SoftOx Solutions AS

Norwegian medtech and biotech company listed on Euronext Growth

Presentation Q2 2022

15 August 2022

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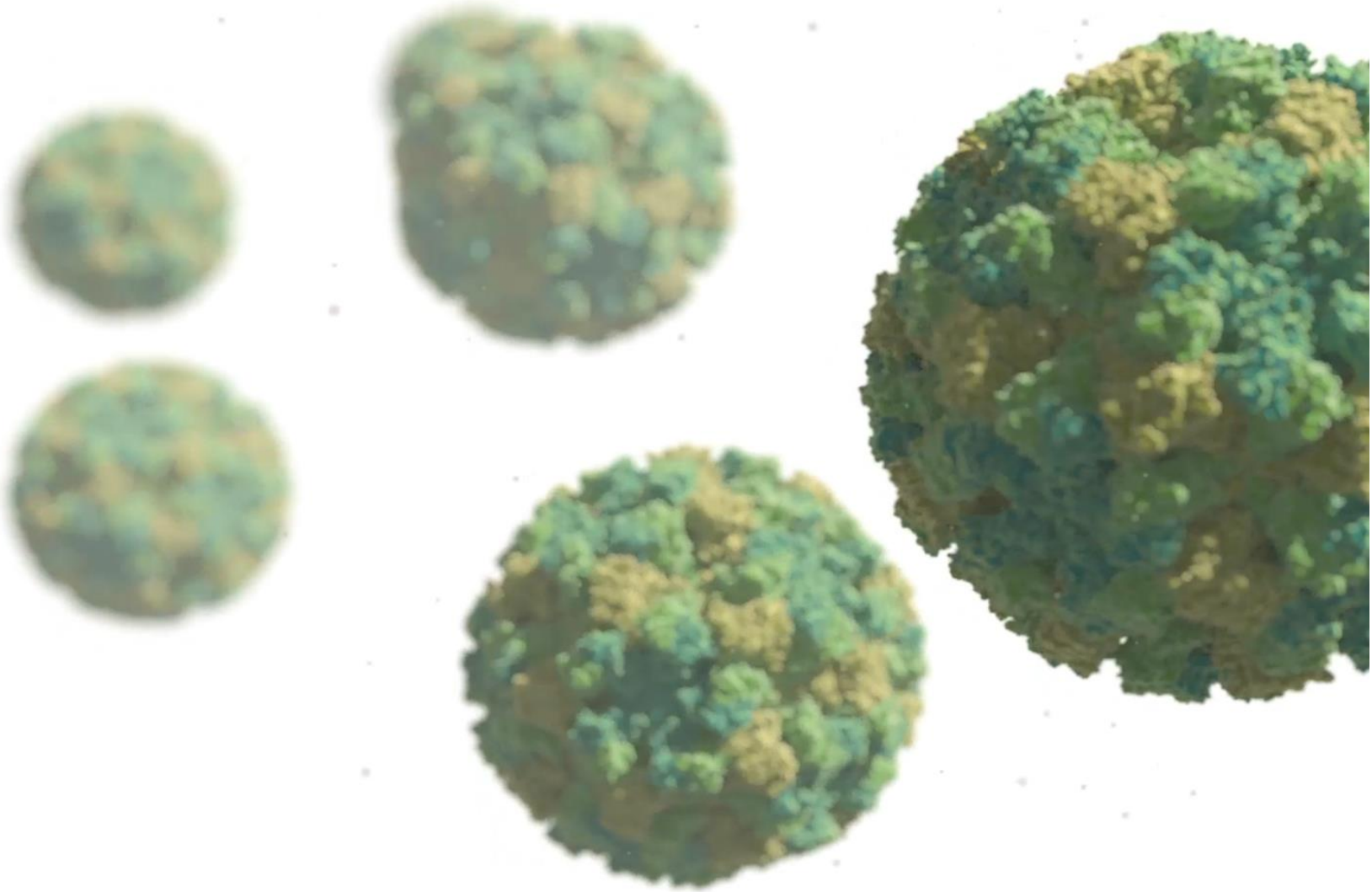
Presenters

Highlights, SoftOx in brief & Commercial and military development
CEO Geir Almås

SoftOx technology development
CMO Dr Christopher Burton

Financial update
CFO Kristine Rød



01

First half-year highlights and SoftOx in brief

First half-year highlights and subsequent events

RESEARCH & DEVELOPMENT

Completed **SIS-01** in April and the study achieved the primary objective of safety and tolerability in healthy subjects

Completed first phase of **SBE-01** (single ascending dose) and progressed to the last phase (multiple ascending dose) which is expected to finish in Q3

Presented **SWIS-02** study at the 2022 EWMA Conference and the study was published in the peer-reviewed journal *Acta Dermato-Venereologica* [1]

Granted approx. **NOK 97 million from the European Defence Fund** to develop an EU military inhalation solution

COMMERCIAL

510(k) application was submitted to FDA to register SWIS as a medical device class II in US

EWMA conference appearance initiated **talks in the wound care sector** with several large market players

FINANCE

Q2 result of NOK -20.6 million (LY: NOK -22.2 million)

Entered into a loan agreement of NOK 15 million with Almhaug Bolig AS, where the main shareholder is one of the shareholders in SoftOx

1) DOI: https://doi.org/10.2340/actadv.v102.1624

Reinforcing nature’s own ability to eradicate unwanted microbes

HYPOCHLOROUS ACID
Documented broad antimicrobial effect

+

ORGANIC ACID
Antimicrobial stabilizer

SOFTOX TECHNOLOGY
Replicating millions of years of evolution

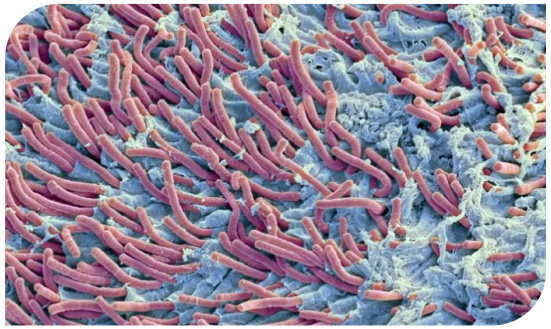
A base technology tailored for different indications and uses

Helping the world fighting infections

VIRUS

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

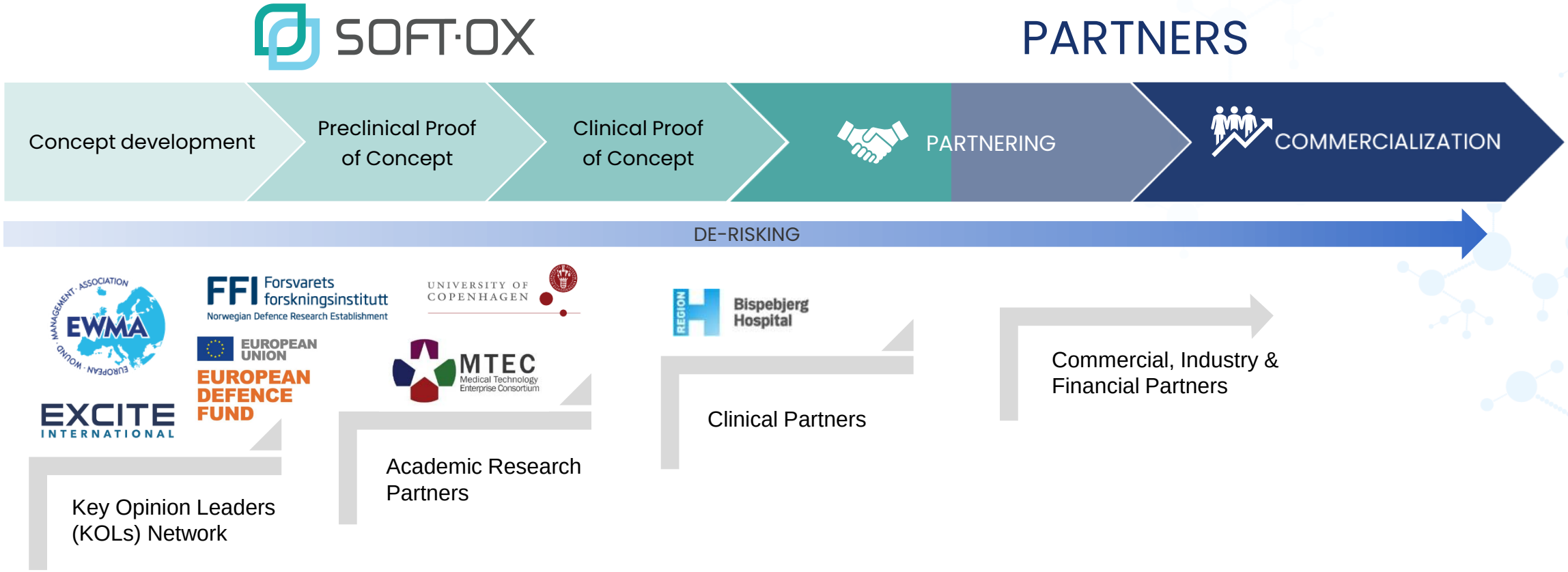
ANTIMICROBIAL RESISTANCE

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

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

1) Forum of International Respiratory Societies (2019). The Global Impact of Respiratory Disease – Second Edition. Sheffield, European Respiratory Society.
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

Product development strategy



Product pipeline

	Project	Indication	Pre-clinical	Phase I	Phase II	Pending regulatory approval	Collaborations
BIOCIDE	Disinfection	Surface disinfectant Hand disinfectant	→	→	→	→	Bispebjerg Hospital, University of Copenhagen
MEDICAL DEVICE	Wound irrigation solution	Wounds	→	→	→	→	Bispebjerg Hospital, University of Copenhagen
DRUG	Infection treatment	Chronic leg wounds	→	→			Bispebjerg Hospital, MTEC Medical Technology Enterprise Consortium
	Inhalation solution	Respiratory tract infections	→	→	→		European Union, European Defence Fund, University of Copenhagen

