Helping the World Fighting Infections

SoftOx Solutions AS

Investor presentation

March 2024

Private & Confidential draft

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New SoftOx Solutions – Boards recommandation

Splitting SoftOx Solutions AS in two separate companies

- Split SoftOx Solutions AS 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 extra ordinary dividend.
- SoftOx Solutions AS will afterwards change name to SoftOx Inhalation Solutions AS
- SoftOx Inhalation Solutions AS will continue to be listed at Euronext Growth, while SoftOx Skin and Wound Care Solutions AS will become a non-listed company

The listed company SoftOx Inhalation Solutions AS will

- Focus on Proof of Concept in Ventilator Associated Pneumonia (VAP)
- Control 100% of SoftOx Defense Solutions AS – Focus on Medical Counter Measurements for Respiratory Biological Treats
- After the split has taken place, a new board and management to be established and headquarter moved to Copenhagen
- Company will seek separate funding for a VAP phase 2 trial – discussions already initiated with strategic investors

The non-listed company SoftOx Skin and Wound Care

- Focus on Wound Care management
- No planned changes in board and management
- The company will seek separate funding from new investors

Helping the world fighting infections

SoftOx Inhalation Solutions AS

Norwegian Pharmaceutical Company

March 2024

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Why focus on Ventilator associated pneumonia (VAP)

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

- **Today's treatment options are costly (USD 6 bn/y US/EU) and have limited effects**
- **Promising study data indicated high probability of success**
- **Moderate administrative risk and short time to market**
  - » The patient group is well-defined and enrolled into ICU
  - » Targeted delivery of SIS through already present tubus (inhalator)
  - » ICU personal are experienced in using inhalation medicine and devices for nebulization
- **Clear pathway to market**
  - » A hospital acquired infection; hospitals pay for treatment – no reimbursement process
  - » Large market, estimated to be USD 2 bn per year, with a cost reduction potential of USD 6 bn per year
  - » Few and easily reachable costumers (only ICU at hospitals)

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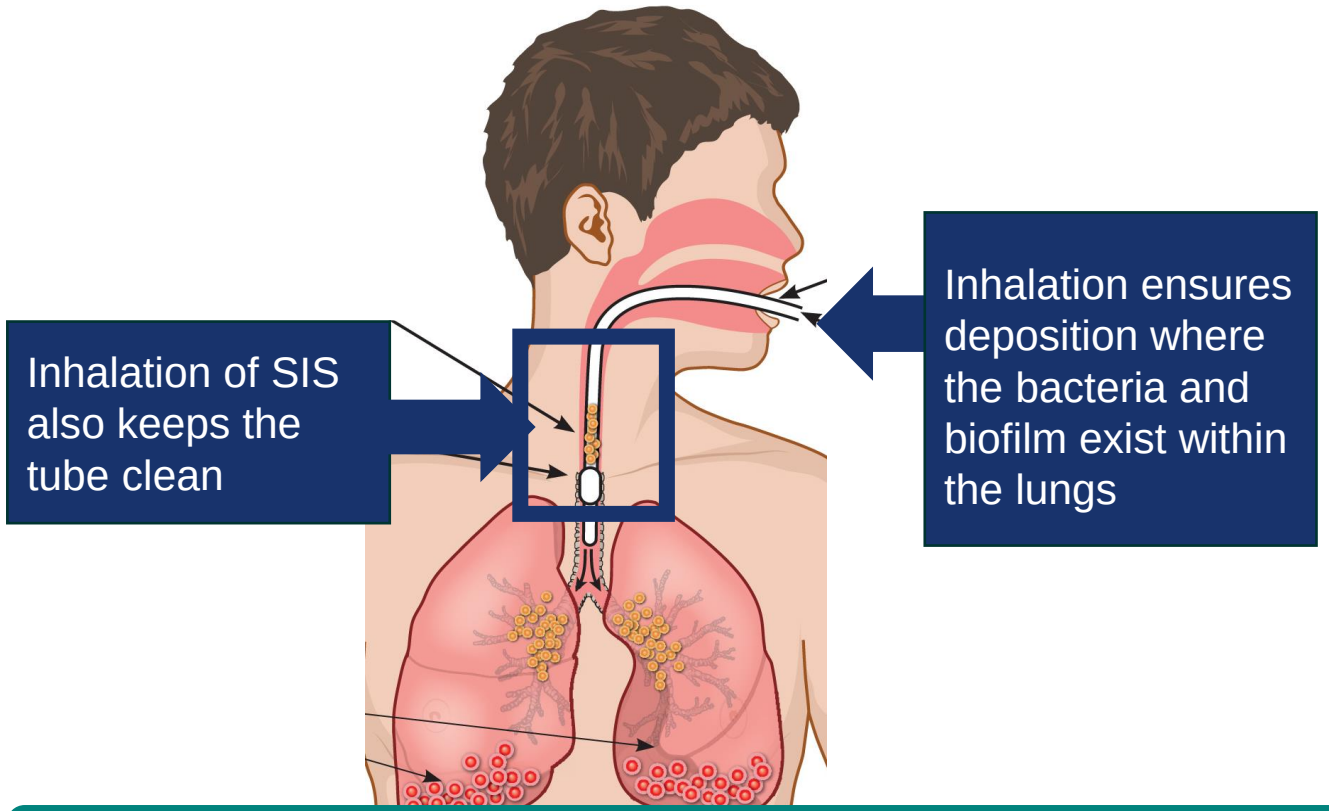
The problem –> The Solution

