



# Helping the World Fighting Infections

**SoftOx Solutions AS**  
**Norwegian Pharmaceutical Company**

**Presentation of "New SoftOx"**  
**18 April 2024**

## Today's Speakers

**Executive Chairman of Board, Co-inventor  
Geir H. Almås**

MSc in business administration (BI) and State authorized public accountant (NHH)  
Extensive experience from business development  
Previously PwC and KLP Asset Management



**Chief Scientific Officer, Co-inventor  
Prof Thomas Bjarnsholt, PhD**

MSc (Danish Technical University); PhD (Danish Technical University)  
Doctor of Medicine (University of Copenhagen)  
Professor of Microbiology and biofilm infections  
250+ peer reviewed publications



**International Senior Project Manager  
Elin Jørgensen, DVM, PhD**

DVM (University of Copenhagen); PhD (University of Copenhagen)  
Profound research experience with infection models.  
Preclinical expert and lead on SoftOx' engagement in EDF development project



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# The “New SoftOx” restructuring after refinancing of company

## The Board suggest to split SoftOx Solutions AS in two separate companies

- » SoftOx Solutions AS is separated into SoftOx Inhalation Solutions AS and SoftOx Skin and Wound Care Solutions AS by doing a drop down of the Skin and Wound care business into a daughter company of SoftOx Solutions AS
- » Shareholders in SoftOx Solutions AS will afterwards receive the shares in the daughter company SoftOx Skin and Wound Care Solutions AS as dividend
- » The listed company SoftOx Solutions AS will afterwards change name to SoftOx Inhalation Solutions AS

### SoftOx Inhalation Solutions AS (listed)

- Focus on Ventilator Associated Pneumonia (VAP)
  - » New board and management to be established and headquarter moved to Copenhagen
  - » Company will seek separate funding for phase 2 trial
    - Discussions already initiated with strategic investors
- Continue developing a solution for Medical Counter Measurements for Respiratory Biological Treats
  - » Fully funded program to complete phase 1 through EDF
  - » Development outsourced to University of Copenhagen

### SoftOx Skin and Wound Care (non-listed)

- Focus on Wound Care management
  - Phase 2/3 for SoftOx biofilm eradicator (SBE)
- No planned changes in board and management
- The company will seek separate funding from new investors
- Current shareholders to retain value upside potential in Skin- and Wound Care segment

**Ownership in both companies according to current ownership in SoftOx Solutions**

# Investment Highlights – SoftOx Inhalation Solutions AS

Following the recent private placement and conversion of debt, listed SoftOx will be a debt free project-oriented company with a slim organization and a well-defined clinical development plan

- ✓ Target indication Ventilator Associated Pneumonia (VAP) represents huge costs for hospitals and high mortality rate
- ✓ Low estimated costs to complete a phase 2 VAP study with relatively high probability of success
- ✓ Fully funded program for military use of SIS through phase 1
- ✓ Strong synergies between the development of SIS for civilian (VAP) and military use
- ✓ Targeting industrial partnership(s) or exit after completion of planned studies, expected early 2026



