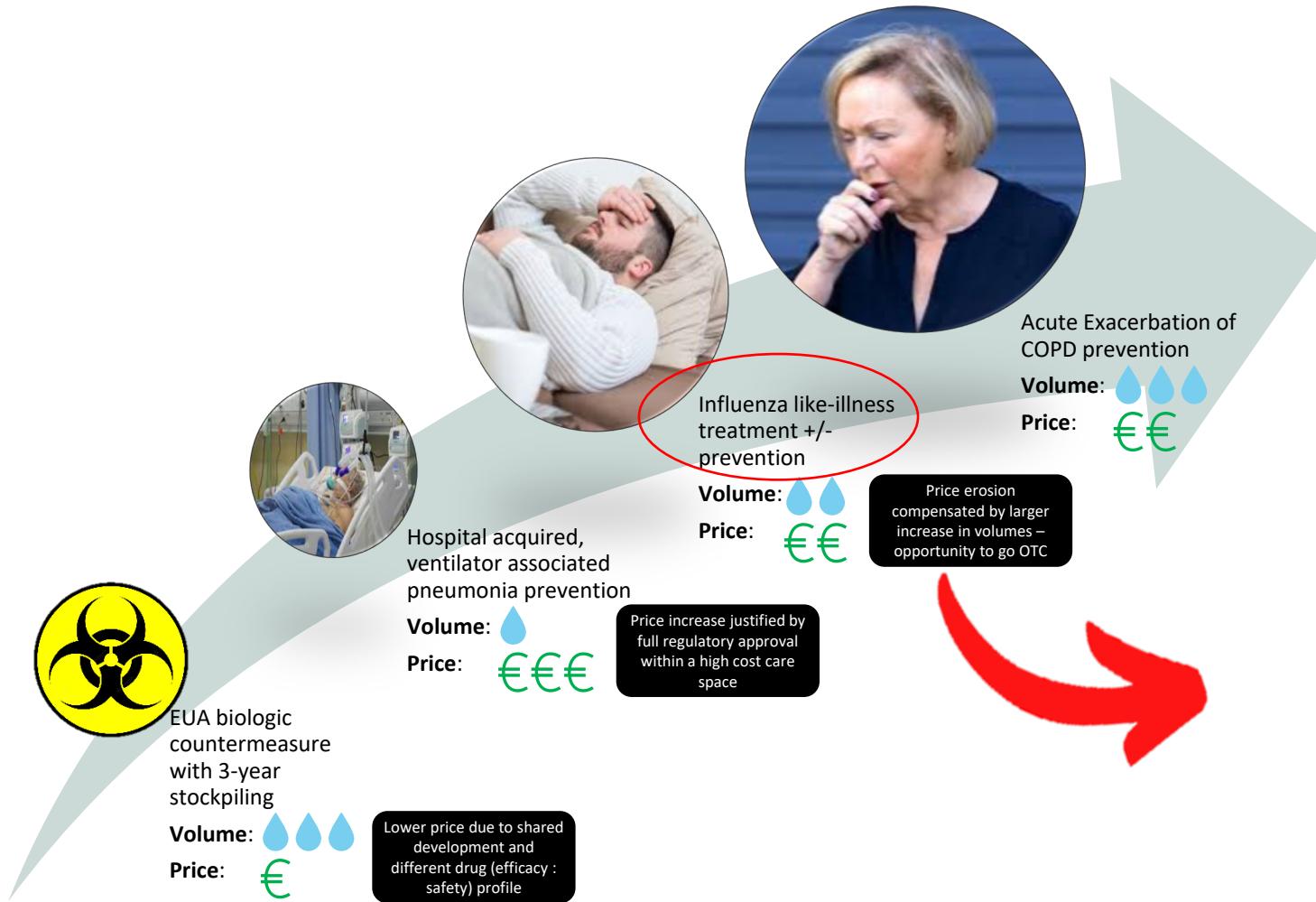
Figure 1: Number of adverse events by preferred term and dose