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 $ 6 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 
- Preclinical Efficacy 
- Proof of Concept in Humans - Phase 2
- Market Adoption

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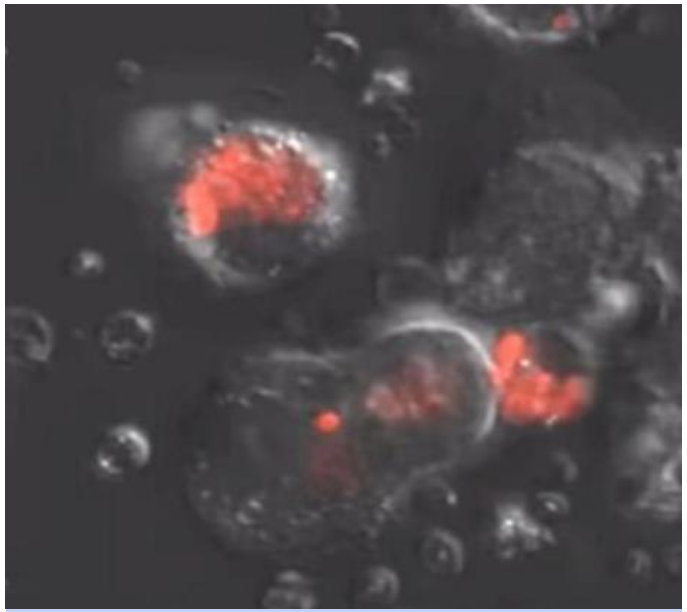
Reinforcing nature's own ability to eradicate unwanted microbes