Business segments

Wounds

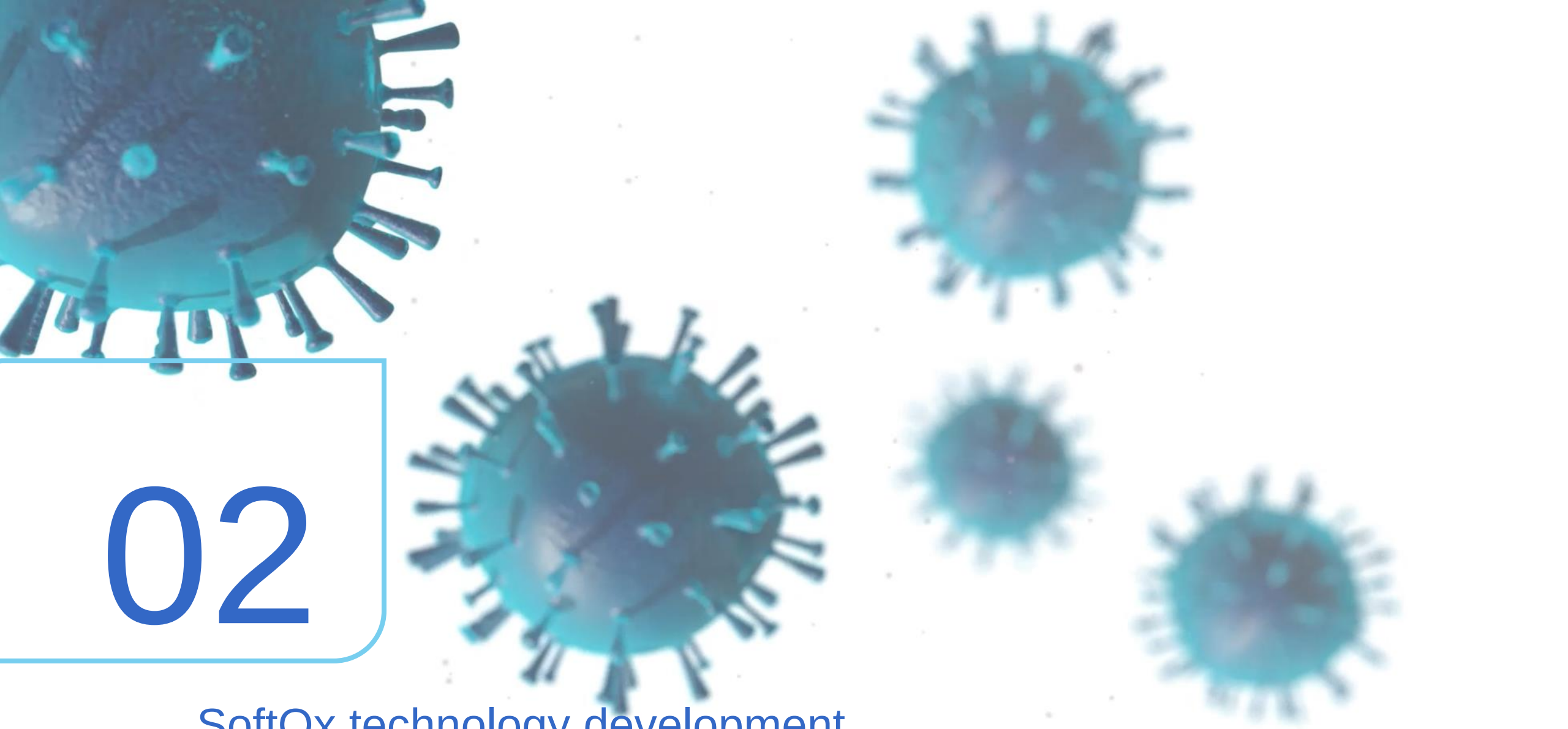
Infection prevention and treatment for acute and chronic wounds

Respiratory

Infection treatment for viral infections

Disinfection

Infection prevention solutions for hands and surfaces



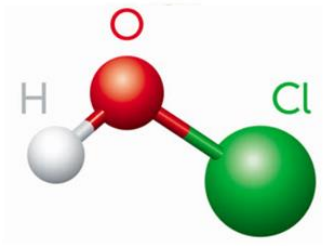
02

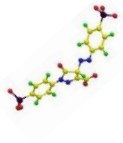
SoftOx technology development

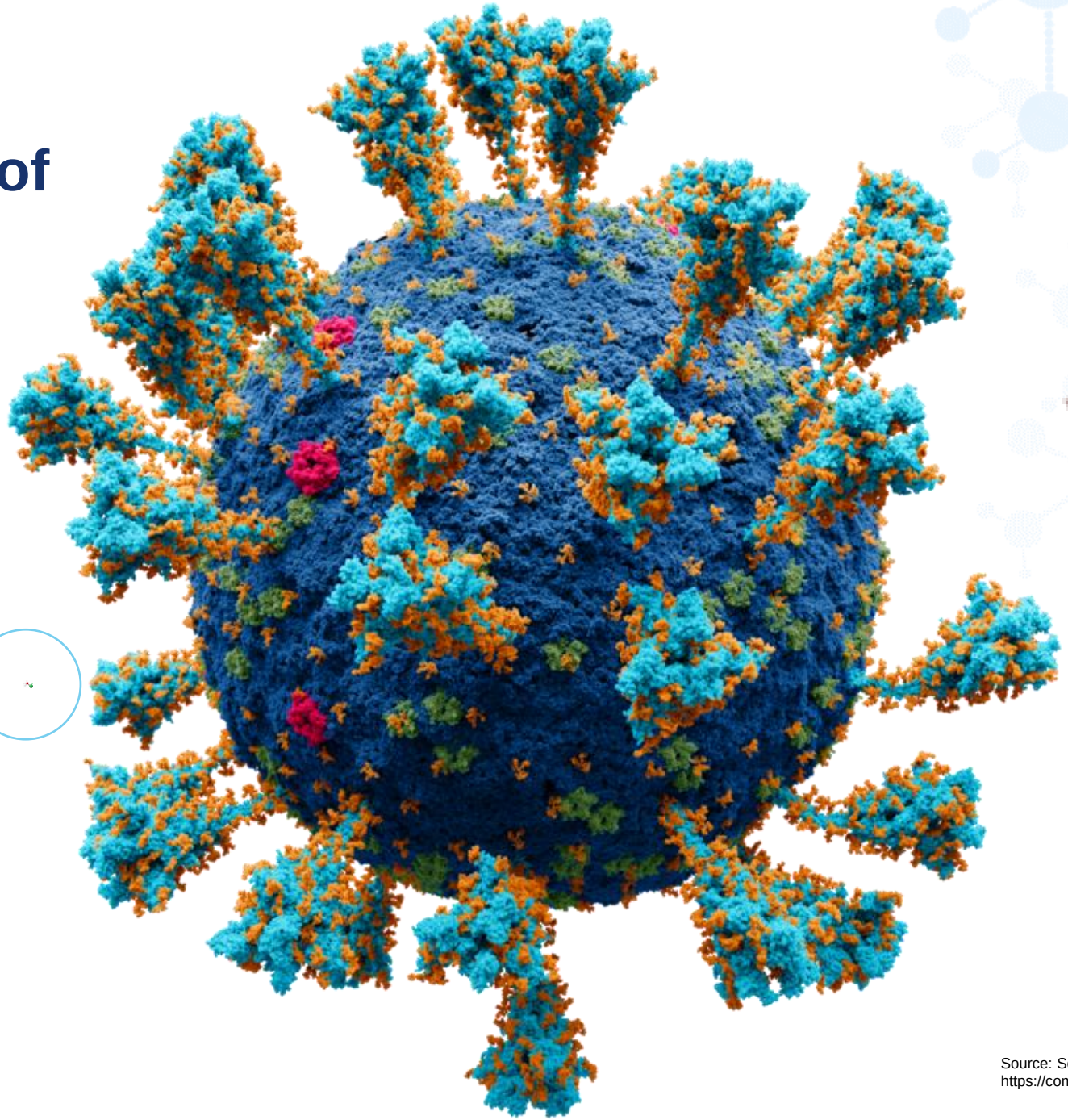
Competitive advantage

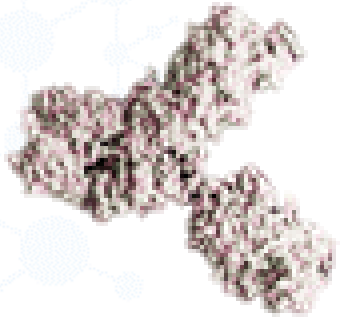
1. Pan-spectrum antimicrobial (virucidal/bactericidal) effects
2. Not shown to induce antimicrobial resistance
3. Good safety and tolerability profile – no systemic side effects
4. Versatile technology platform

Mechanism of Action





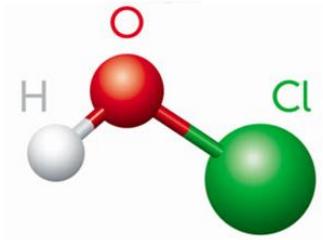


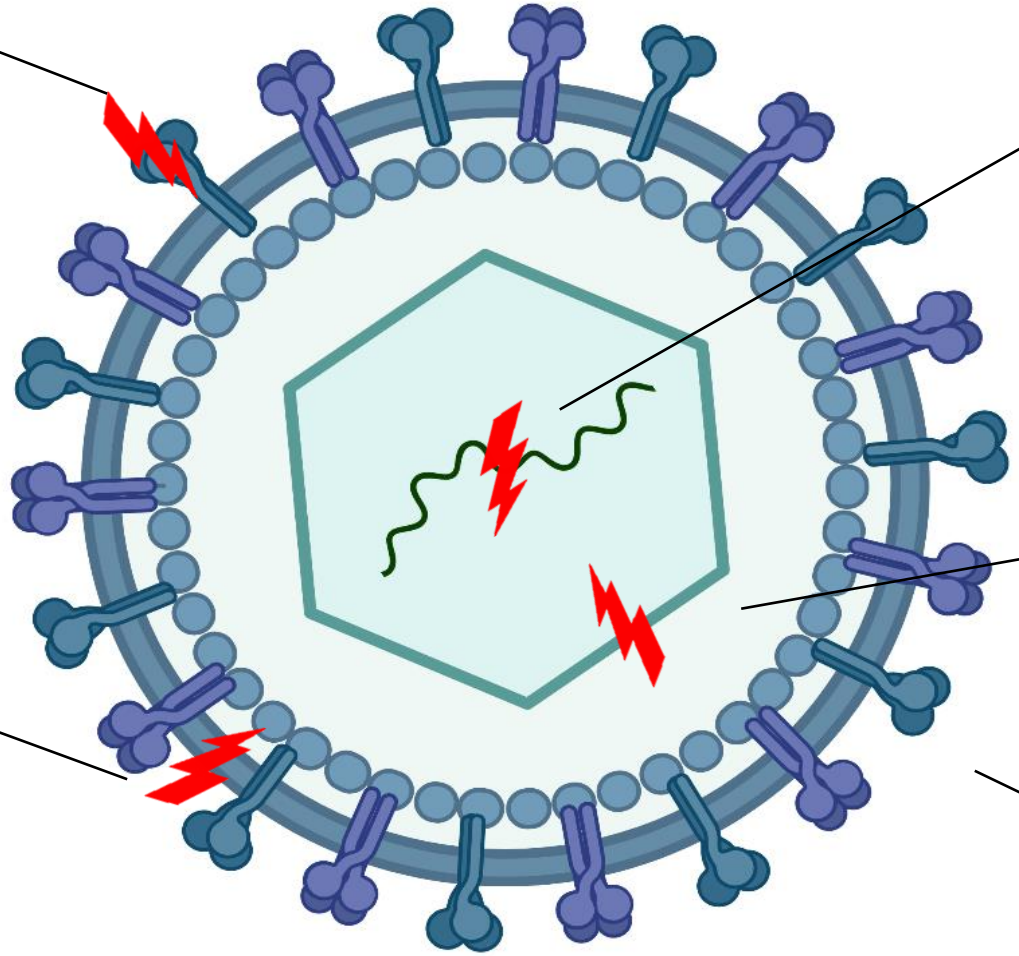


Source: Solodovnikov, A, & Arkhipova, V. (2021). SARS-CoV-2. https://commons.wikimedia.org/wiki/File:Coronavirus._SARS-CoV-2.png#file

Direct and indirect antimicrobial MoA, independent of biological processes and unreliant on a metabolic target or receptor

Oxidation of microbial surface glycoproteins disrupt viral replication, budding and cell entry





Nucleic acid oxidation leads to proteome-wide unfolding and oxidation of proteins at cysteine and methionine residues.