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

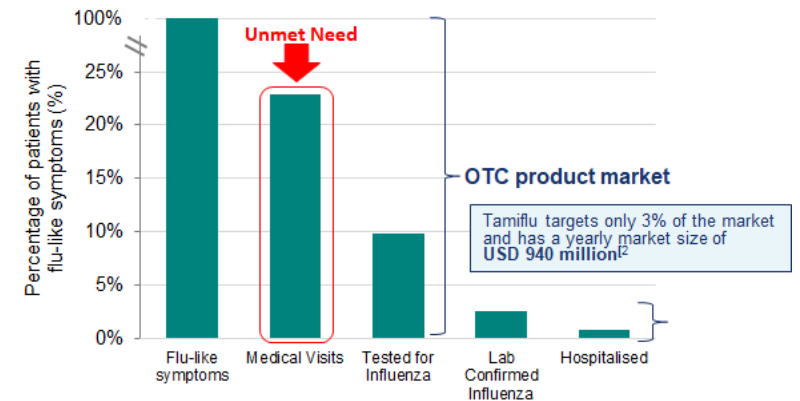
Figure 3: Boxplot of spirometry FEV₁ change from pre-dose by treatment group and assessment in relation to last dose (summary over days/dose)

Market potential of aerosolised SoftOx formulations

Example roll out across indications and evolution of price vs. volume



Civil
12% experiences flu-like symptoms annually



Generic Tamiflu is one of four FDA approved drugs for the treatment of influenza A/B ... which is still valued to be a billion dollar market

02

Business segment: Wound care

Significant unmet need for effective treatment in wound care



UNMET NEED:

6.5 million

chronic wound patients
in the US

Patient population drivers:

- Obesity
- Diabetes
- Population over 65 years of age

\$25 billion

Annual treatment costs of chronic
wounds in US

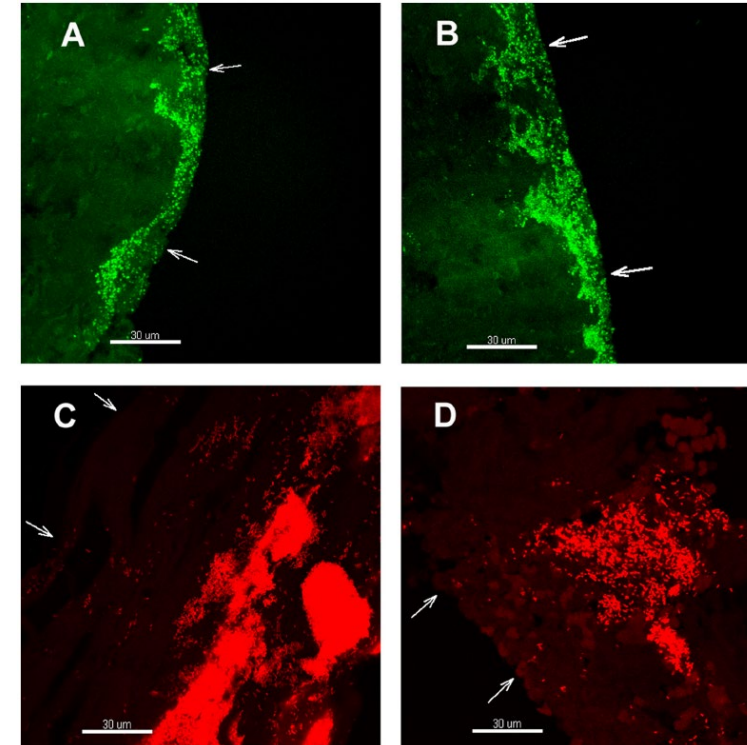
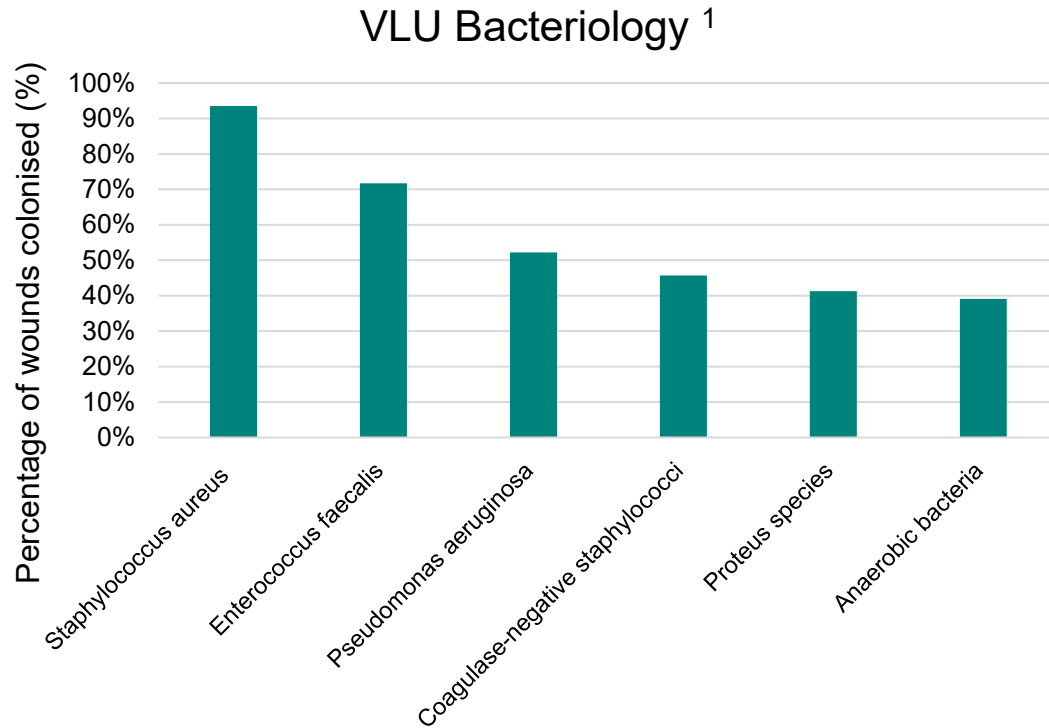
POTENTIAL MARKET:

Lack of innovative products to treat non-healing chronic wounds

- Human skin wounds: a major and snowballing threat to public health and the economy
- The US Food and Drug Administration (FDA) understands that innovative product development is essential to addressing the unmet medical need of non-healing chronic wounds



An effective wound product must be broad spectrum because of many types of bacteria in the wound



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

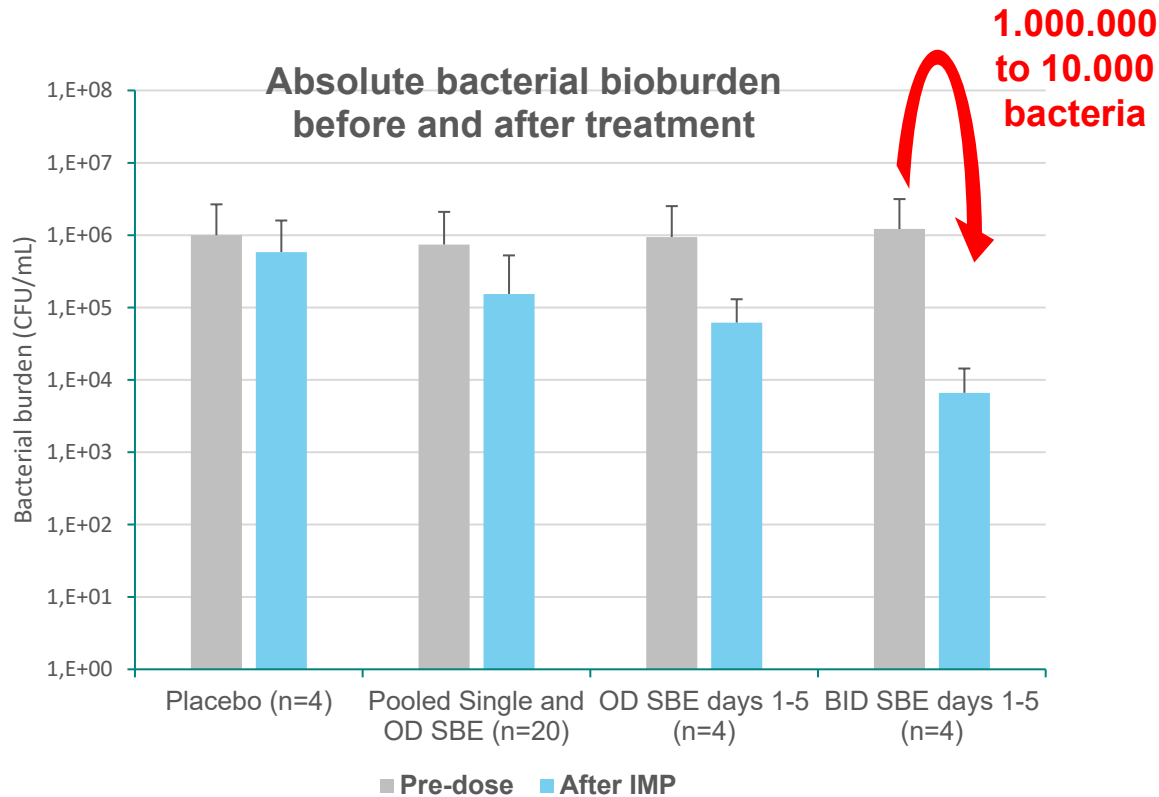
40-70% of venous leg ulcers are colonized by multiple (~5 to 6) bacterial species¹ which often cluster in biofilms with variable distance to the wound surface