# Helping the world fighting infections

**SoftOx Inhalation Solutions AS**  
**Norwegian Pharmaceutical Company**

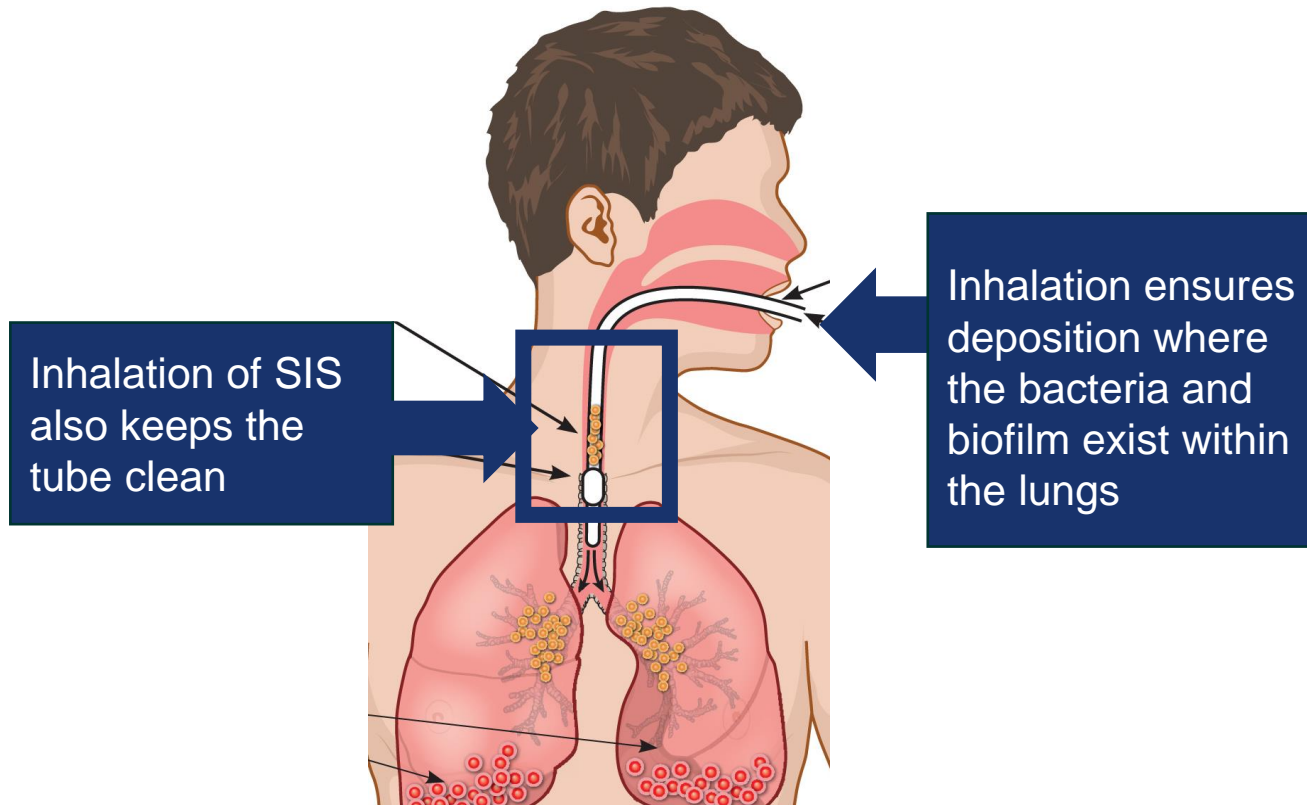
**April 2024**

The problem → The Solution

# Next Generation Respiratory Antimicrobial Solutions

Ventilator Associated Pneumonia (VAP)

High risk – Difficult to Cure



## Frequency

- Intubated patients at ICU (Intensive Care Unit) have **10-30%** risk of developing VAP<sup>1)</sup>

## Mortality

- Up to **50%** mortality<sup>2)</sup>

## Difficult to cure

- Often antimicrobial resistance and biofilms limits effects of using antibiotics

Treatment costs of USD 4 bn per year in EU and US

# Why start with Ventilator associated pneumonia (VAP)

A severe type of pneumonia occurring for intubated patients at intensive care units (ICU)

- **Currently limited effectful treatment options and high mortality rate**
- **Considered to have favorable possibility of clinical success with low study costs**
- **Benefits of a VAP cohort**
  - » The patient group is well-defined and enrolled into ICU
  - » Targeted delivery of SIS through already present tubus (inhalator)
  - » ICU personal are experience in using inhalation medicine and devices for nebulization
- **Favorable pathway to market**
  - » A hospital acquired infection; hospitals pay for treatment – no need for reimbursement before we can start to sell
  - » Large market with a cost reduction potential of USD 4 bn per year
  - » Few and easy reachable costumers (only ICU at hospitals)



## Project Plan VAP

Technology



Toxicology & Phase I (in humans)