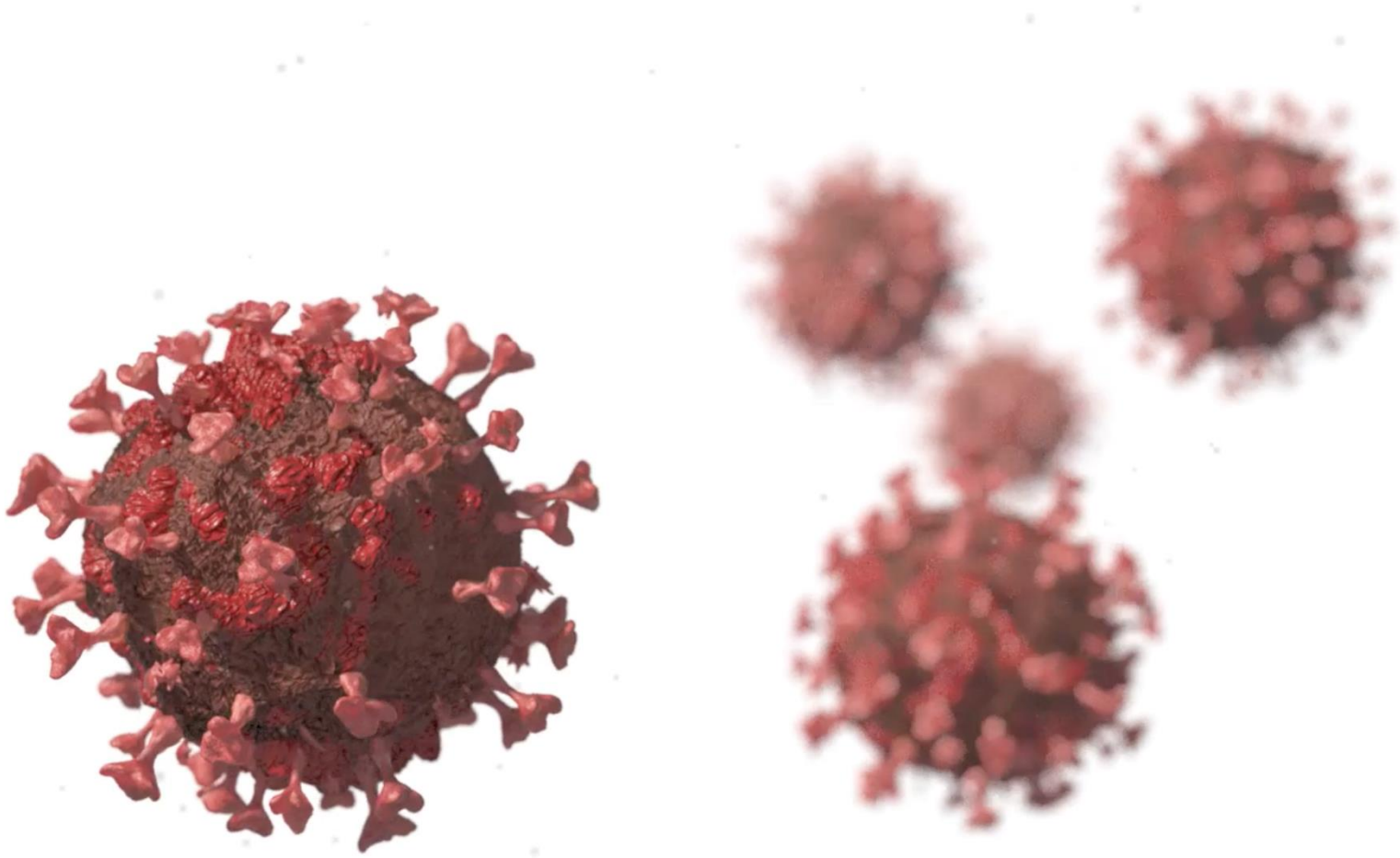
Oxidation of thiol-containing proteins and enzymes inhibits nucleic acid and protein synthesis, and disrupts microbial cell metabolism

Oxidation leads to pore formation, disrupting microbial cell integrity and repair functions

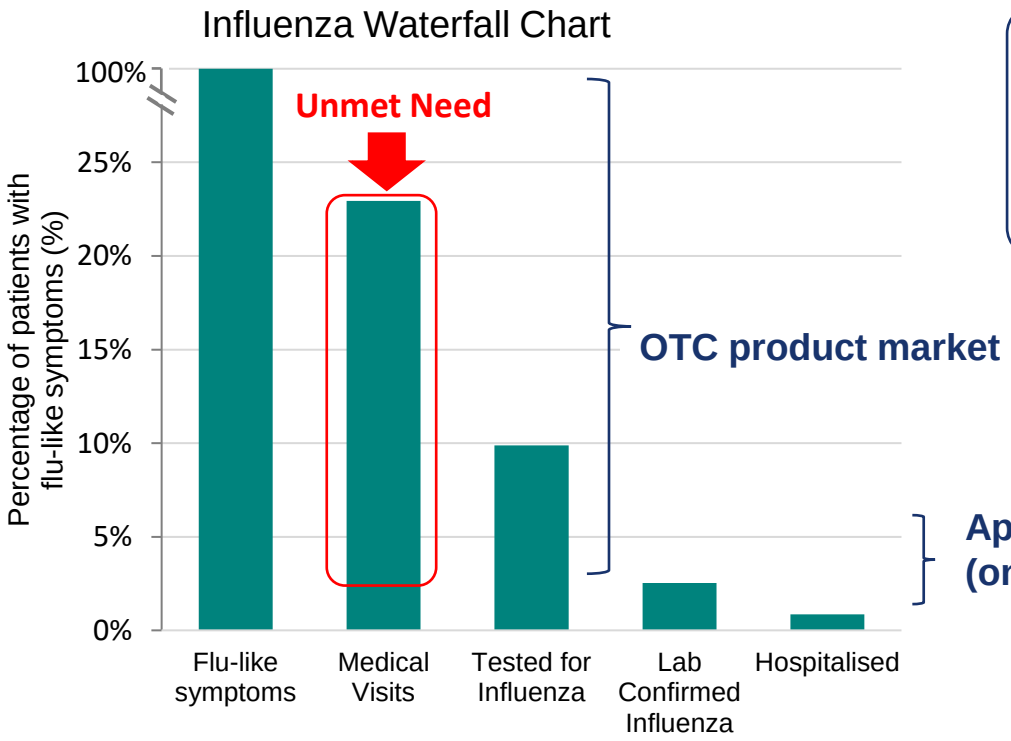
Increased immunogenicity as resultant pathogen-derived proteins are endocytosed by dendritic cells drives subsequent MHC-II, IL-2, Th2 immune response

2.1

Respiratory



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



OTC products focused on reducing symptoms, but not:

- curing disease,
- shortening the duration of disease,
- altering the course of the disease,
- or reducing disease transmission

Influenza approved drugs have demonstrated specific antiviral activity but:

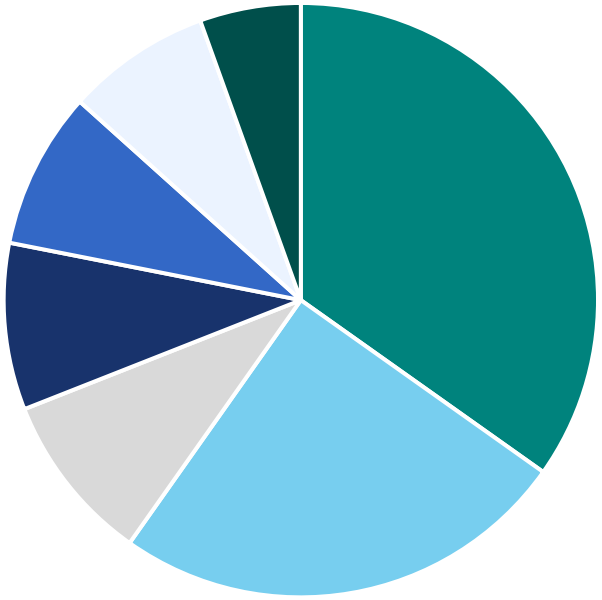
- clinical efficacy is limited to earlier resolution of symptoms (approx. 1 day) in treatment of uncomplicated influenza within 48 hrs of symptom onset.
- documented cross-resistance to neuraminidase inhibitor drug class

A significant unmet need remains as currently available treatment options **do not address the underlying microbial cause or provide limited clinical efficacy** in uncomplicated influenza A

SOFT·OX

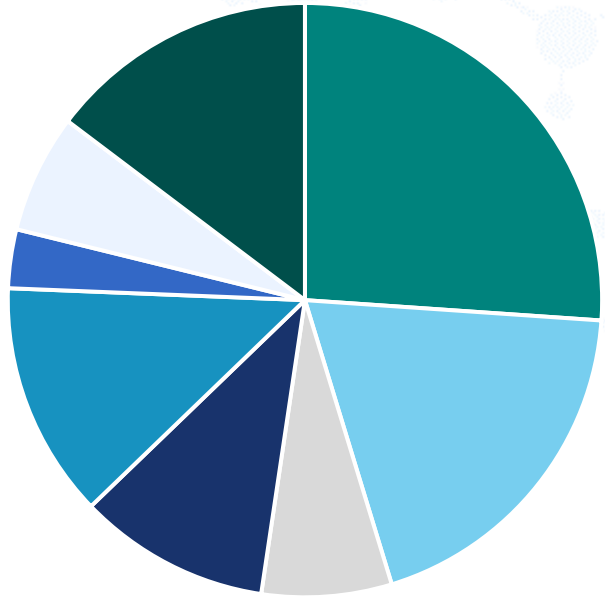
The majority of influenza-like illness is caused by viruses other than Influenza A/B

Viral causes of Influenza-like illness
Multiple geographies (2012-2018) [1



- Influenza
- Rhinovirus Or Enterovirus
- Respiratory Syncytial Virus
- Human Coronavirus
- Parainfluenza
- Adenovirus
- Human Metapneumovirus

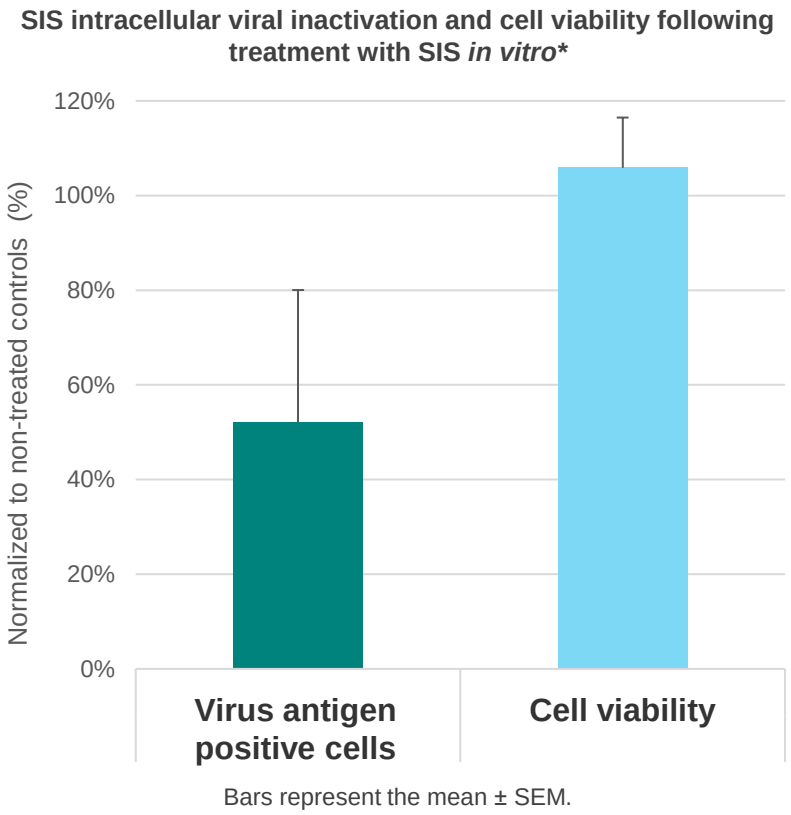
Viral causes of Influenza-like illness
Denmark (2021-2022) [2

