Helping the world fighting infections

SoftOx Solutions AS

Company Presentation

August 2024

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Today's presenters

Incoming Chairman of Board (COB)
Ulrik Spork
Civ Ing/MSc (Danish Technical University)
Civiløkonom (Copenhagen Business School)

Extensive experience as Chairman, board member and advisor to emerging Life Science Companies

- Served on more than 30 boards internationally
- Deployed venture and PE investments into the global life-science industry for 20+ years

Previous Managing Partner in Novo Holdings and head of Corporate Business Development in Novo Nordisk

Incoming Chief Executive Officer (CEO)
Prof Thomas Bjarnsholt, PhD & DMSc
MSc (Danish Technical University)
PhD (Danish Technical University)
Doctor of Medicine (DMSc) (University of Copenhagen)
Professor of Microbiology and biofilm infections
250+ peer-reviewed publications

Chief Financial Officer (CFO)
Ingrid Juven, MBA
MBA (Norwegian Business School/ Handelshøyskolen BI)
Over 25 years of consulting and management expertise within a variety of industries

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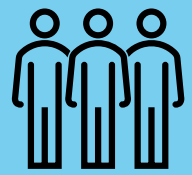
Restructuring Pillars

FOCUSED STRATEGY

FINANCIAL RESTRUCTURING & COST REDUCTION

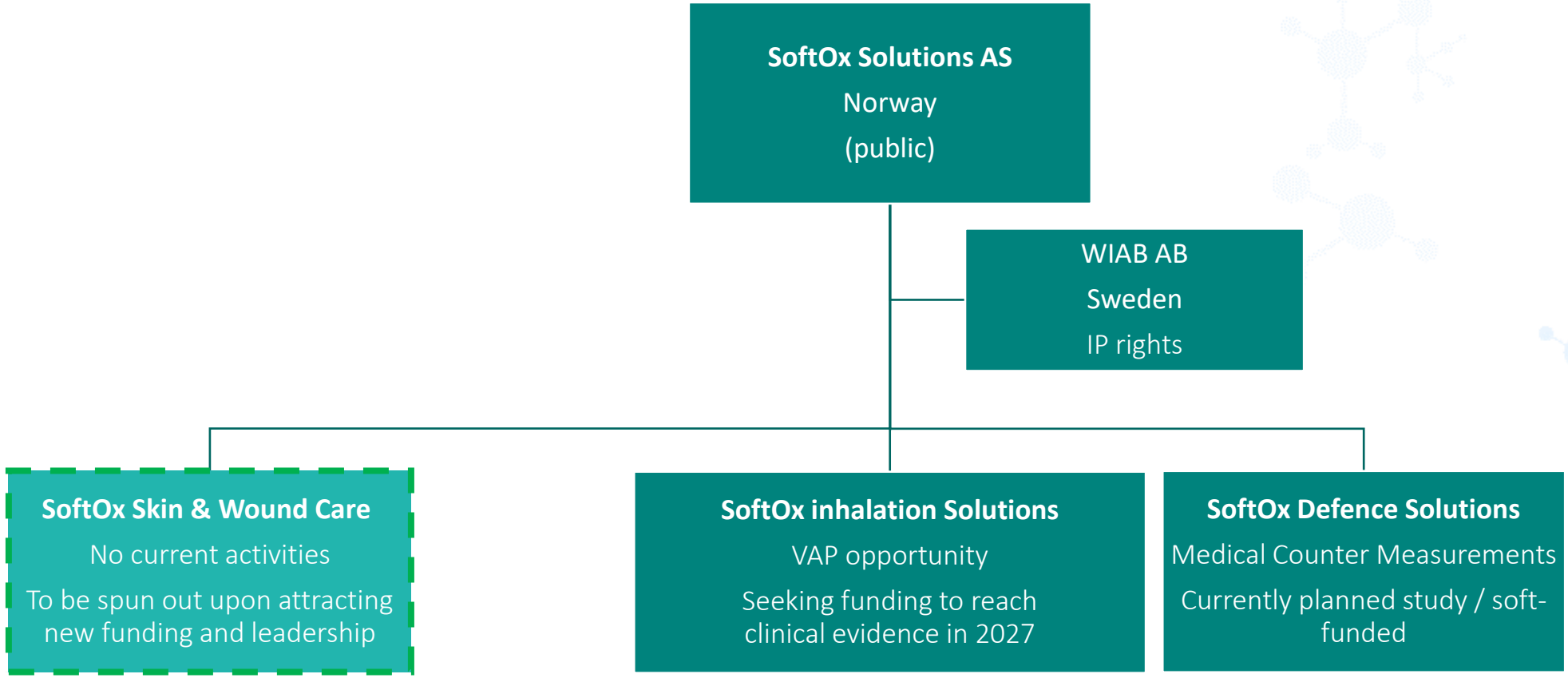
PROFESSIONALIZATION



Investment Case

- After completing ongoing **Rights Issue**
  - No outstanding debt
