



SoftOx Solutions AS

A Norwegian BioTech Company listed on Euronext Growth

Presentation Q2 2021
8 September 2021





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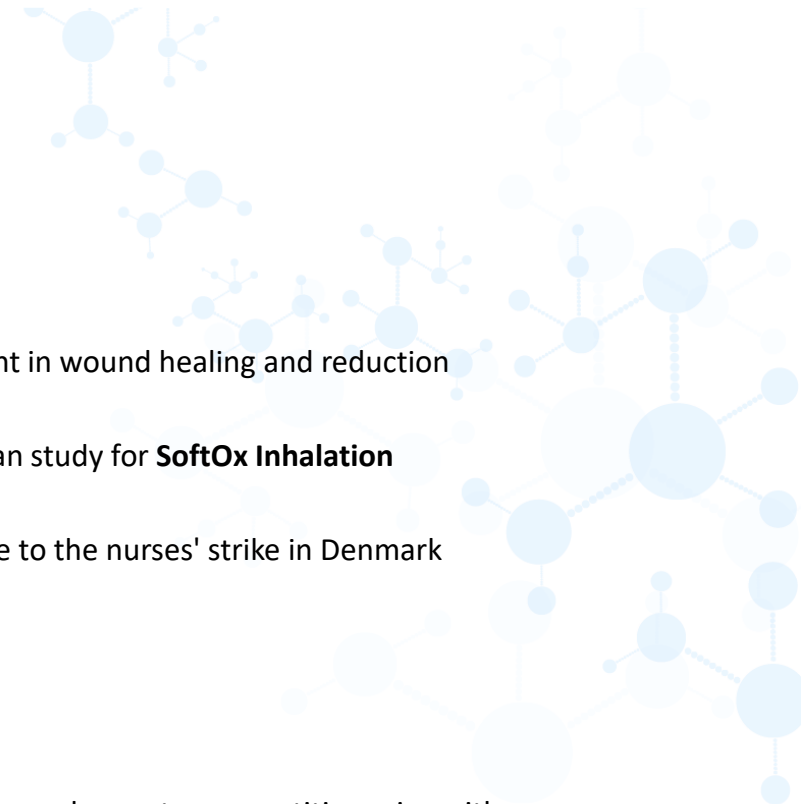
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Second Quarter 2021



Research & Development

- **SoftOx Wound Irrigation Solution (SWIS)** study results showed both significant improvement in wound healing and reduction in bacterial burden compared to Normal Saline (NS)
- The Danish Medicines Agency (DKMA) has given a conditional approval for the first-in-human study for **SoftOx Inhalation Solution (SIS)** for the treatment of respiratory infections.
- **SoftOx Biofilm Eradicator (SBE)** study started as planned at the end of May, but delayed due to the nurses' strike in Denmark

Commercialization and Operational update

- **SafeDes®** won the Norwegian national hospital tender (HINAS).
- New application for national approval of SoftOx's **biocidal products** submitted in Norway.
- SoftOx has entered into an agreement with **Ose Water AS**, the agreement ensures production volume at a competitive price with high quality.

Finance

- 2Q pre-tax results ended with a loss of 21.2 million (loss of NOK 9.8 million).



Financial highlights

Profit and loss statement Accounts for second quarter and first half year 2021

SoftOx Solutions Group NOK 1,000

	Q2 2021	Q2 2020	Change	FY 2020
Operating revenue	797	4 649		3 689
Grants	1 801	1 617		6 150
Total operating revenues	2 599	6 266	-59%	9 839
Personnel expenses	3 615	3 304	9%	18 869
Other operating expenses	19 479	12 238		39 631
Depreciation	710	618		2 703
Total operating expenses	23 805	16 160	47%	61 203
Operating result	-21 206	-9 894	114%	-51 364
Net financial items	-68	93		1 650
Net result before taxes	-21 273	-9 801	117%	-49 714
Tax				12 308
Net result after tax				-37 406

Operating revenue

Reduced due to regulatory issues

- Withdrawal of sold products. Actual operation revenue 2020, approx. NOK 1,6 million
- Postponed marketing

Operating expenses

increase driven by

- Research and development



Financial highlights

Cash flow statement	Q2 2021	Q2 2020
SoftOx Solutions Group <i>NOK 1,000</i>		
Cash flow from operating activities	-22 820	- 13 876
Net result before taxes	-21 273	-9 801
Depreciation	710	618
Change in current assets	-802	-5 000
Change in current liabilities	-1 456	306
Cash flow from investment activities	-1 038	-6 230
Investments in non-current assets	-1 038	-6 230
Cash flow from financing activities	-10	1 173
Proceeds from equity issues	0	1 010
Other financing activities	0	0
Translation differences	-10	163
Net change in cash and cash equivalents	-23 866	-18 934
Cash and cash equivalents at end of period	31 131	35 431

Net change in cash and cash equivalents

The Board is monitoring the Company's liquidity position and financing closely.