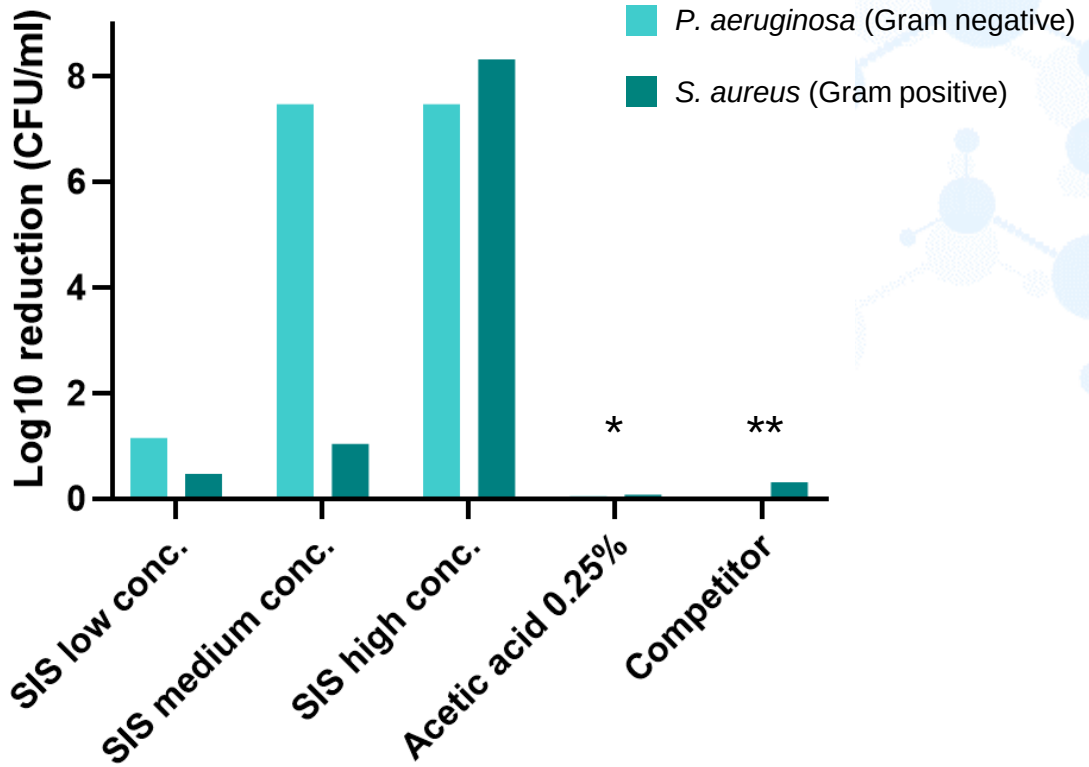


- Influenza
- Rhinovirus Or Enterovirus
- Respiratory Syncitial Virus
- Human Coronavirus (Other)
- SARS-CoV-2
- Parainfluenza
- Adenovirus
- Metapneumovirus

1. Cinemre et al. 2016, Fowlkes et al. 2014, Thiberville et al. 2012, Nguyen et al. 2016, Li et al. 2013, Lekana-Douki et al. 2014, Keske et al. 2018, Fu et al. 2015
2. https://www.ssi.dk/sygdomme-beredskab-og-forskning/sygdomsovervaagning/i/influenza-ugens-opgoerelse

In vitro virucidal and bactericidal effects of SIS





Data on file..

Data on file. Samples tested against bacterial biofilms grown for 24 hours with one hour contact time afterwards for the different products.
*Acetic acid tested against planktonic bacteria (both *S. aureus* and *P. aeruginosa*, grown for one hour) with 15 minutes of contact time.
** Competitor (Niclosamid 0,05-0,30µg/ml) only tested against *S. aureus* biofilm.

SIS-01: Randomized, placebo controlled, first in human trial in healthy volunteers

Subjects (N=56) will be enrolled and randomised to receive SIS or placebo in a 3:1 ratio (42 will receive SIS; 14 will receive placebo).

Inclusion Criteria:
- Healthy adults between 18-55 years of age,
- Body Mass Index (BMI) of ≥ 18.5 and ≤ 29.9 kg/m^2

Exclusion Criteria:
- Recent participation in another clinical trial or blood donation
- Medical condition or a history of drug hypersensitivity
- Using concomitant medication
- Positive drugs of abuse test

- Single dose of nebulised SIS @ 25 ppm/placebo
- Single dose of nebulised SIS @ 50 ppm/placebo
- Single dose of 5 mL nebulised SIS @ 100 ppm/placebo
- 5 mL nebulised SIS @ x ppm/placebo q24h for 5 days #
- 5 mL nebulised SIS @ y ppm/placebo q24h for 5 days #
- BID dosing of nebulised SIS @ y ppm/placebo for 4 days + morning dose on Day 5
- QID dosing of nebulised SIS @ y ppm/placebo for 4 days + morning dose on Day 5

Primary Endpoints

1. Nature, occurrence, and severity of adverse events (AEs).
2. Change from baseline, in forced expiratory volume in 1 second (FEV_1)
3. Change from baseline, in oxygen saturation measured by pulse oximetry
4. Change from baseline, in local tolerability

The dose to be administered in the multiple dose groups will depend on the results obtained in the single dose groups and will be decided by the SMC. The dose tested in the first multiple dose group will be the second highest well-tolerated single dose or lower.

SIS-01: Results & Conclusions

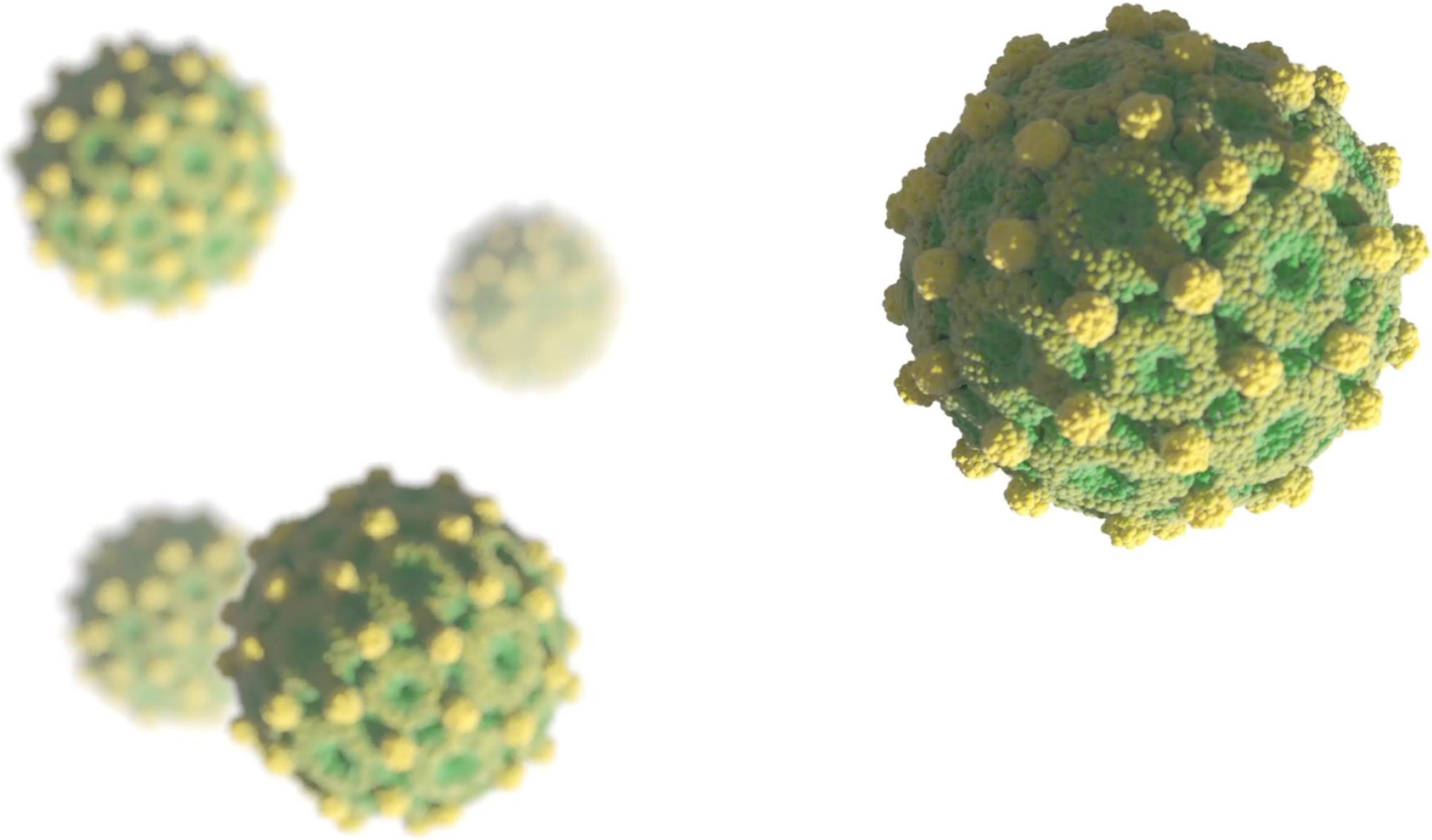
- No SAEs
- Mild, self-limiting AEs related/unrelated to drug administration
- Acceptable local tolerability
- No effect on spirometry
- No effect on vital signs
- No effect on safety laboratory values
- No effect on ECG

At all dose levels

Regardless of dosing frequency

SIS at concentrations of up to 100 ppm (100 ug/ml) administered four times daily via a nebuliser over 15 minutes was **safe and well tolerated,** in this study population of healthy volunteers.