Preclinical Efficacy



Proof of Concept in Humans - Phase 2

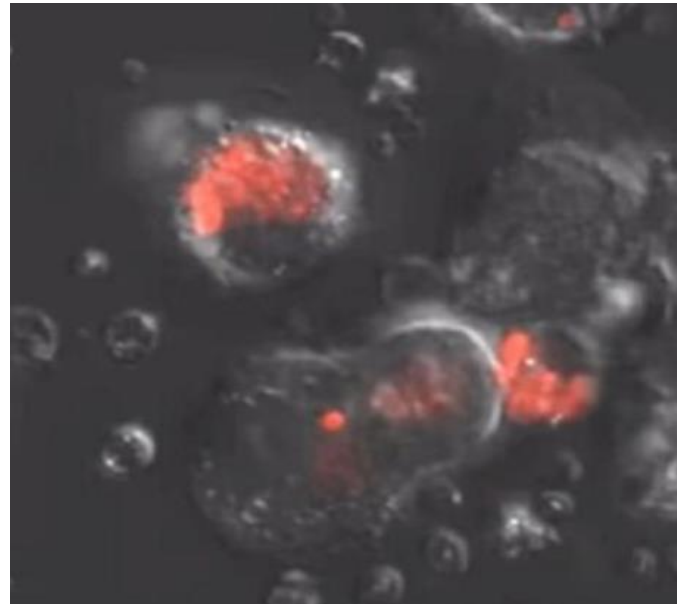
Market Adoption



# Reinforcing nature's own ability to eradicate unwanted microbes

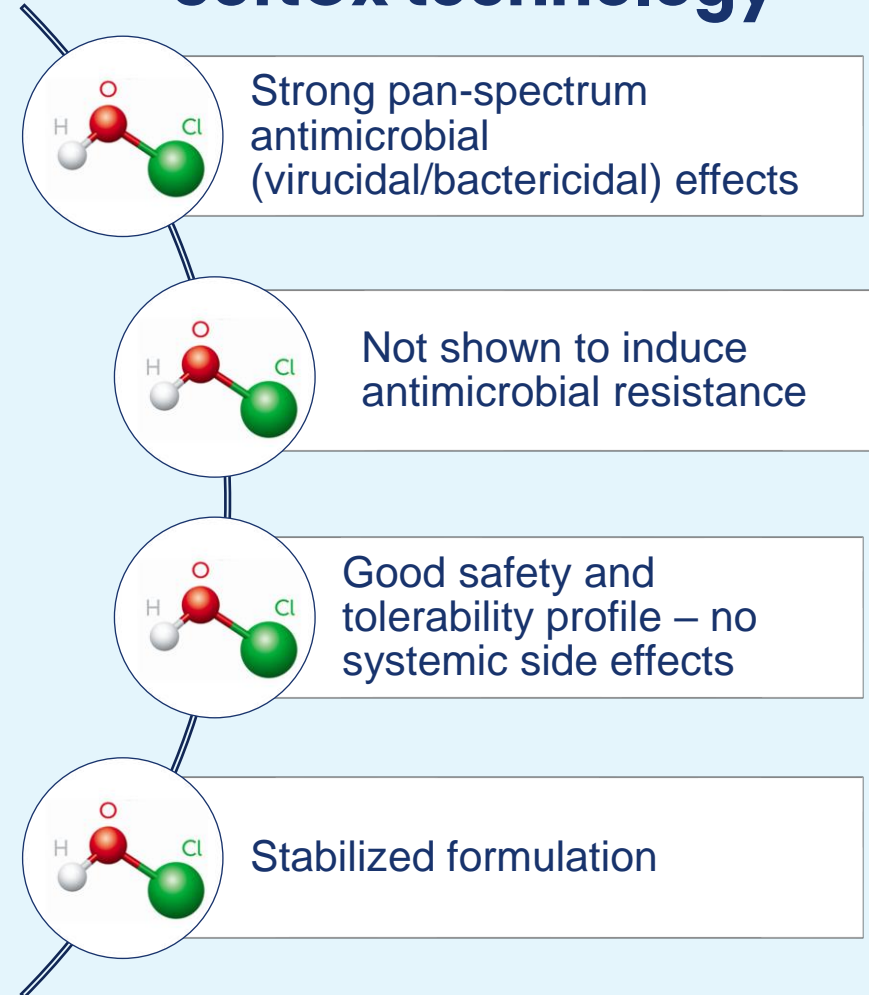
## HYPOCHLOROUS ACID

Documented broad  
antimicrobial effect



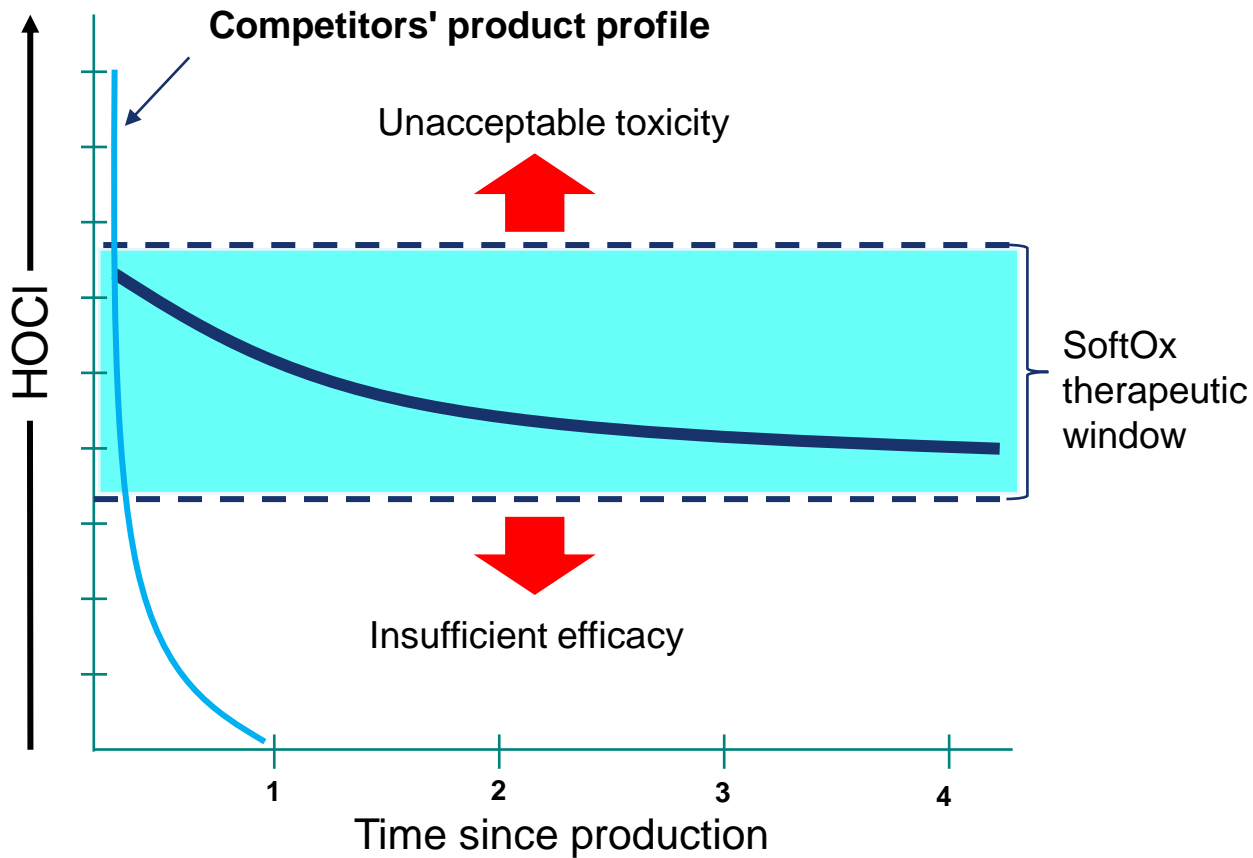
HOCl (red) in action  
produced by immune cells

## SoftOx technology



**SoftOx = Stabilized HOCl**

# Managed to solve Medical Grade Stabilized HOCl



## SoftOx product profile gives

- Dose optimization within designated therapeutic window
- Stability - less than 5% degradation over 2 years
- Robust Patent Protection > 90 granted
- Remain lifetime on vital applications > 15 years