HYPOCHLOROUS ACID

Documented broad antimicrobial effect



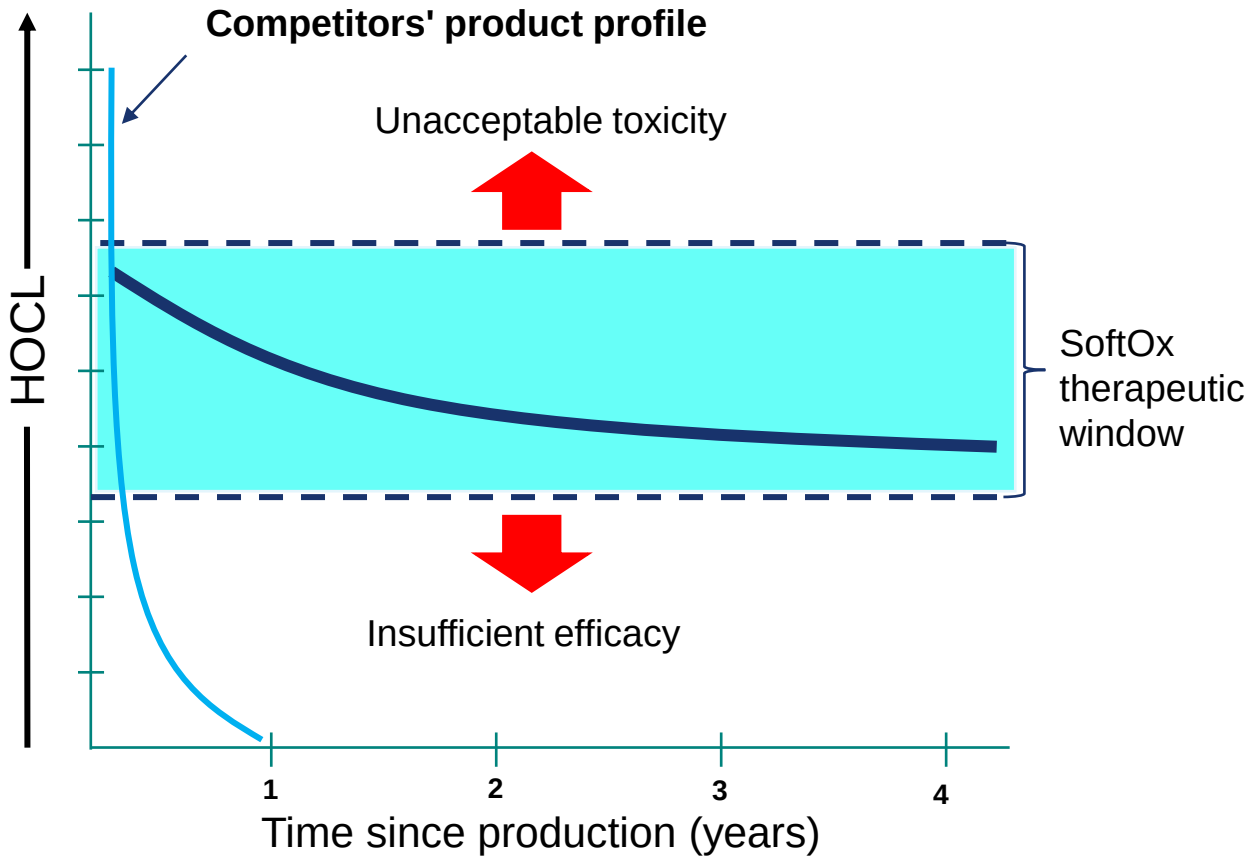
HOCl (red) in action
produced by immune cells

SoftOx technology

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

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

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Complete Toxicology Package

	Test	Conformance Standards	Document number	Summary	Status
Repeat-Dose Toxicity	Inhalation Study - Intubated (minipigs)	NA	SIS_EJ_001 SIS_EJ_002	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	SIS_EJ_008 SIS_EJ_007	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	8458986	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	8458991	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	20/291-103PE	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	20/291-103P	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	20/291-030C	1000, 500, 200, and 100 µg/mL showed no cytotoxic effects on cultured L929 cells	Complete
Genotoxicity	Bacterial Reverse Mutation Assay (in vitro)	GLP	20-291-007M	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	20-291-013C	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	SIS_EJ_004	In vitro lung surfactant test of 500 µg/mL HOCl SS0330.	Complete
	Ocular Irritation Test (Isolated Chicken Eye Method)	GLP	20-291-038CS	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	20/291-038SZ	100 and 200 µg/mL SIS tested and was found to be non-irritant to eyes	Complete