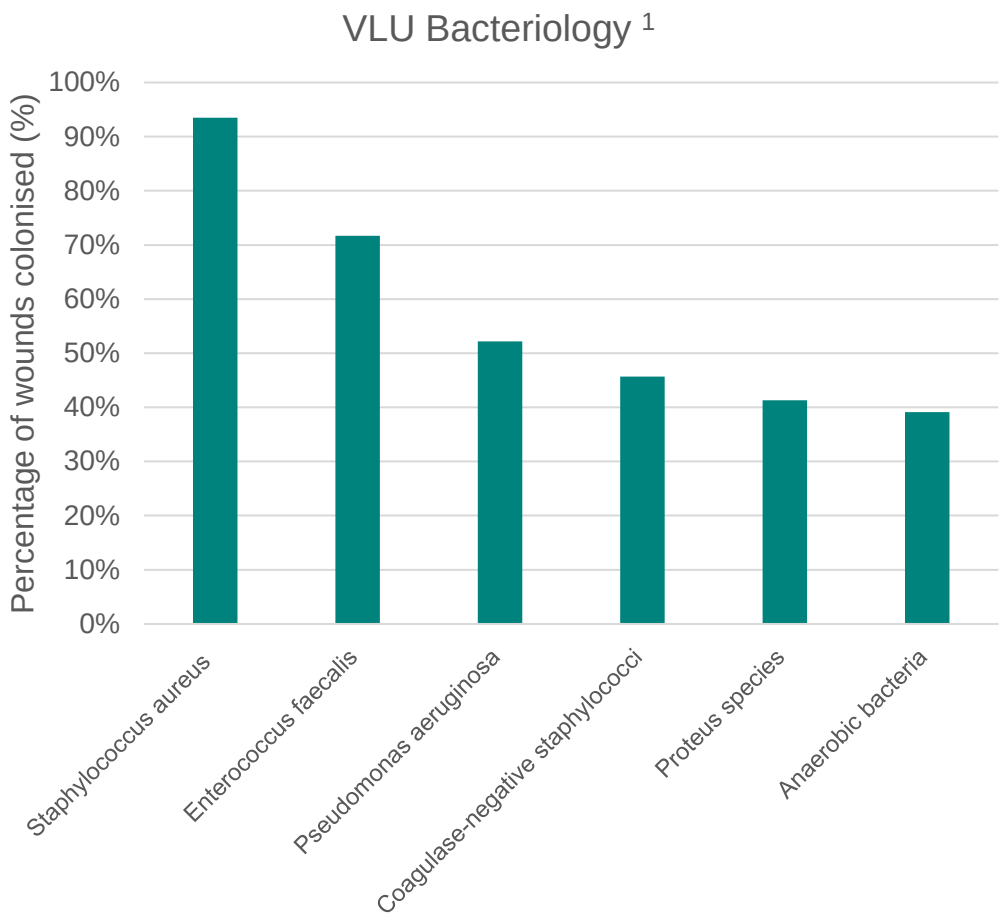
SIS-01 study, NCT05188638, Safety of Ascending Single and Multiple Doses of Nebulised SoftOx Inhalation Solution in Healthy Subjects

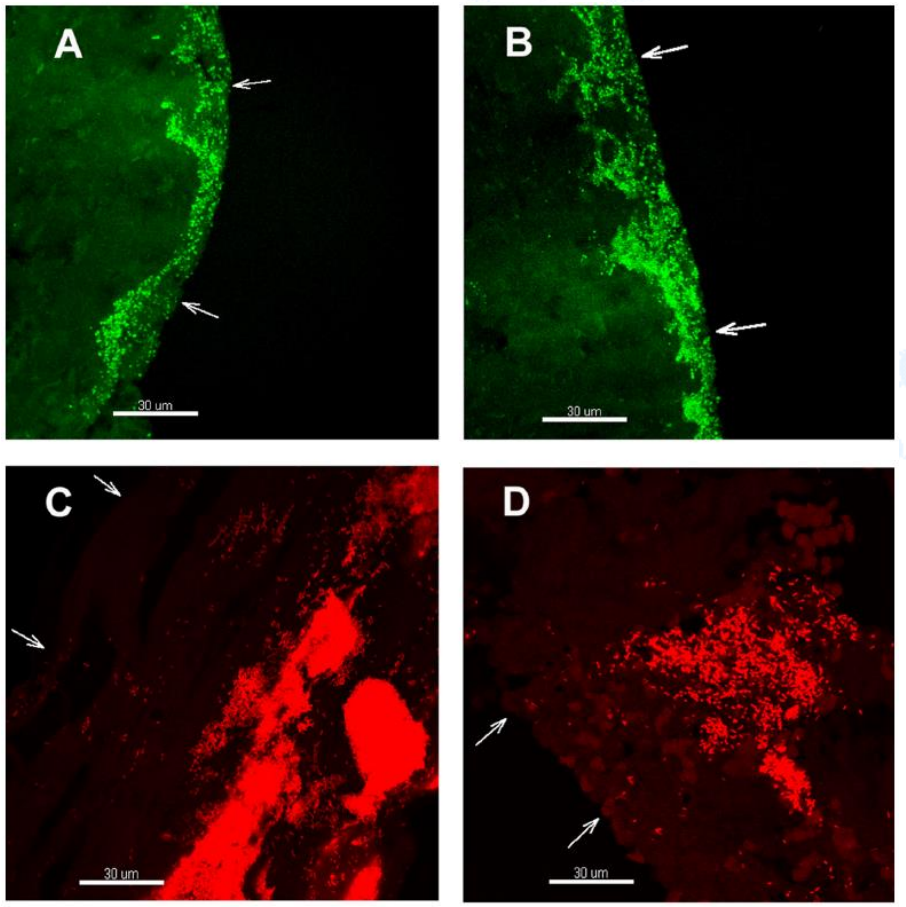


2.2

Wound care

40-70% of venous leg ulcers are colonized by multiple (~5 to 6) bacterial species[1] at variable distance to the wound surface[2]

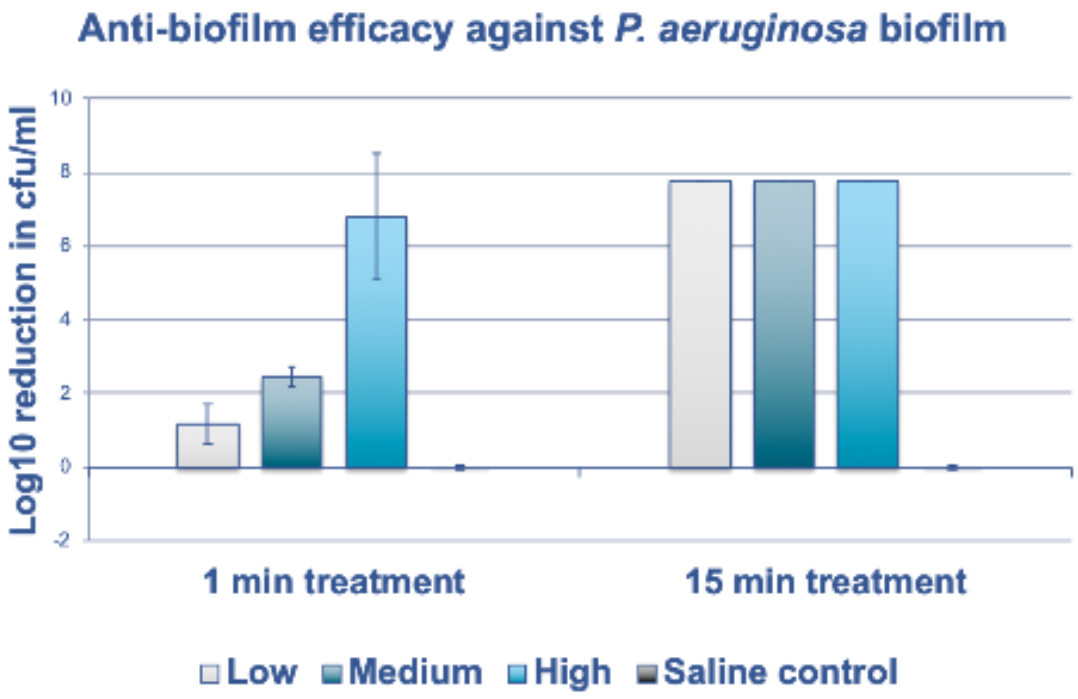


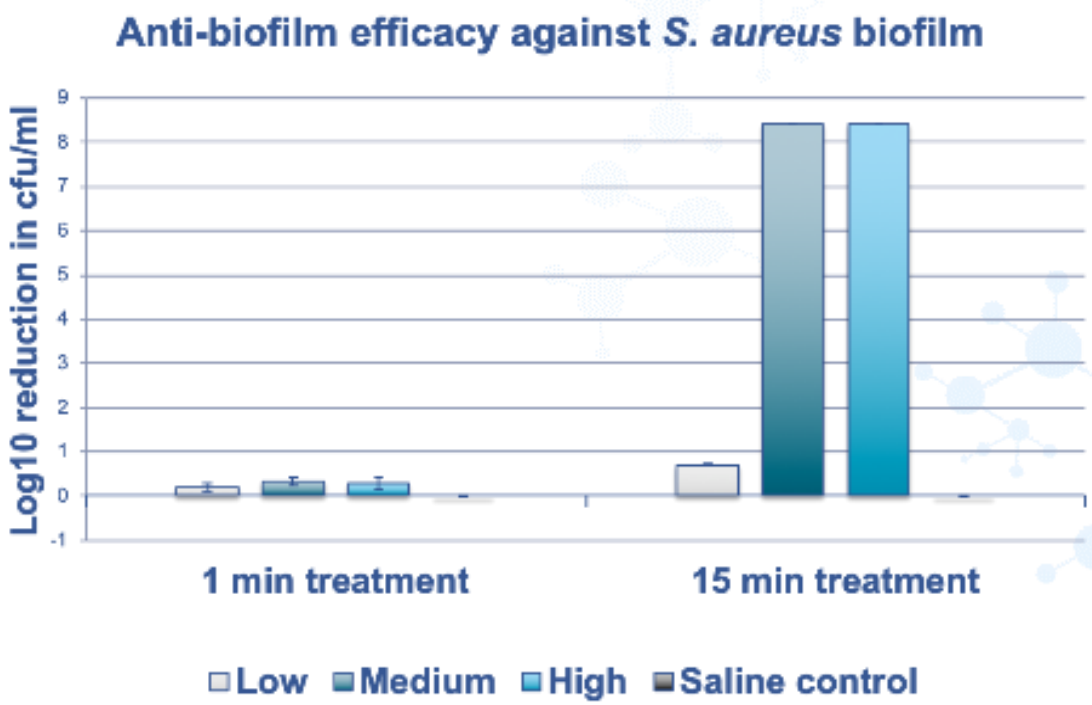


1. Gødsbøl et al, Copenhagen Wound Healing Center; 2. Fazli et al. J Clin Microbiol 2009 Dec;47(12):4084-9.

2. Representative CLSM images of *S. aureus* (A and B), *P. aeruginosa* (C and D). Arrows point to the wound surfaces. [2]