Medical Grade HOCl

# Complete Toxicology Package

	Test	Conformance Standards	Summary	Status
Repeat-Dose Toxicity	Inhalation Study - Intubated (minipigs)	NA	Inhalation safety study of SIS (5 mL x 50, 100, or 200 µg/mL HOCl) daily for five days in Göttingen minipigs with/without recovery (2-4 weeks) using intubation.	Complete
	Inhalation Study – Masked (minipigs)	NA	Inhalation safety study of SIS (8.8 mL x50 or 100 µg/mL HOCl) daily for five days in Göttingen minipigs inhaling per mask.	Complete
	Multi-Dose Safety Study (minipigs)	NA	Inhalation 7-day repeat dose study of SIS (18 mL x 50, 100, or 200µg/mL HOCl) in Göttingen minipigs inhaling per mask.	Complete
	Multi-Dose Safety Study (minipigs)	GLP	2-week inhalation toxicology study of SIS with 2-week recovery in Göttingen minipigs inhaling per mask	Complete
	Dose range finding repeat dose study (rats)	NA	5-day (phase I, 1-6 hours exposure, 1000 µg/mL HOCl) and 14-day (phase II, 2-6 hours, 1000 µg/mL HOCl) inhalation of SIS in rats (nose only exposure)	Complete
	28-day Multi-Dose Safety Study (rats)	GLP	Inhalation toxicity +/- 2-week recovery in rats with exposure up to 4 hours and 1000 µg/mL HOCl SIS (nose only exposure)	Complete
Cytotoxicity	Cytotoxicity of SIS (100-1000 µg/mL HOCl) (in vitro)	GLP	1000, 500, 200, and 100 µg/mL showed no cytotoxic effects on cultured L929 cells	Complete
Genotoxicity	Bacterial Reverse Mutation Assay (in vitro)	GLP	Bacterial strains used TA98, TA100, TA1535, TA1537, E Coli WP2 uvrA. SIS test concentrations used resulting in 250, 100, 50, 25, 10, 3.162, 1.0, 0.3162 µg HOCl/plate.	Complete
	Mammalian Cell Micronucleus Assay (in vitro)	GLP	In vitro micronucleus test using mouse lymphoma L5178Y TK <sup>+/+</sup> 3.7.2 C cells. SIS concentrations tested were 10, 7, 6, 5, 2 and 1 µg/mL.	Complete
	Lung Surfactant Functionality (in vitro)	NA	In vitro lung surfactant test of 500 µg/mL HOCl SS0330.	Complete
Other	Ocular Irritation Test (Isolated Chicken Eye Method)	GLP	SS0330 was tested at 500, 200, 100 or 50 µg/mL HOCl in a standard test according to OECD 438.	Complete
	In vitro Epi-ocular test of SIS	GLP	100 and 200 µg/mL SIS tested and was found to be non-irritant to eyes	Complete

## Phase 1 trial showed that SIS is safe and tolerable to inhale

Up to 4 times 5 mL 100 µg/mL SIS per day for five days is safe:

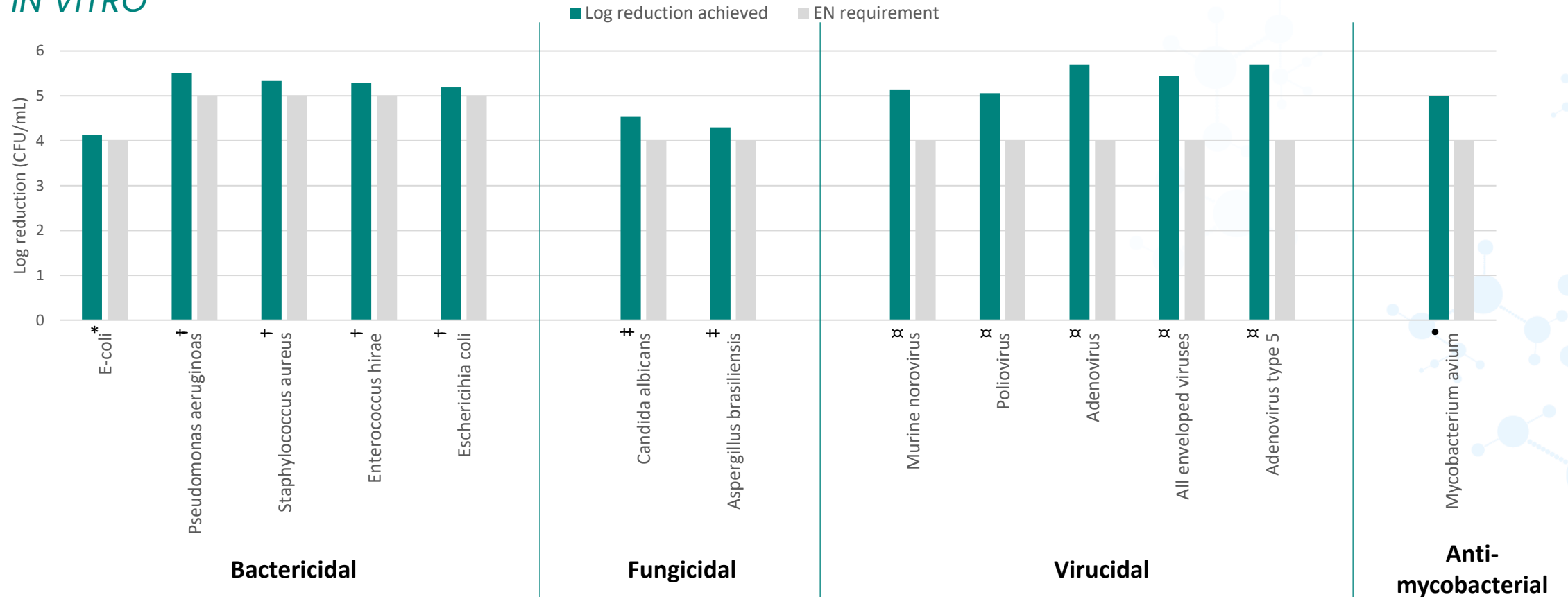
- NO SAE (Serious Adverse Events)
- Predominately mild AEs:
  - 27.9% of volunteers receiving SIS
  - 21.4% of volunteers receiving placebo
- Great tolerability profile
- Easy to use