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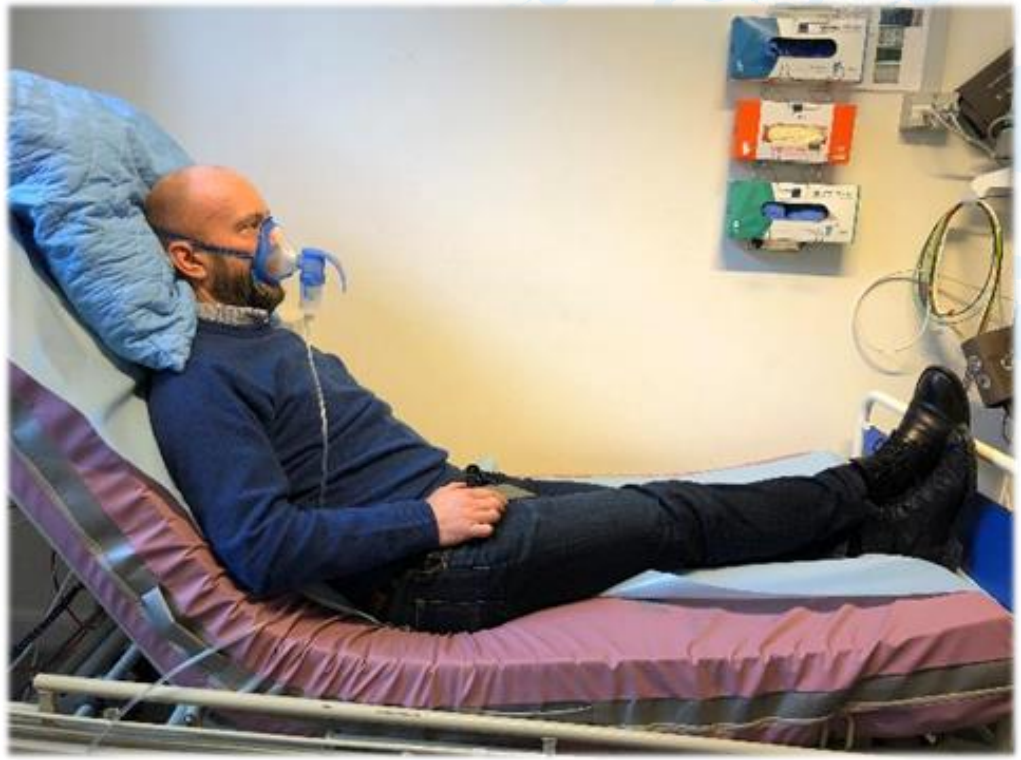
Phase 1 trial showed that SIS is safe and tolerable to inhale

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

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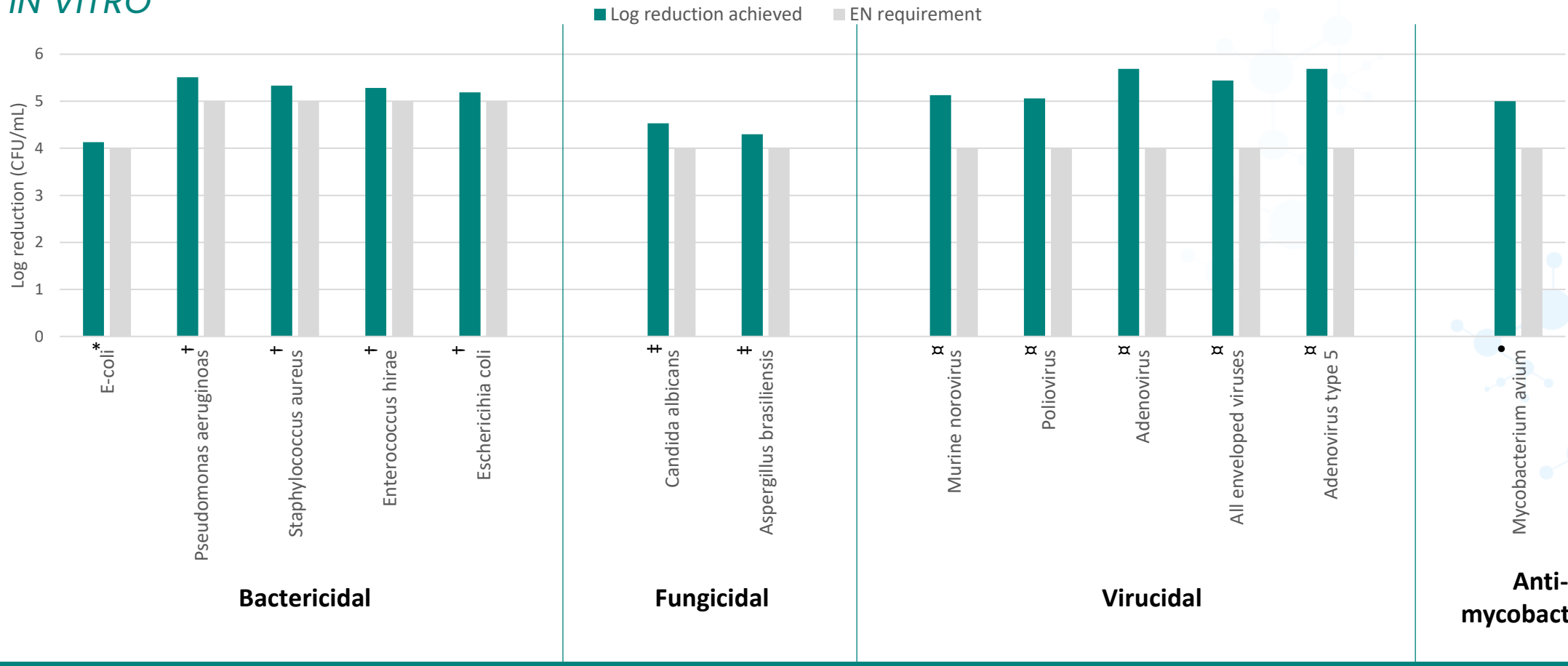
Broad spectrum effect proven in antimicrobial EU Norm tests