In vitro antibacterial efficacy in biofilms

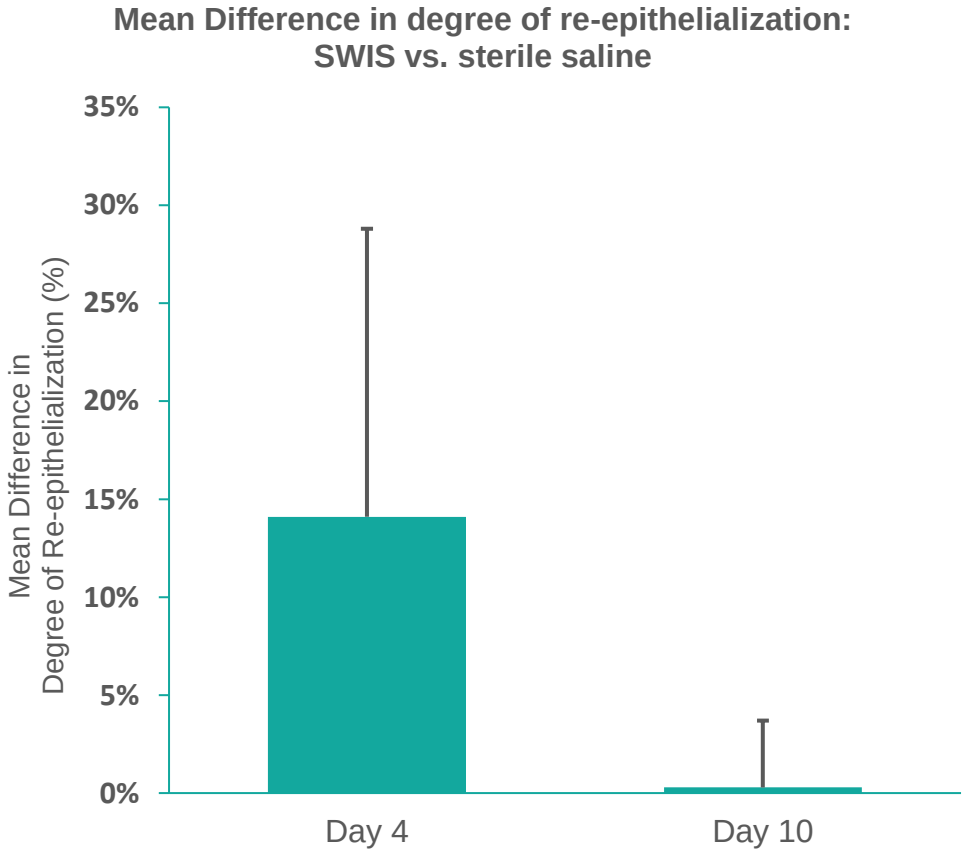


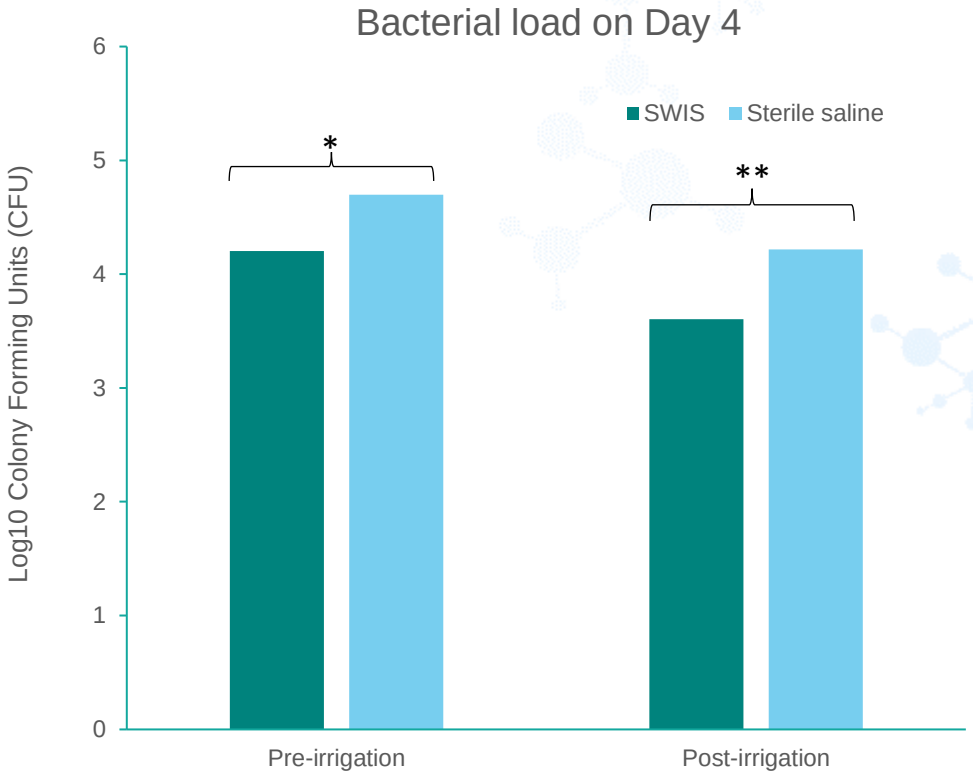


Data on file.

SOFT·OX

SWIS-02 findings demonstrate relative improvement in wound healing of 32.6%† on day 4





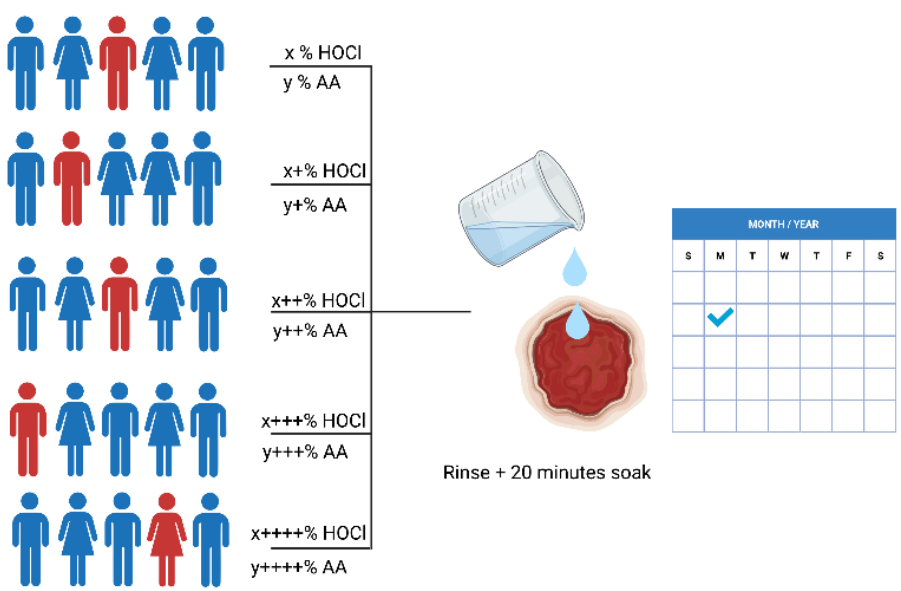
n.s.- not significant, * $p < 0.05$, ** $p < 0.001$, † compared to sterile saline

SWIS-02 study, NCT04771819, Effect of Stabilized Hypochlorous Acid on Re-epithelialization and Bacterial Bioburden in Acute Wounds: A Randomized Controlled Trial in Healthy Volunteers. Burian et al. Acta Derm Venereol 2022. DOI: 10.2340/actadv.v102.1624

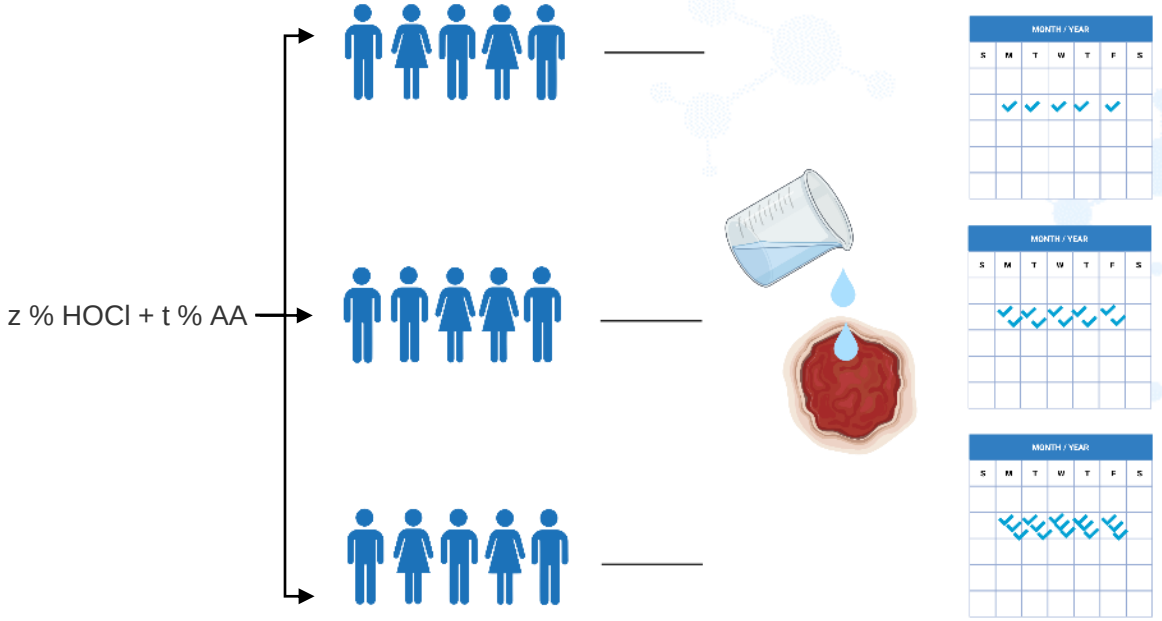
SBE clinical studies (phase 1a & 1b) in chronic wounds:

Blinded, randomized safety study of single & multiple ascending dose

Phase 1a



Phase 1b



SBE Positioning: First line treatment of locally infected wounds (i.e. no evidence of systemic infection)