  - Secured and professionalized new Board and management and lean and project-oriented organization
  - Runway to enable funding of the VAP Phase II project
- **SoftOx Inhalation Solutions /** Target Indication **Ventilator Associated Pneumonia (VAP)**
  - Large unmet medical need, high costs for hospitals, and high mortality rate
  - Well-defined clinical development plan
    - Promising data from completed studies
    - Well defined ‘mode of action’ - relatively high probability of success
  - Tangible value inflection point reachable with modest funding
- Targeting industrial partnership(s) or exit after completion of phase II study in VAP, expected early 2027

SoftOx Solutions Group



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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**
  - Patient group well-defined and enrolled into ICU
  - Targeted delivery of SIS through already present ventilation tubes
  - ICU staff have experience in using inhalation medicines and devices for nebulization
- **Favorable pathway to market**
  - VAP is a hospital acquired infection; hospitals responsible of cost of treatment – limits reimbursement hurdle before commercialisation can be initiated
  - Large market potential
  - Narrow and identifiable target customers (ICU's at hospitals)

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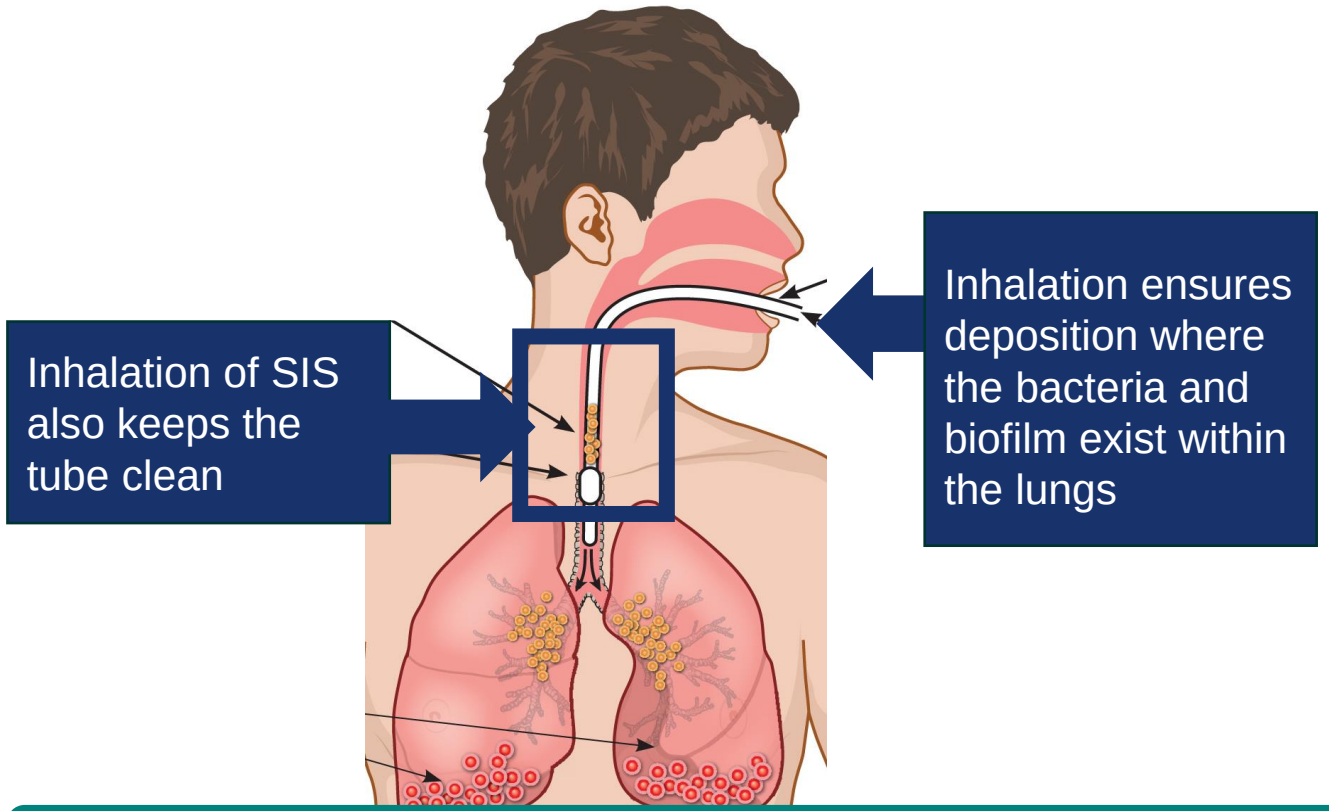
The problem –> The Solution