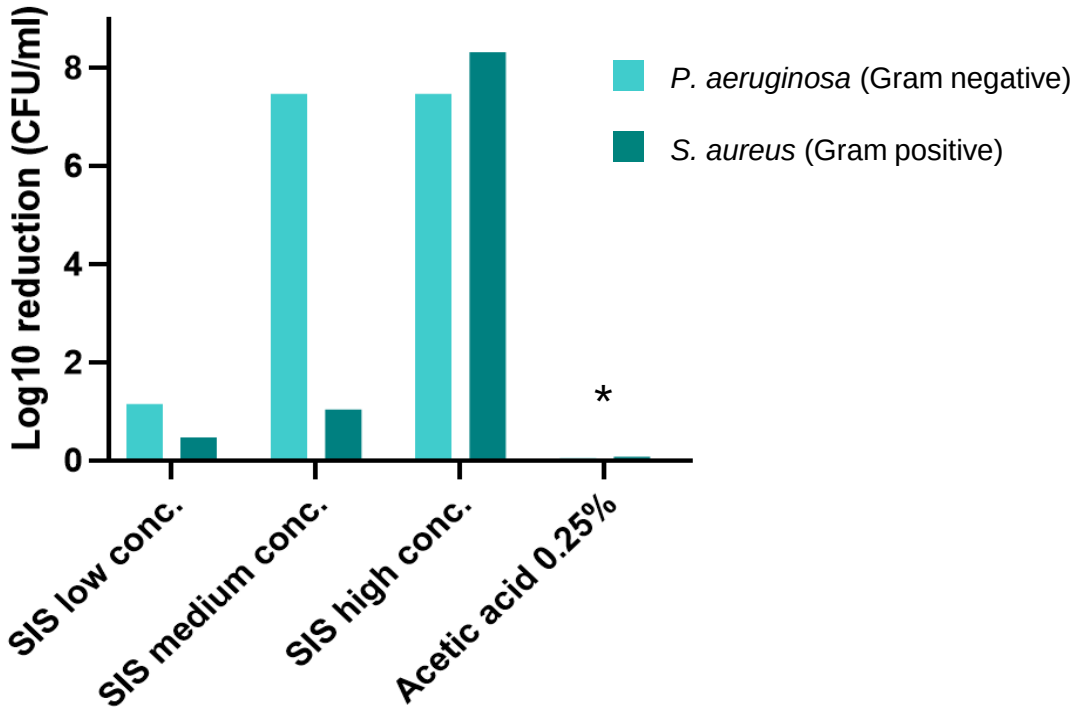
IN VITRO



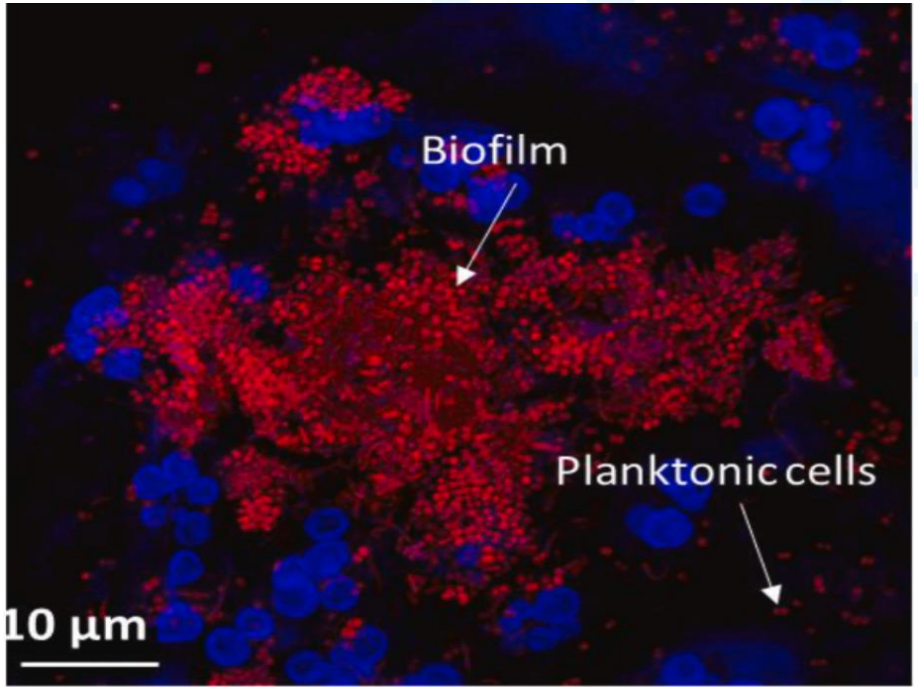
Pan-antimicrobial effect against bacteria, fungi and viruses

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