PREVENTION

TREATMENT

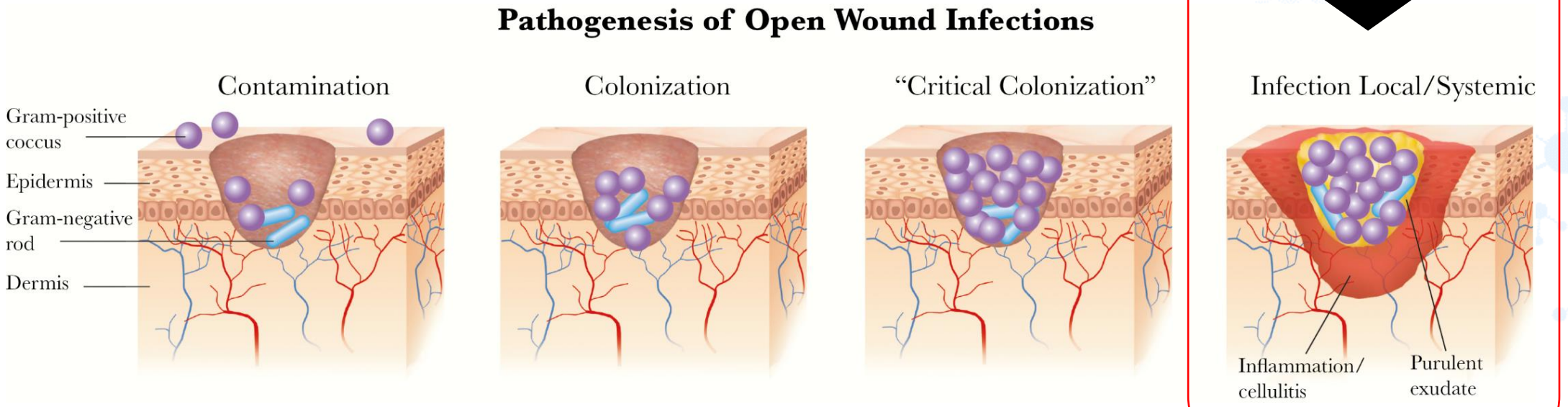
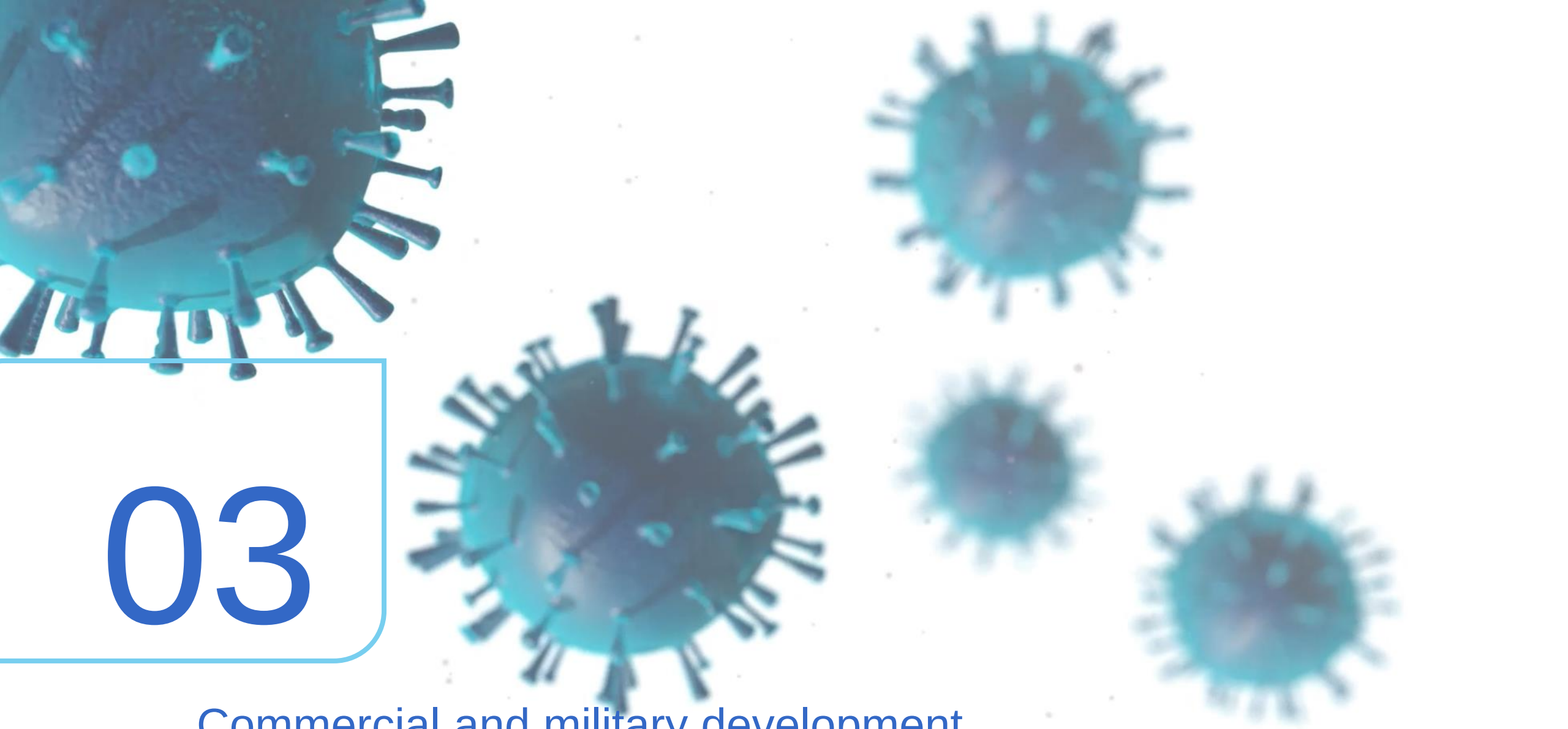


Figure. The typical evolution of a superficial wound infection.

A Proposed New Classification of Skin and Soft Tissue Infections Modeled on the Subset of Diabetic Foot Infection, Open Forum Infect Dis. 2016



03

Commercial and military development

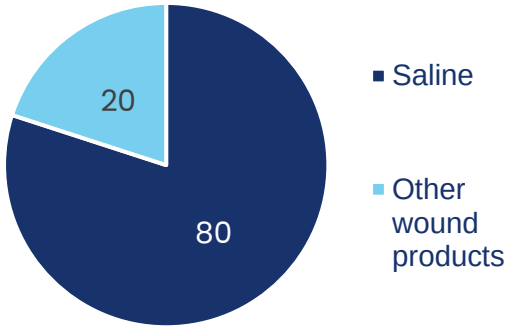
Unmet need in wound care

ACUTE WOUNDS

180 million

Individuals have skin wounds worldwide each year[1]

Today's wound rinse market is **dominated by saline**



CHRONIC WOUNDS

40 million

Chronic wounds worldwide[1]

1-2%

of population are projected to have a chronic wound in developed countries[2]

Venous leg ulcers (VLUs)

Target US patient population (2018)	2,323,804
Prevention of infections (costs) / patient	**-$643**

Estimated **$1.5 billion potential cost savings** in prevention of infections in VLUs [3

Replacing today's wound rinse products with a better or equal risk profile and profound antimicrobial effect

Improving today's chronic wound treatment with more effective removal of infections protected by biofilm

1) MedMarket Diligence (2011). Wound prevalence and wound management: 2012-2020
2) Sen, C.K. et al. (2009) Human Skin Wounds, Wound Repair Regen, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2810192/
3) MedValue & Radboud University (2019). Decision Modeling Assessment.

European Defence funds military inhalation solution

Granted approx. NOK 97 million to develop a military medical countermeasure for the EU and allies

- Supported by the Norwegian Ministry of Defence (FD) joint financing

International consortium involving:

- **20** R&D and industry partners
- **10** countries
- **3** technologies

Led by the Commissariat a l'Energie Atomique et aux Energies Alternatives (France)

Status: Grant agreement negotiation phase – expected signing by end of 2022

EUROPEAN UNION
EUROPEAN DEFENCE FUND
FFI Forsvarets forskningsinstitutt
Norwegian Defence Research Establishment

"The project "European agile network for medical COUNTER measures Against CBRN Threats" (COUNTERACT) aims to establish a robust and agile network within the EU to be **capable to develop and deploy medical countermeasures (MCMs) against major Chemical-Biological-Radiological and Nuclear (CBRN)** threats such as terror plots, nuclear accidents, weapon developments and epidemics caused by emerging or re-emerging high-consequence pathogens. COUNTERACT will increase EU preparedness for immediate response to such threats."[1]

1. https://defence-industry-space.ec.europa.eu/system/files/2022-07/Factsheet_EDF21_COUNTERACT.pdf

The main objective for European Defence Fund (EDF)

- **Identifying technologies critical for EU security** and defence, boosting them through European (RTD&I) programs[1
- **Foster transborder cooperation** in defence research and development in the EU[2
- The Defence package strives to complement the European Defence Fund by **integrating all relevant phases** from [2
  - » research and development
  - » complete industrial cycle
  - » joint procurement of defence assets

1)European Commission Strasbourg 15.02.2022 Communication from the Commission to the European Parliament: ec.europa.eu/info/sites/default/files/com_2022_61_1_en_act_roadmap_security_and_defence.pdf
2) https://eufundingmag.eu/2022/04/18/european-defence-fund-2/

EU Action plan on synergies between civil, defence and space industries

- **Spin-offs:** Promoting that EU funding for research and development, including on defence and space, has economic and technological dividends for EU citizens
- **Spin-ins:** Facilitating the use of civil industry research achievements and civil-driven innovations in European defence cooperation projects
- **Synergies: EU Multinational Financial Framework 2021-2027 (MFF)** significantly scales up investments in technologies for defence or related civilian use

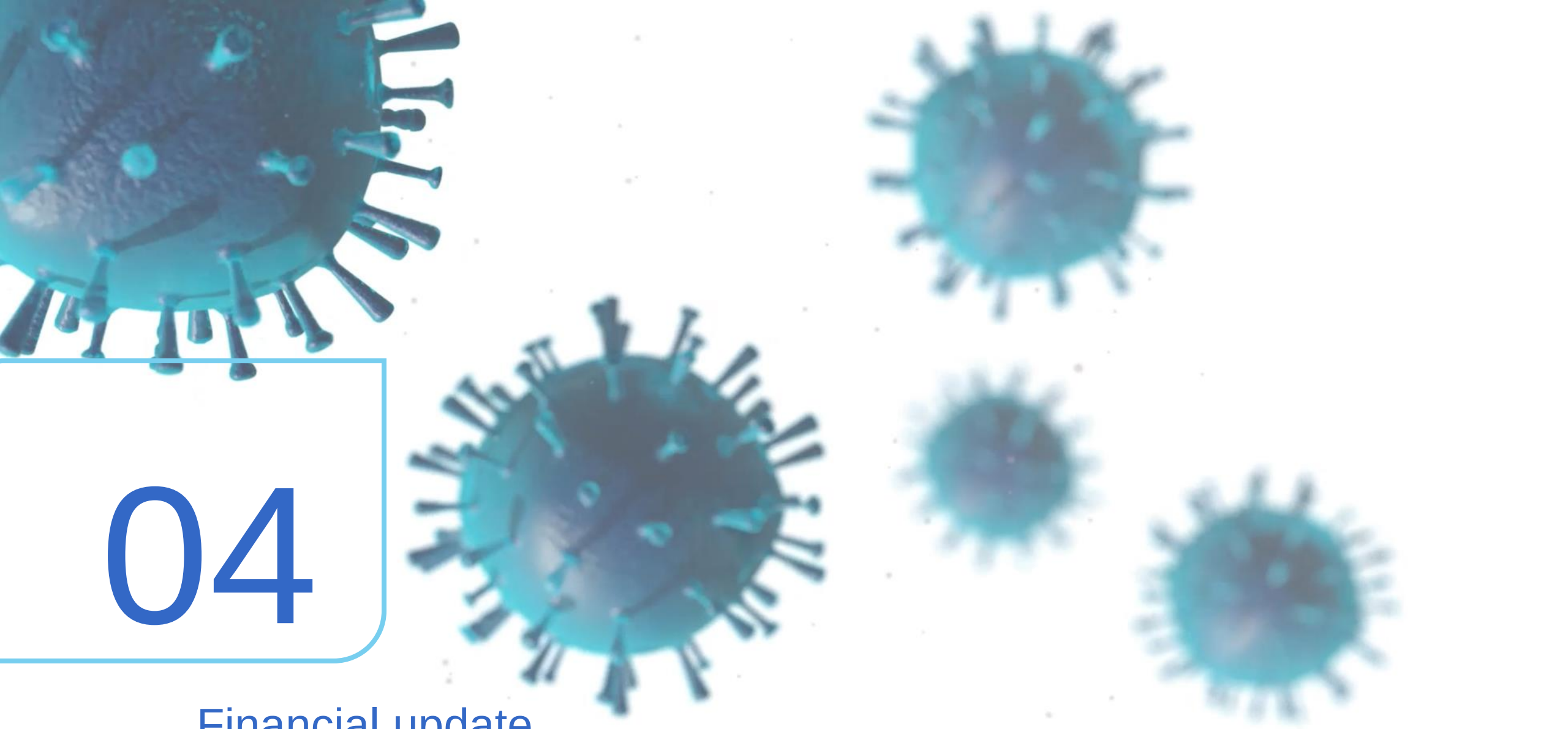
European Commission Brussels 22.02.21 Communication from Commission to European Parliament, page 1: ec.europa.eu/info/sites/default/files/action_plan_on_synergies_en.pdf