**No safety signals for inhalation of SIS in healthy volunteers**

# Broad spectrum effect proven in antimicrobial EU Norm tests

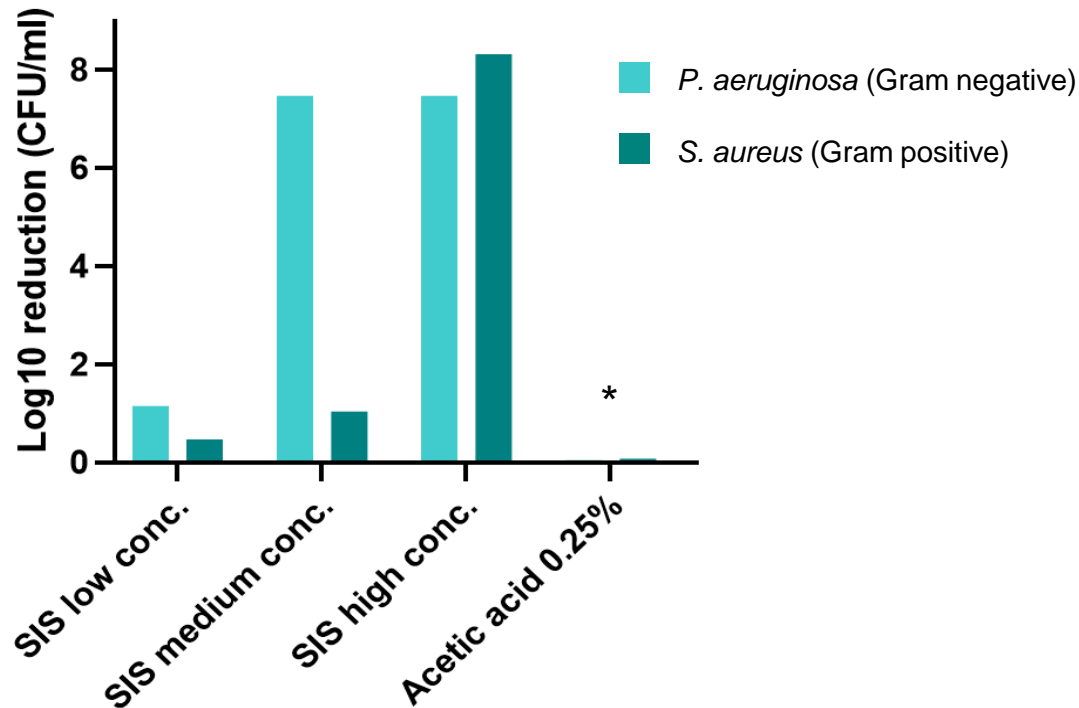
## IN VITRO



**Pan-antimicrobial effect against bacteria, fungi and viruses**

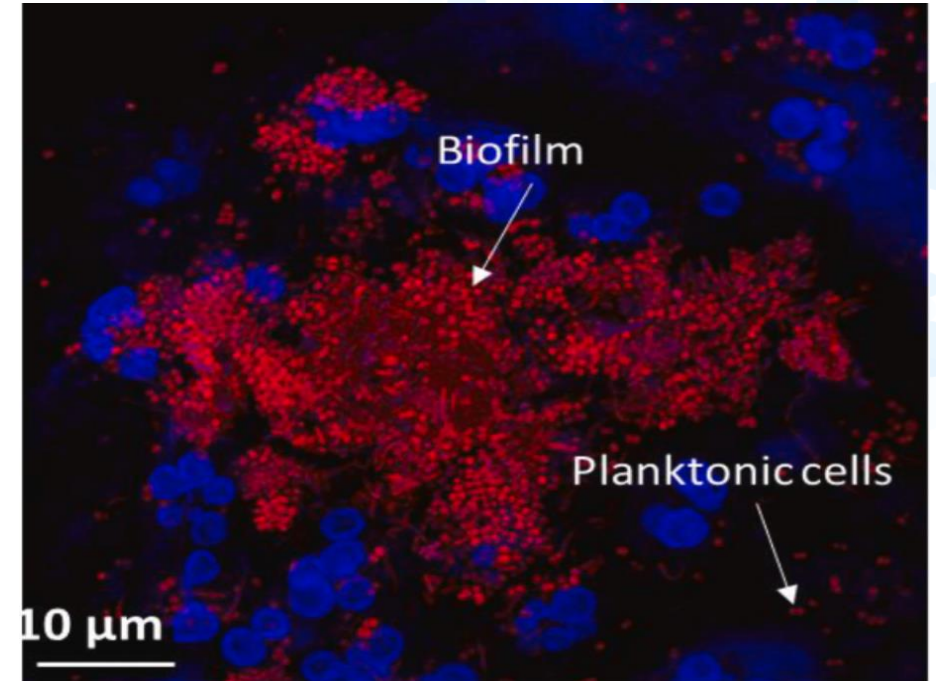
\* EN-1500:2013-07; †EN-1327+A2:2015-12; ‡EN-13624:2013-12; ⌘EN-14476+A2:2019; •EN-14348

# Strong antibiofilm activity of SIS against pulmonary pathogens



Data on file. SIS at various concentration tested against bacterial biofilms grown for 24 hours with one hour contact time.