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.

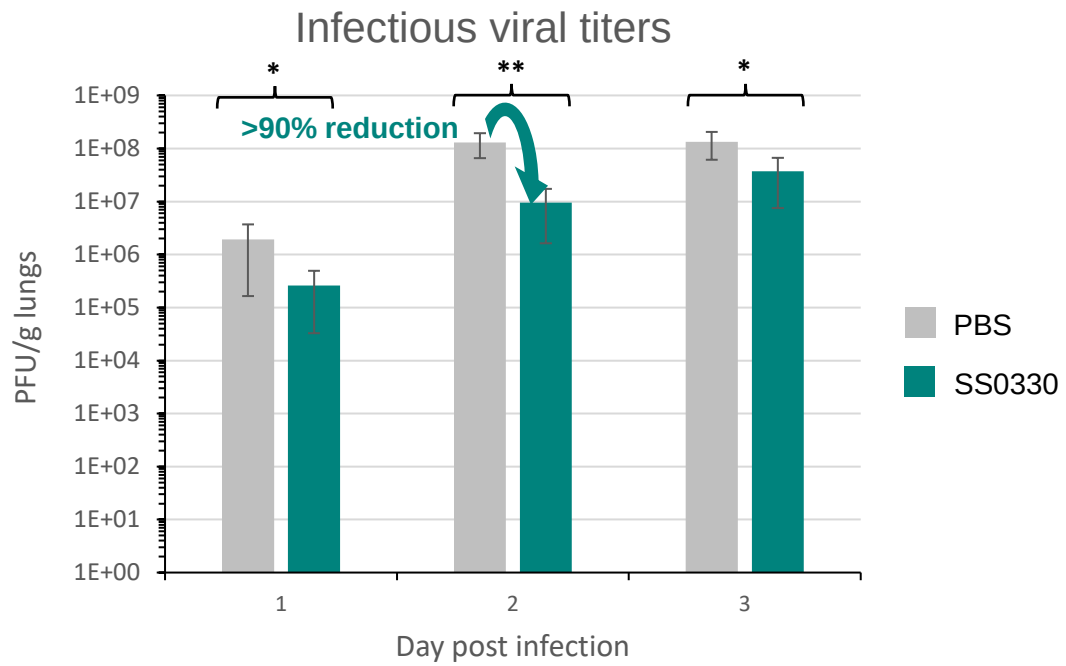


Biofilm (red) in sputum from pneumonia patient.
P. aeruginosa and *S. aureus* are among the most common pathogens in VAP and often present as biofilms