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[1)]

Mortality

- Up to **50%** mortality[2)]

Difficult to cure

- Often antimicrobial resistance and biofilms limits effects of using antibiotics

VAP costs $ 4 bn per year in EU and US – Good probability of clinical success

Picture from: https://www.britishjournalofnursing.com/content/clinical/does-oral-care-with-chlorhexidine-reduce-ventilator-associated-pneumonia-in-mechanically-ventilated-adults/

1) https://emedicine.medscape.com/article/304836-overview?form=fpf
2) https://www.ahrq.gov/hai/pfp/haccost2017-results.html

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Project Plan VAP

- Technology 
- Toxicology & Phase I (in humans) 
- Preclinical Efficacy 
- Proof of Concept in Humans - Phase 2
- Phase 3
- Market Adoption

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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 $TK^{+/-}$ 3.7.2 C cells. SIS concentrations tested were 10, 7, 6, 5, 2 and 1 µg/mL.	Complete
Other	Lung Surfactant Functionality (in vitro)	NA	In vitro lung surfactant test of 500 µg/mL HOCl SS0330.	Complete
	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

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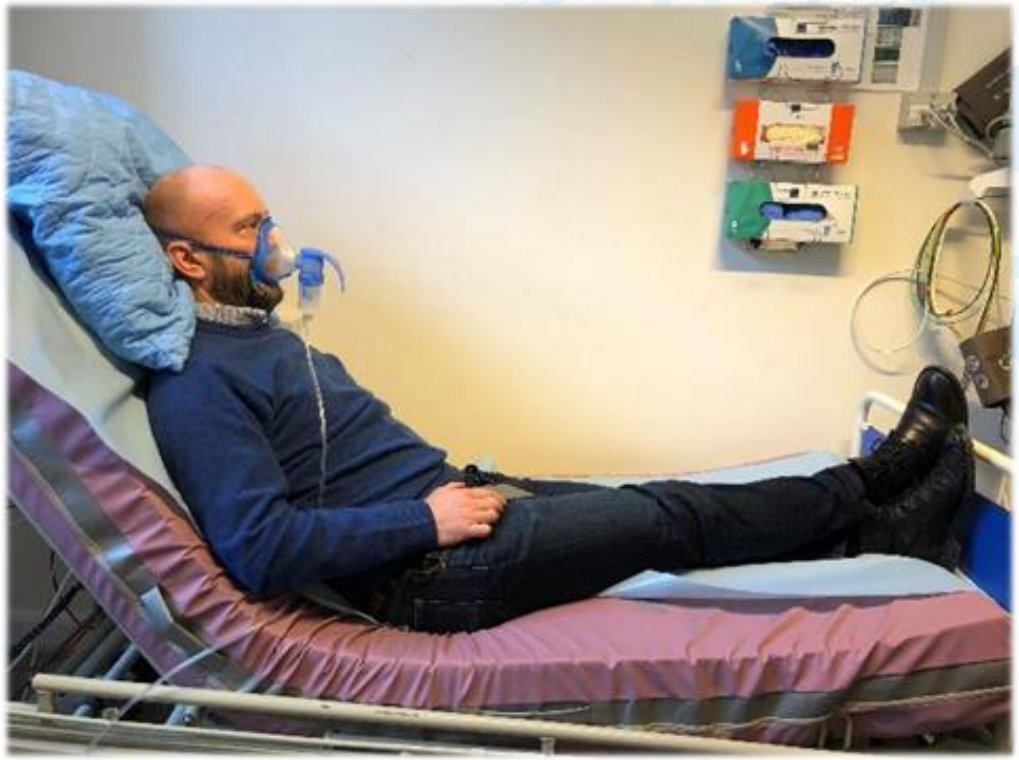
Phase I trial showed that SIS is safe and tolerable to inhale