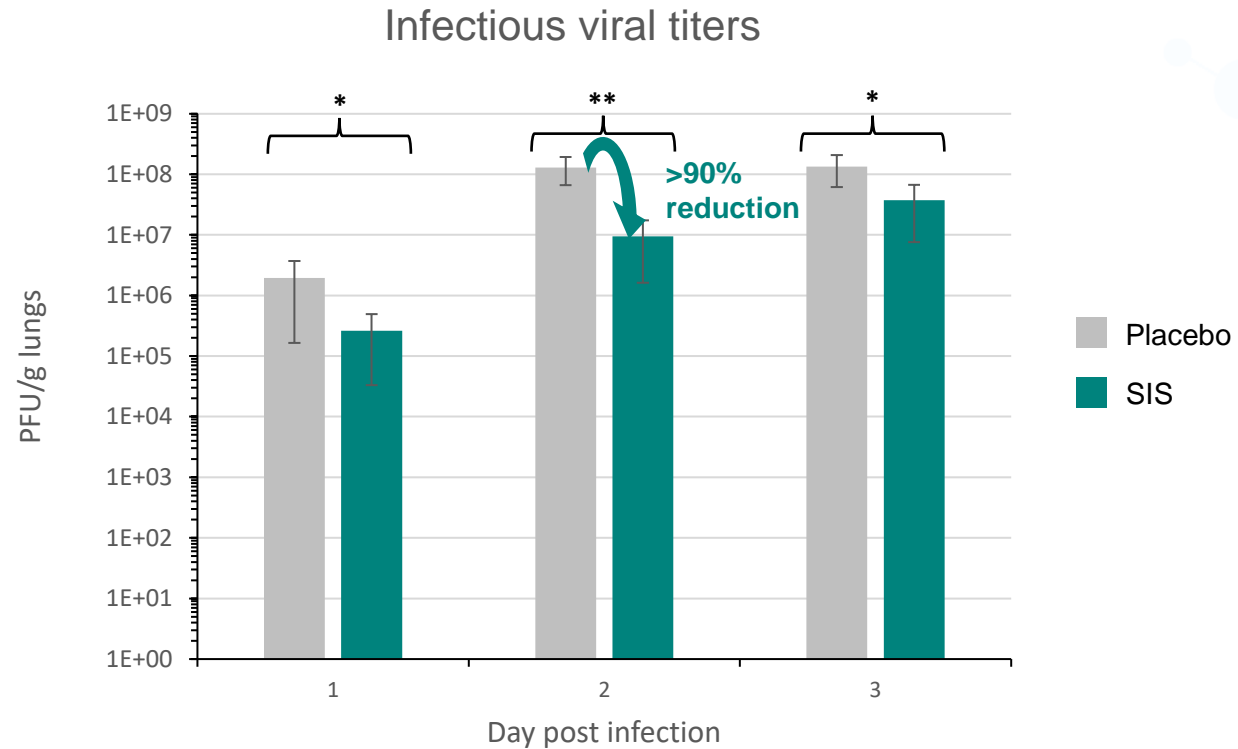
\*Acetic acid tested against planktonic bacteria with 15 minutes of contact time.



Biofilm (red) in sputum from pneumonia patient. *P. aeruginosa* and *S. aureus* are among the most common pathogens in VAP and often present as biofilms

Picture from: M. Kolpen et al., Bacterial biofilms predominate in both acute and chronic human lung infections. Thorax, (2022).

# Effective treatment of Influenza A in mice



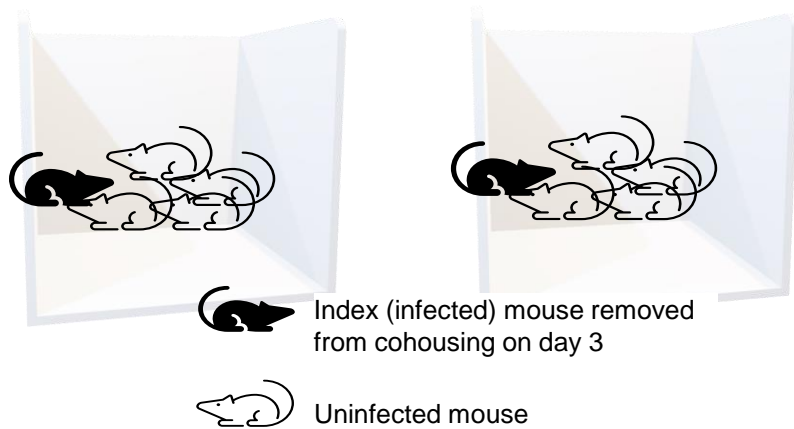
Twice daily SIS treatment resulted in lower viral lung titers on post-infection days 1-3





# Post-exposure prophylaxis efficacy against Sendai virus in mice

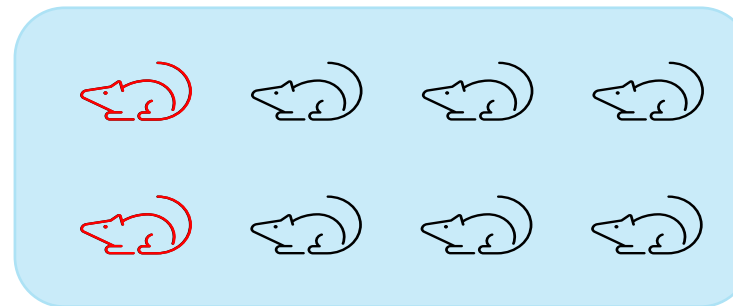
Co-housing with infected mice & post-exposure prophylaxis with saline or SIS



Saline Treatment Group



SIS Treatment Group



Infected mouse  
(determined by IVIS  
[average radiance  $\geq 10^3$   
p/s/cm<sup>2</sup>/sr])

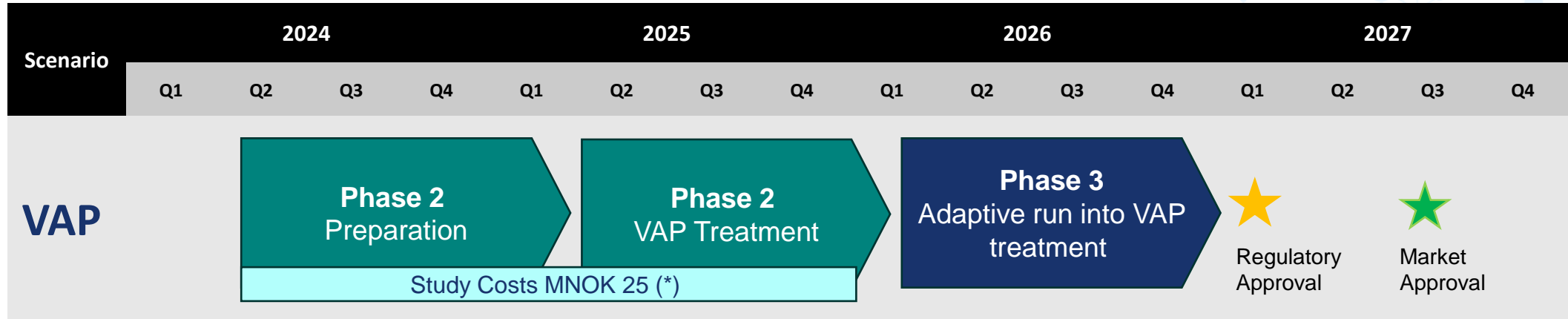
Data on file.