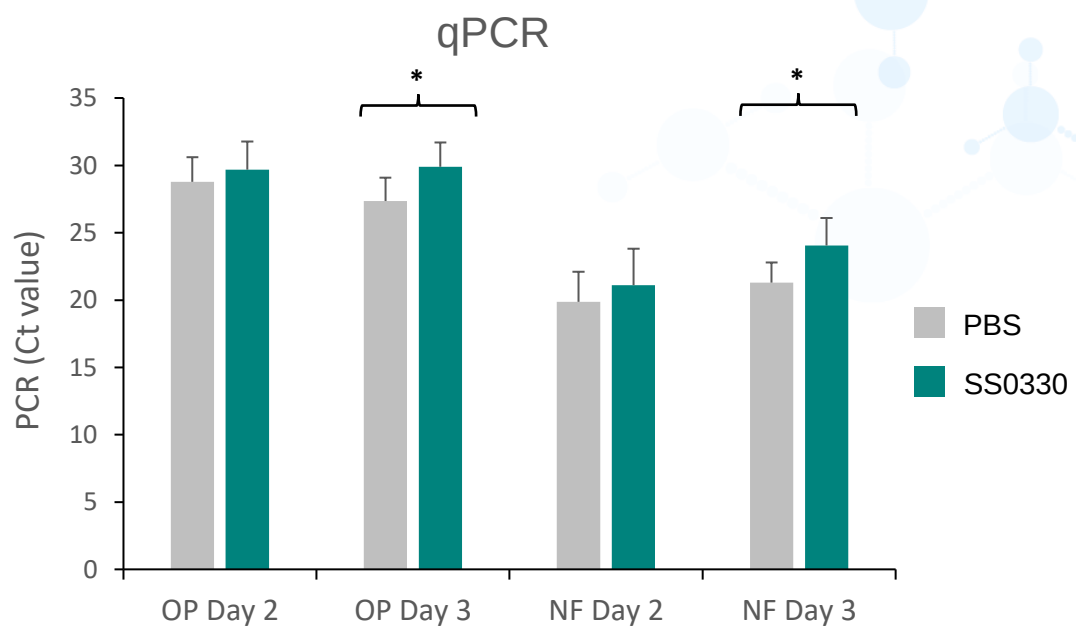
Picture from: M. Kolpen et al., Bacterial biofilms predominate in both acute and chronic human lung infections. Thorax, (2022).

Effective treatment of Influenza A in mice

Twice daily SIS-treatment resulted in lower viral titers 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, *($p < 0.01$), ** ($p < 0.0001$).

Post-exposure prophylaxis efficacy against Sendai virus in mice

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

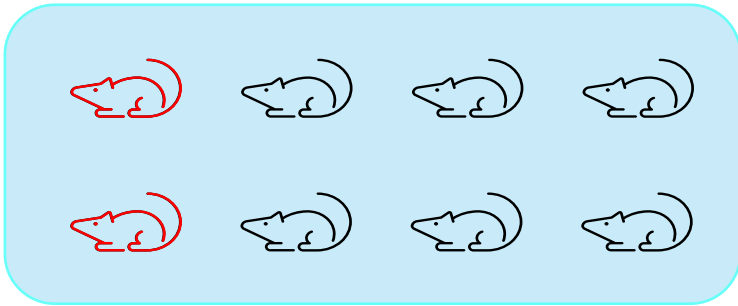
Index (infected) mouse removed from cohousing on day 3