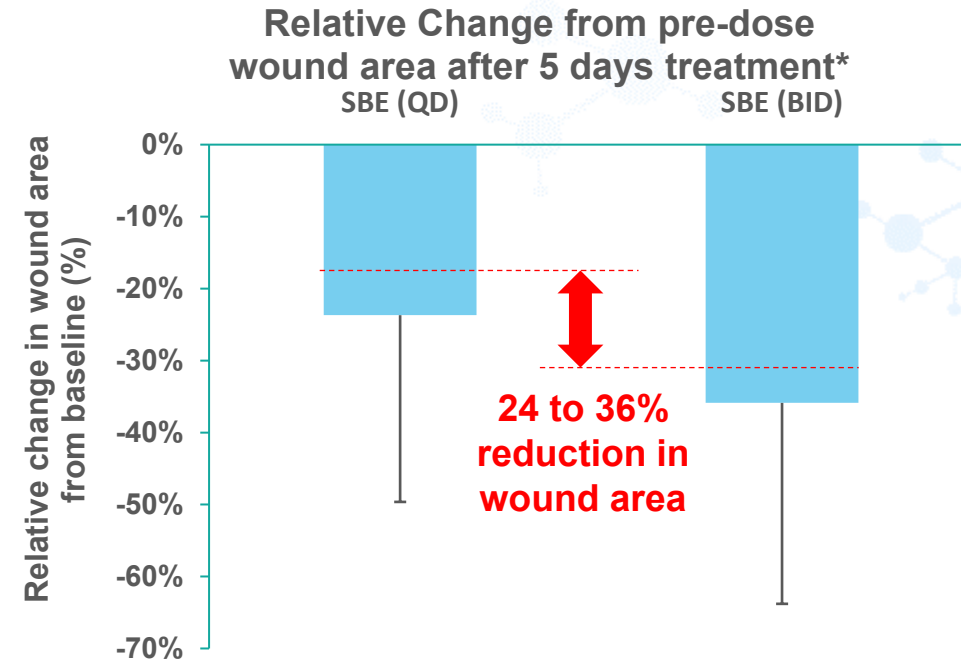
Safe and well tolerated in patients with chronic leg wounds:

Observed reductions in bacterial burden and wound size with dose response

> 99% reduction
in bacterial bioburden



up to 36% improvement
in wound healing after 5 days



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

First indication gives large market opportunities



UNMET NEED:

6.5 million

chronic wound patients
in the US¹

Patient population drivers:

- Obesity
- Diabetes
- Population over 65 years of age

\$25 billion

Annual treatment costs of chronic
wounds in US¹

POTENTIAL MARKET:

Compared to usual care, as shown through a decision analytic model developed by MedValue and Radboud University¹:

2.3 million

Targeted annual patient population
with VLU in the US

\$4 983

Est. cost savings of faster wound
healing per patient

\$11.5 billion

Cost savings of reduced time to
healing in VLUs

1) <https://pubmed.ncbi.nlm.nih.gov/19903300/>
2) MedValue and Radboud University. Data on file.



Unique platform technology

with combination effects
& supported by clinical
evidence



Significant unmet medical needs

in wound care and infection
disease



70+ patents issued

Strong patent
family protecting IP



Co-funded development

Expect 50–90% military
co-funding in US and
Europe



For further information, please contact

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CMO Dr Christopher Burton

Euronext Growth ticker: SOFTX