**SIS treatment prevents infection after exposure**

# Ventilator Associated Pneumonia (VAP)

## Clinical Development Plan (estimated timelines)



### Relatively high probability of success

- Collected all documentation to prepare CTA (Clinical Trial Application)
- Well defined group of patients
- Safe to inhale
- Reaches both upper and lower respiratory parts of the lungs
- Eradicate or inactive all relevant microorganisms
- Proof of concept for treatment and prevention in mice
- The study is suggested to be conducted with Incept.dk at the ICUs in the Capital Region of Denmark

**(\*) Total MNOK 50 to take the company through Phase II**

# Market adoption

## Patient

### Mortality

- 10-30% risk of developing VAP
- Up to 50% mortality

## Hospital

### Hospital Acquired Infection

- Hospital costs – USD 4bn
- No reimbursement

### Easy to implement – ICU

- Health Care Personnel
- Standard equipment

## Commercial

### Pathway to market

- Easier market penetration
  - Smaller sales force
  - Build market share faster

**Short and well-defined pathway to market**

# Financial Potential

> 130,000 yearly VAP cases US & EU

US: 60,000 cases<sup>1)</sup>

EU: 70,000 cases<sup>2)</sup>

USD 4 bn in extra treatment costs per year

US: USD 47,000 per patient<sup>3)</sup>

EU: USD 30,000 per patient<sup>4)</sup>

**Significant potential to reduce extra treatment costs**

## Value Proposition

Reduced hospital costs up to USD 4 bn

Reduced mortality

Reduced ICU days

# Countermeasures against biological threats Financed by European Defense Fund and Norwegian MoD

**COUNTERACT** - European agile network for medical COUNTERmeasures Against CBRN Threats

SoftOx/SIS is the main research target for the Biological threats (budget ~90M NOK)

Main partners are University of Copenhagen and CR Competence

## Highlights:

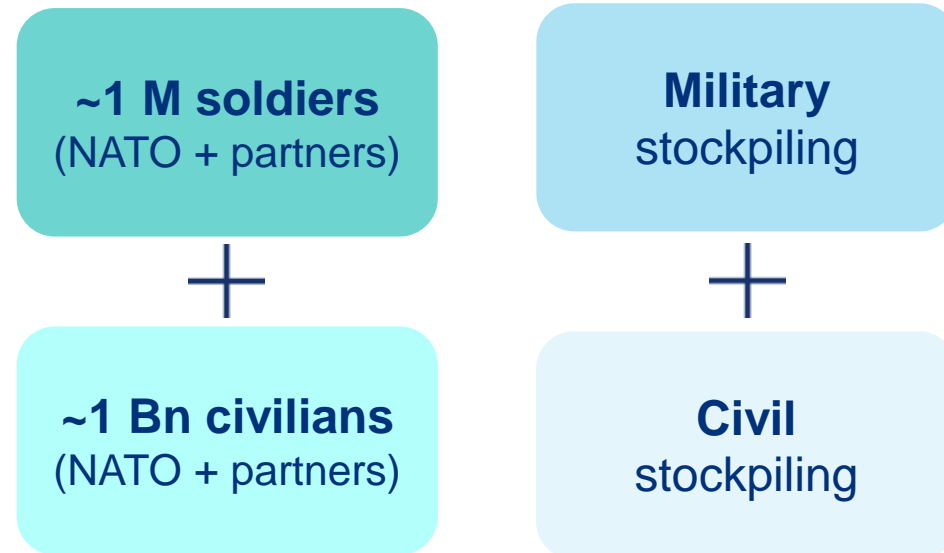
- Scientific advice on SIS 2.0 and phase 1B obtained
- Optimization of SIS 2.0 performed
- SIS 2.0 is tested against a diverse array of pathogens (in vitro/vivo)
- Phase 1B study planned to start 2025
- Setup of GMP production of SIS 2.0 at CMO included in budget



**Fully funded program - All commercial rights belong to SoftOx**

# EDF project market potentials

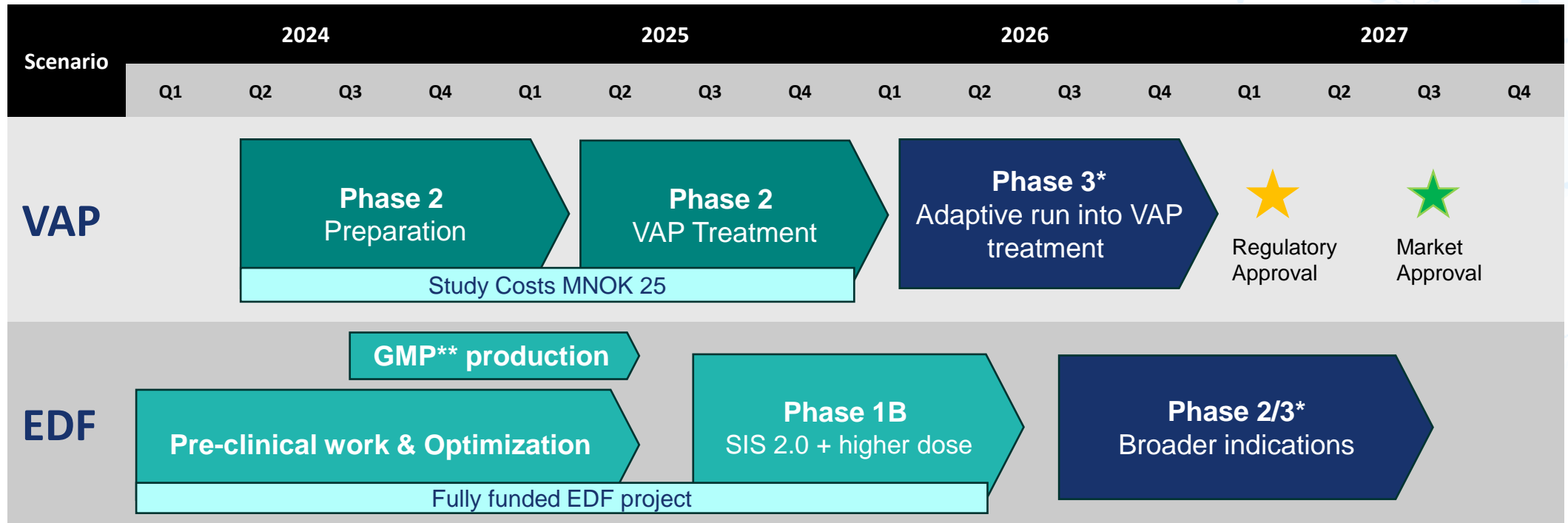
We expect 3-years stockpiling within NATO + partner countries