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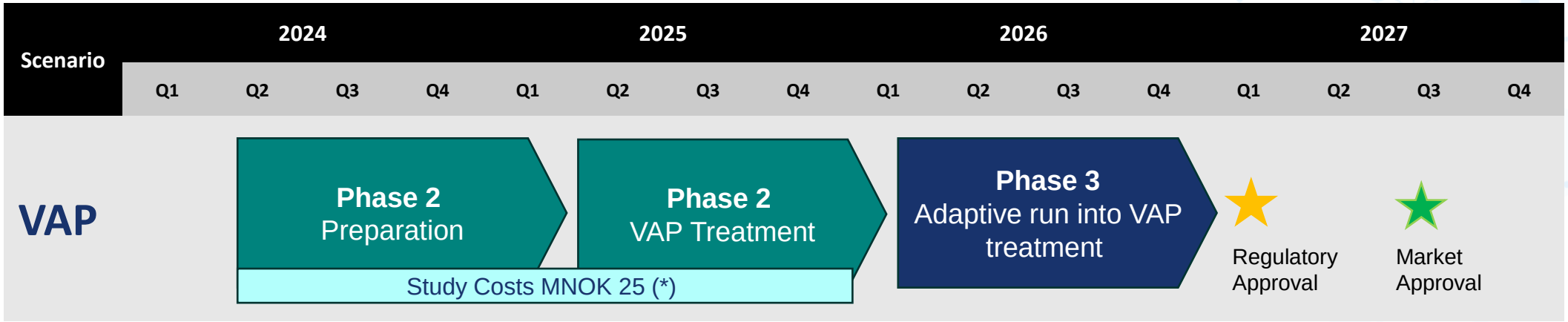
Ventilator Associated Pneumonia (VAP)
Clinical Development Plan (estimated timelines)



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 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

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Market adoption

Patient	Hospital	Commercial
Mortality • 10%-30% risk of developing VAP • Up to 50% mortality	**Hospital Acquired Infection** • Hospitals must pay the extra cost themselves – USD 6bn • No need for reimbursement **Easy to implement use** • Handled by Health Care Personnel • Need only standard equipment	**Pathway to market** • Focused Market Segment • Easier market penetration (smaller sales force, higher market share faster)

Pathway to market is short and well defined

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Financial Potential

> 160 000 yearly VAP cases US & EU

- US 93 000 cases[1)]
- EU 70 000 cases[2)]

$ 6 bn in extra treatment costs per year

- US $ 47 000 per patient[3)]
- EU $ 30 000 per patient[4)]

Value Proposition

- Reduced hospital costs up to $ 6 bn
- Reduced mortality
- Reduced ICU days

Great possibility to reduce $ 6 bn in Extra Treatment Costs

1) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9051358/ 2) https://www.sundhed.dk/content/cms/12/4712_did_aarsrapport2022.pdf 3) https://www.ahrq.gov/hai/pfp/haccost2017-results.html 4)

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

COUNTERACT* - EU research project to develop 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

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

Fully funded program / All commercial rights belong to SoftOx

Further Potential

COUNTERACT program benefits both civil and military SIS development

Scientific advice input on SIS 2.0 benefits the overall ongoing development of SoftOx's 2nd generation products

The COUNTERACT phase 1B trial increases dosing possibilities in future trials on both the civil and military program of SIS

- Open for use of Second-generation SIS for VAP
- Optimize dose for a virucidal Influenza challenge Phase 2 trial, planned in 2026

Both military counter measurement and civilian application will benefit from a virucidal challenge study

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.

Key Takeaways

- Following the contemplated private placement, SoftOx will be debt free and focused on the clinical development plan for VAP
  - Representing a market with large unmet medical need and high mortality rate
  - Expect to significantly reduce today's high cost of treatment (USD 6 Bn)
  - Well defined user group with infrastructure in place
  - Promising study data indicated high probability of success
  - Relatively low clinical study costs and short time to market

- A successful phase 2 study will open up for exit alternatives in 2026

- Continue to develop medical counter measurement towards biological treats and next pandemic in cooperation with University of Copenhagen – A world leading University within the field – and funded by EDF