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

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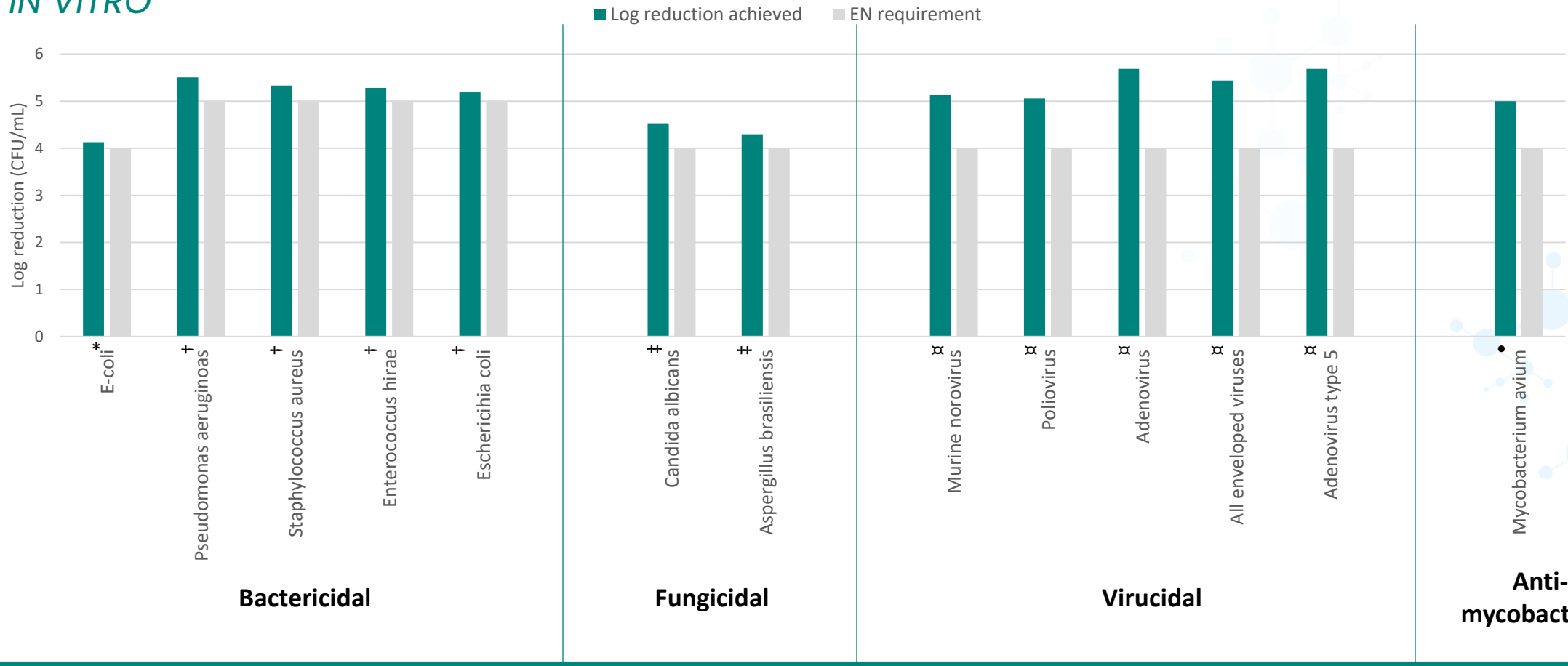
Broad spectrum effect proven in antimicrobial EU Norm tests