Expected value as a preventative preparedness tool for soldiers and the civilian population

Estimated Unmet Need

- 10-20 pcs for each soldier
- 3.5 million soldiers (NATO & EU)
- 2 million soldiers (partner countries)
- Stockpiling for 15-20% of civilian population

The company estimates that this cooperation can double the potential sale of SoftOx inhalation solutions



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Financial update

Financial highlights

Profit and loss statement
Accounts for Q2 and FY 2021

SoftOx Solutions Group *NOK 1,000*	**Q1 2022**	**Q2 2022**	**Q2 2021**	***Change***	**FY 2021**
Operating revenue	50	53	703		1 752
Grants	999	1 297	1 895		6 150
Total operating revenues	**1 049**	**1 350**	**2 599**	**-48%**	**7 901**
Personnel expenses	6 538	5 448	3 615	**51%**	21 113
Other operating expenses	17 795	15 154	19 479		69 107
Depreciation	906	918	710		3 784
Total operating expenses	**25 238**	**21 520**	**23 805**	**-10%**	**94 004**
Operating result	**-24 189**	**-20 171**	**-21 205**	**-5%**	**-86 102**
Net financial items	**-87**	**-396**	**-68**		**-189**
Net result before taxes	**-24 276**	**-20 566**	**-21 273**	**-3%**	**-86 291**
Tax					20 888
Net result after tax					**-65 403**

Operating revenue

Low operating income due to low sales

Operating expenses

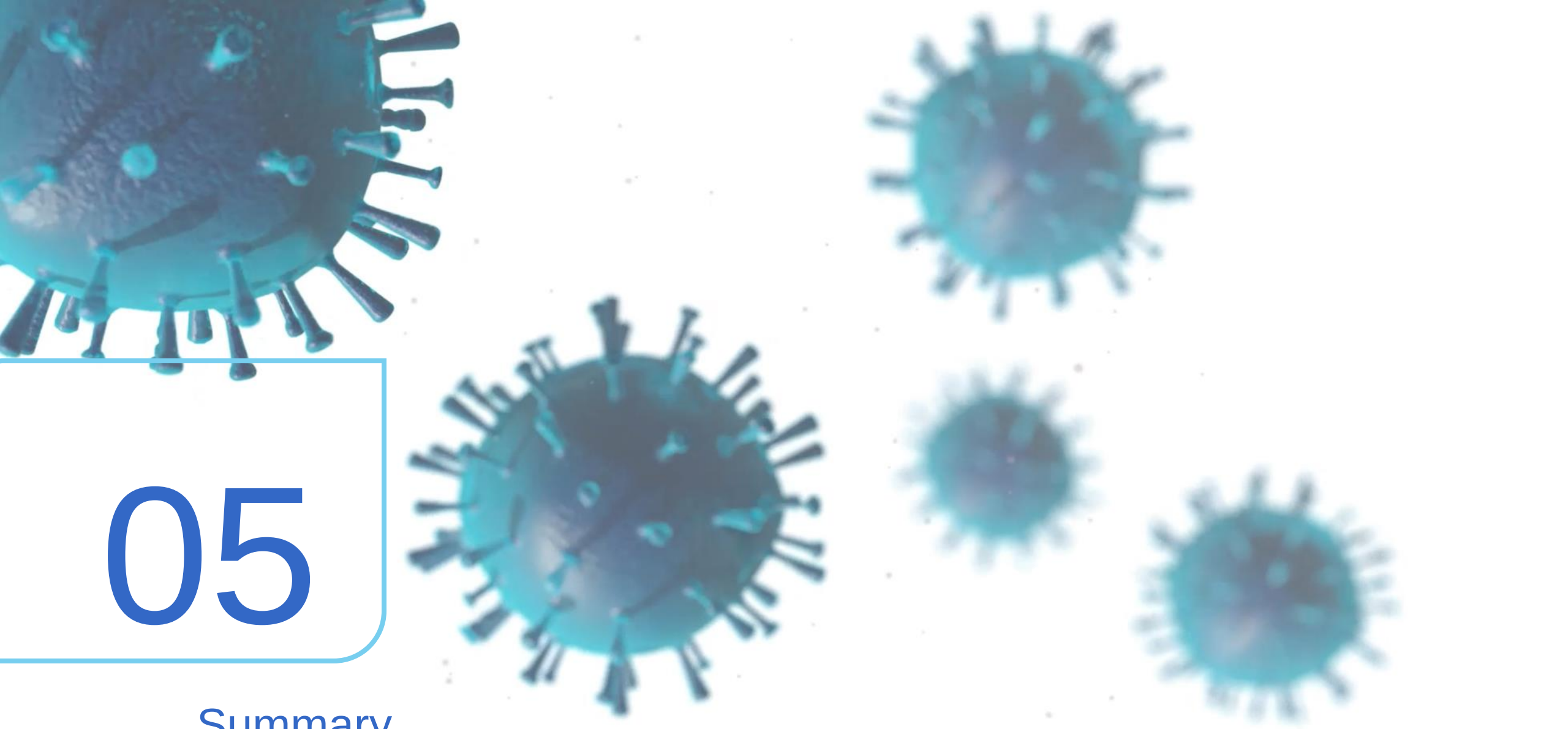
- R&D expenses accounted for approx. 60% of operating expenses year to date 2022.

Financial highlights

Cash flow statement SoftOx Solutions Group *NOK 1,000*	Q1 2022	Q2 2022	Q2 2021	FY 2021
Cash flow from operating activities	**-21 141**	**-25 603**	**-22 820**	**-72 561**
Net result before taxes	-24 276	-20 566	-21 273	-86 291
Depreciation	906	918	710	3 784
Change in current assets	865	-10 067	-802	3 061
Change in current liabilities	1 364	4 112	-1 456	6 886
Cash flow from investment activities	**-847**	**-1,314**	**-1 038**	**-4 596**
Investments in non-current assets	-847	-1,314	-1 038	-4 596
Cash flow from financing activities	**-809**	**146**	**-10**	**99 339**
Proceeds from equity issues	0	0	0	89 018
Other financing activities	-350	0	0	10 355
Translation differences	-460	146	-10	-34
Net change in cash and cash equivalents	**-22 797**	**-26 770**	**-23 866**	**22 182**
Cash and cash equivalents at end of period	**34 187**	**7 414**	**31 131**	**56 984**

Net change in cash and cash equivalents

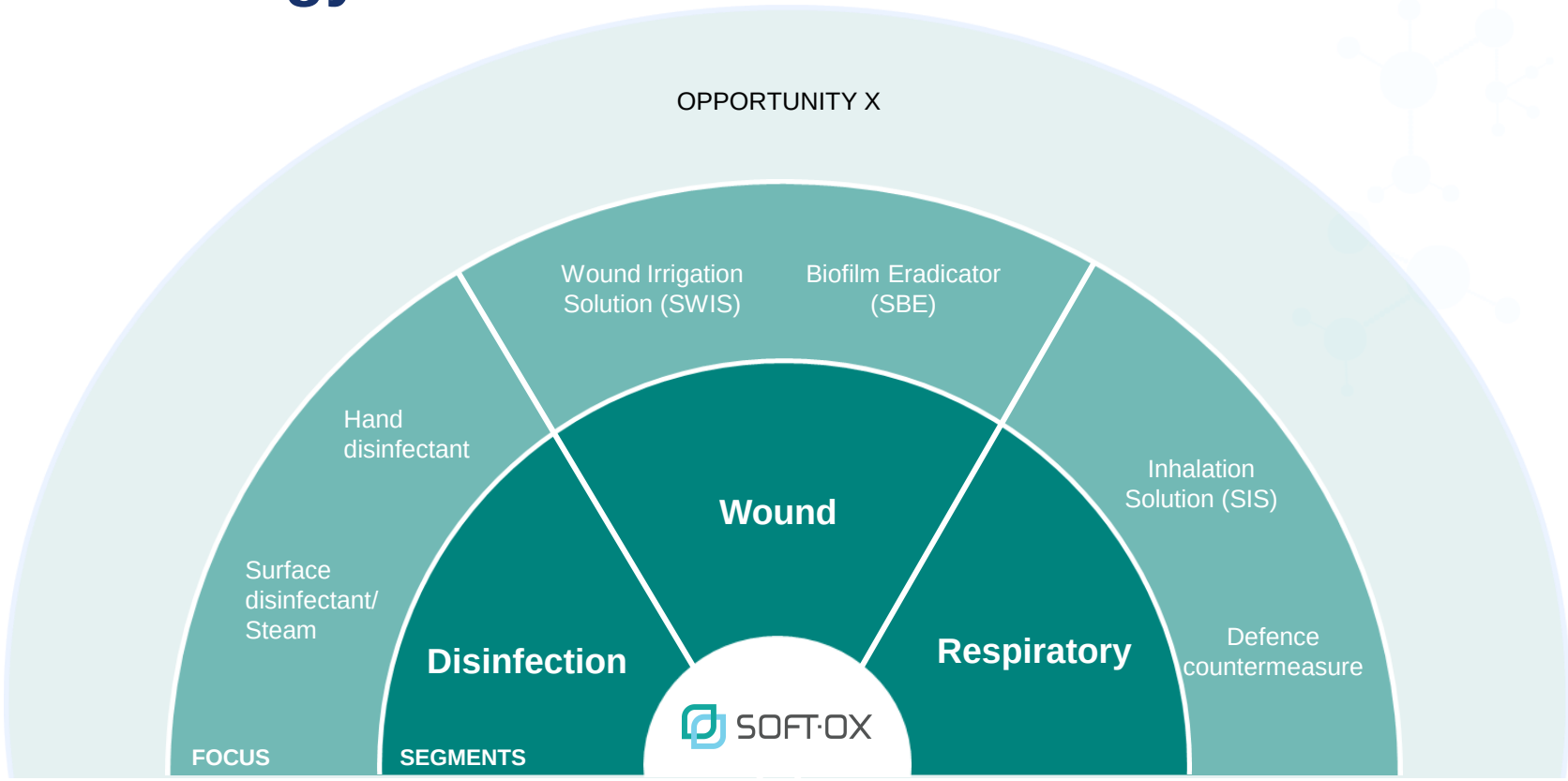
- Strong focus on the product development and commercialisation processes while managing cash situation carefully
- Entered into a loan agreement of NOK 15 million in June. Accounted as receivables



05

Summary

Multiple opportunities for development of products based on SoftOx technology



SoftOx will remain as a development company and is seeking strong commercial partners

Expected news flow 2022

Wound care

- Talks with major distributors and partners
- GMP production line
- Achieve a 510(k) clearance for the US market
- Complete phase 1 of SBE
- Initiation of phase 2

Respiratory

- Initiation of phase 2 will be aligned with EDF process
- Financial and strategic partner
- Entering into a contractual phase to prepare for pan-European research activity

Disinfection

- Partner discussions – EU and RoW
- Regulatory approval

Key takeaways

Solid progress on the projects targeting **large global markets**

Highly skilled team
12 PhDs & 3 professors/researchers

Endogeneous ingredients
Well known & well tolerated by human body

Strong platform
with great potential for many products/segments

58 granted patents
Strong patent family protecting IP

Co-funded development
with the US Naval Medical Research Center and European Defence Fund

Collaboration
with world-leading scientists

Significant unmet needs & potential to **reduce healthcare costs**

New ways of eradicating infections and fighting antimicrobial resistance

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Chief Financial Officer