If successfully developed, the product is expected to be directly purchased by the military forces

**EDF cooperation on SIS represents a huge income potential**

# Overall Clinical Development Plan (estimated timelines)



\*SoftOx plan to partner up with relevant partner(s)

## Key synergies;

- The EDF/COUNTERACT phase 1B trial increases and optimizes dosing possibilities
- EDF project funds the GMP production setup (drug production) and provides safety data on SIS 2.0

**Strong synergies between civilian and military studies**

## Key Takeaways

- Following the recent refinancing, SoftOx is a debt free company with a well-defined clinical development plan and a clear market pathway
  - ✓ SIS for treatment of VAP answers to a large unmet medical need with high mortality rate
  - ✓ Modest clinical development costs due to well defined user group with infrastructure in place
  - ✓ Promising data from earlier phase studies indicate relatively high probability of clinical success
  - ✓ Short time to market
- Strong synergies with the fully funded clinical development plan on SIS for military use, representing a large unmet need for medical preparedness towards biological treats
- Outsourcing of work-flow and partnership with University of Copenhagen – A world-leading University within the field
- Focus on maximizing shareholder value – possible exit through partnerships or sale of company after completion of planned clinical studies, expected within 2-3 years



# Summary of risk factors 1:2

## Specific to the market in which SoftOx operates

- The Company relies on various partnerships for development, production, and distribution, and any failure to maintain these could hinder product development, increase costs, or prevent product commercialization.
- The Company's success relies on retaining and attracting skilled personnel, and competition for such individuals is high. Failure to maintain or protect against competitive actions from former employees could adversely affect operations.
- There is a risk that the Company's obtained patents is insufficient to prevent other competitors to commercialize competing products incorporating the Company's methods.
- The Company faces intense competition from established and new entities, and any inability to compete effectively could necessitate changes in clinical programs, increase costs, or impede product commercialization.
- The biopharmaceutical market's rapid evolution requires the Company to innovate and adapt continuously; failure to do so could materially affect its business and financial success.
- The Company's competitive position and revenue depend on protecting its intellectual property, and failure to do so could allow competitors to erode its market share or lead to costly legal disputes.

## Specific to the industries in which SoftOx operates

- Pharmaceutical investments are speculative, with substantial risks due to high initial costs and the possibility that product candidates may not be effective, obtain regulatory approval, or become commercially viable.
- Completing clinical trials is critical for the Company and is subject to various internal and external factors that could cause delays or failures, impacting the ability to obtain regulatory approval and commercialize products.
- Clinical programs may need changes due to technological advances, shifts in medical science, or regulatory demands, potentially affecting the Company's capital requirements and revenue flow.
- Early positive results in product development may not predict later success, and most product candidates may never receive approval or reach the market, which could significantly impact the Company's finances and operations.
- Side effects in product candidates can hinder clinical development, prevent regulatory approval, and limit commercial potential, leading to significant negative consequences including legal disputes.
- Late-emerging side effects of approved products could lead to withdrawal of approvals, additional warnings, or reduced acceptance, potentially resulting in legal disputes and reputational damage.

# Summary of risk factors 2:2

## Key risks specific to financial risks

- The Company's success hinges on its ability to commercialize product candidates, which involves numerous challenges including funding, clinical trials, regulatory approval, and acceptance within the medical community.
- Existing or future debt arrangements could limit the Group's liquidity and flexibility in obtaining additional financing and/or pursuing other business opportunities.
- Dependence on third-party manufacturers and suppliers exposes the Company to risks that could increase costs and delay or limit product supply, affecting the development process and time to market.
- The Company may require more funds to cover operational and development costs, and there is no guarantee that additional financing will be available on acceptable terms, if at all.
- Public grants and reimbursements play a significant role in funding the Company's projects, and the inability to secure such funding could have a material adverse effect on its operations.
- The Company cannot make any assurances that the Company will be able to continue to obtain public grants or reimbursements or to have grant applications approved in the future, on the same terms or at all.

## Key risks related to laws and regulations etc.

- The Company may become subject to new or increased burdensome government regulations affecting the industry
- Legal disputes and liability claims related to clinical trials or product use could result in significant costs, distract management, damage reputation, and adversely affect the Company's finances and operations.
- The Company may not be able to obtain the required approvals or marketing authorization from health authorities (domestic or multi-national (EU, etc.) for its products, which is required in order to enter the commercial phase
- Compliance with extensive regulations is crucial for the Company, and failure to comply or adapt to new regulations could lead to increased costs, fines, or operational shutdowns.
- Expansion into international markets involves regulatory challenges and compliance with various laws, which could lead to litigations, penalties, and other sanctions, adversely affecting the Company's business and reputation.
- The Group may be subject to legal disputes in the future.