IN VITRO

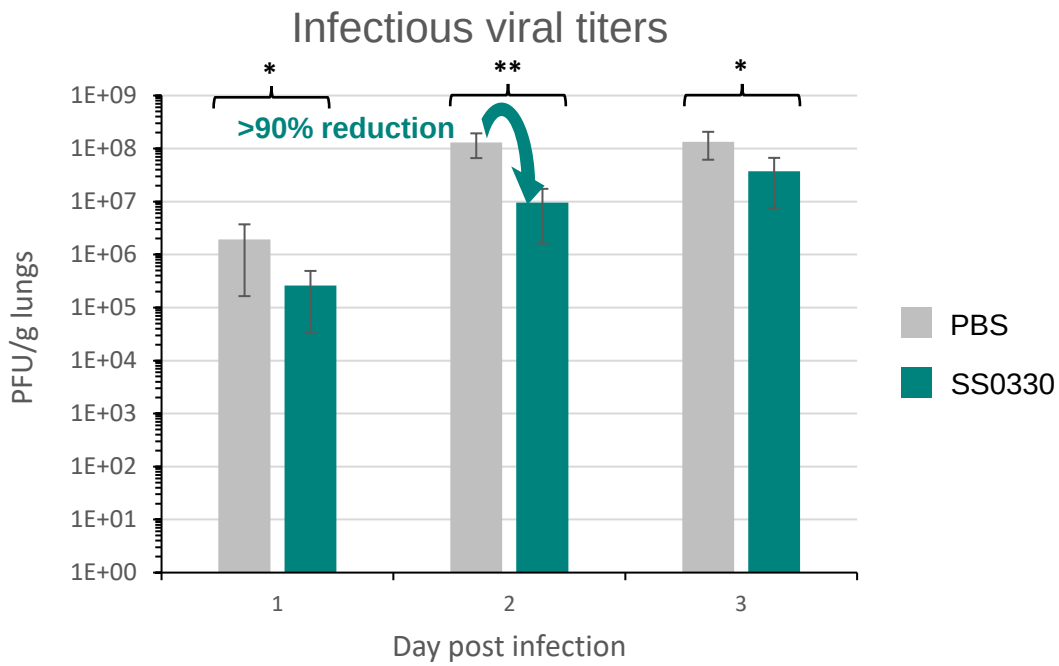


Pan-antimicrobial effect against bacteria, fungi and viruses

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

Effective treatment of Influenza A in mice

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



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

Post-exposure prophylaxis efficacy against Sendai virus in mice

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

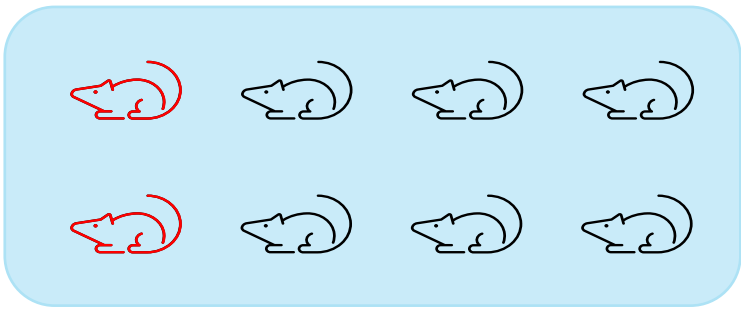
Index (infected) mouse removed from cohousing on day 3

Uninfected mouse

DAY 3

Saline Treatment Group

SIS Treatment Group



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

Data on file.

SIS treatment prevents infection after exposure

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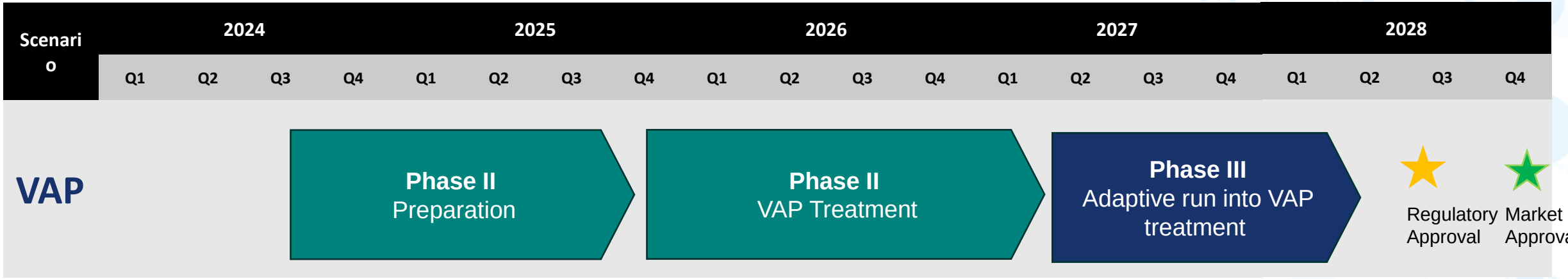
Ventilator Associated Pneumonia (VAP)
Clinical Development Plan (estimated timelines)



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 inactivate 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 60-80 to take the company through Phase II

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Pathway to market is short and well defined

VAP Patients	Hospital	Commercial
Cases • Annually 130 000 US/EU **Mortality** • 10%-30% risk of developing VAP • Up to 50% mortality	**Hospital Acquired Infection** • Hospitals pay – USD 4bn in yearly treatment costs • No need for reimbursement **Low implementation hurdle – ICU** • Very experienced staff at ICU's • Standard equipment	**Pathway to market** • Easier market penetration • Targeted sales force • Build market share faster

Financial Potential to reduce $ 4 bn in yearly Treatment Costs

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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)

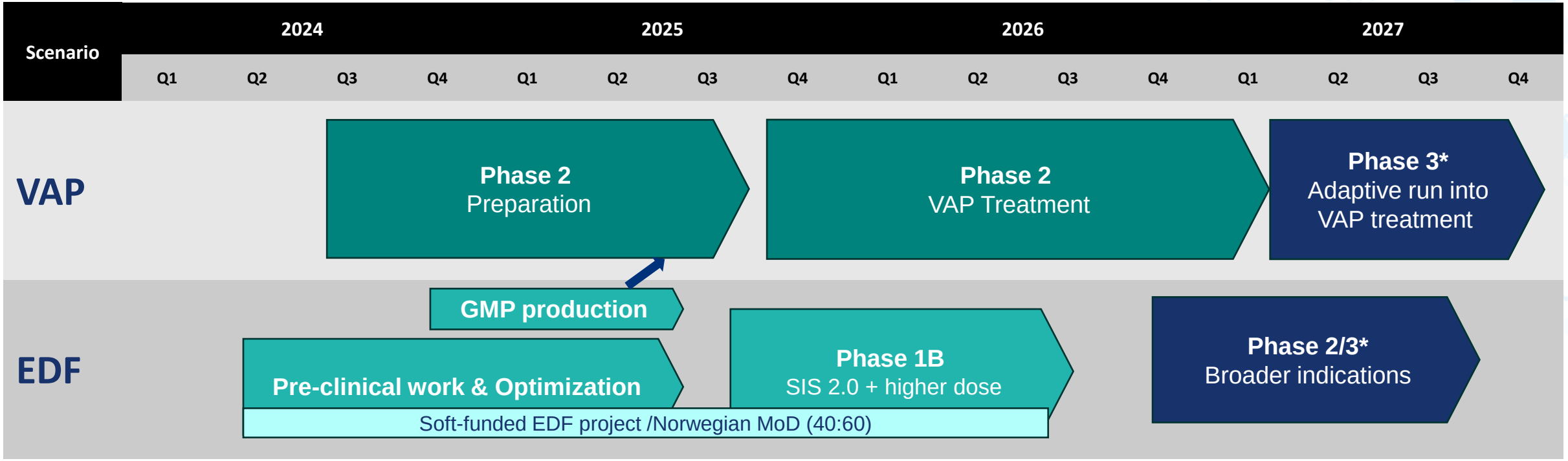
Main partners are University of Copenhagen and CR Competence

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

Soft funded program - All commercial rights belong to SoftOx

Overall Clinical Development Plan (estimated timelines)



The EDF/COUNTERACT phase 1B trial increases and optimizes dosing possibilities

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

Strong synergies and large market potentials

Key take-aways

- Following recent restructuring, SoftOx is now a debt-free company with a well-defined, promising and cost-effective clinical development plan in place
- New Board and Management team with strong track record
- Target indication VAP represents a significant value potential, while study costs to complete a phase II study is unusually low. If successful, will leverage development for additional indications
- Strong synergies with the soft-funded EDF project (inhalation solutions for military use)
- Leadership approach will be to maintain ‘venture style’ sharp focus on use of proceeds and conducting ‘mission-critical’ activities only, until value-inflection points are reached
- No use of management or financial resources on Skin and Wound care business – to be spun off at the right point in time
- Seeking industrial partnership(s) upon successful clinical data for VAP