SoftOx at a Glance

Eradicating infections and fighting resistance

- A strong medical technology platform developed over 10+ years
- The medical products being developed on this platform will effectively eradicate bacteria and viruses without creating resistance unlike existing antibiotics
- The product portfolio is divided between infection prevention and infection removal

Robust patented product portfolio

- 87 filed patents worldwide, where of 57 are granted addressing formulations, uses, methods and devices
- Experienced research and development team, with support from Bispebjerg Hospital and Copenhagen University

Strong market support

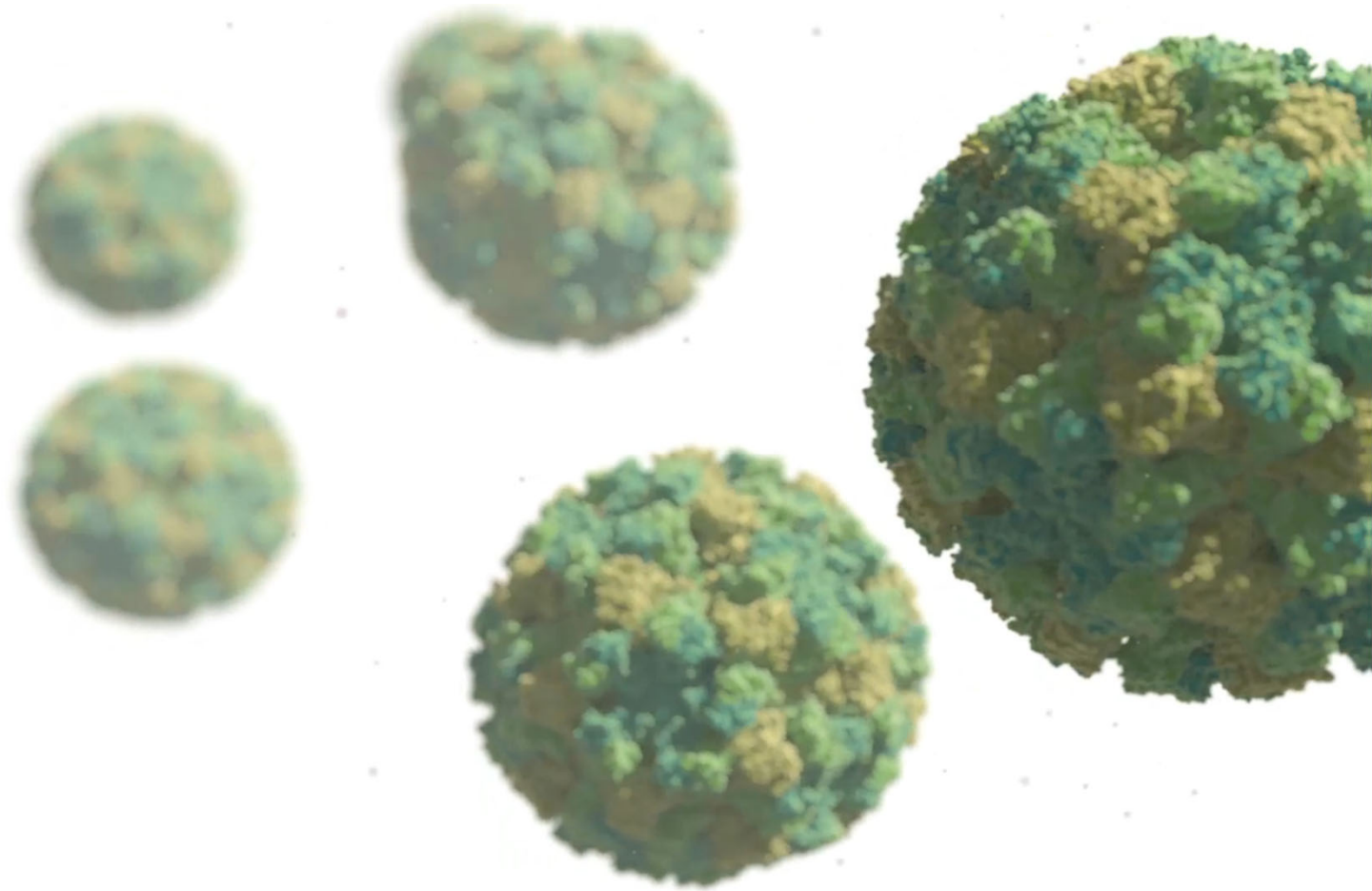
- US Navy Medical Research Center sponsoring the development of the SBE
- Norwegian Defence Research Establishment will co-develop and field test SoftOx's technology
- Market approval of winning HINAS

Targeting large markets

- The largest market opportunities for SoftOx are in the healthcare, business-to-business and military markets worldwide
- All markets targeted by SoftOx are billion \$ opportunities

01

New Ways of
Eradicating Infections





Global Challenges Targeted by SoftOx

Antibiotic resistance

- The ability of bacteria and other microorganisms to resist the effects of an antibiotic to which they were once sensitive
 - » WHO estimates that drug-resistant diseases could cause **10 million deaths each year** by 2050 ^[1]
 - » *The world needs a new antibiotic preventing and removing resistant infections without inducing new resistance*

Biofilm resistance

- Aggregated bacteria often covered by slime (biofilm matrix), which acts as a fortress and protects bacteria
 - » **1-2% of the total population** are projected to experience a chronic wound during their lifetime in developed countries ^[2]
 - » *The world needs a new antibiotic preventing and removing infections protected by a biofilm*

Virus

- A submicroscopic infectious agent that replicates only inside the living cells of an organism ^[3]
 - » The COVID-19 pandemic will likely end up costing between **\$8.1 and \$15.8 trillion** globally ^[4]
 - » *The world needs a broad spectrum, first-line alternative to vaccines*

1) https://www.who.int/antimicrobial-resistance/interagency-coordination-group/IACG_final_report_EN.pdf?ua=1

2) [Chandan K. Sen, PhD, Wound Repair Regen, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2810192/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2810192/)

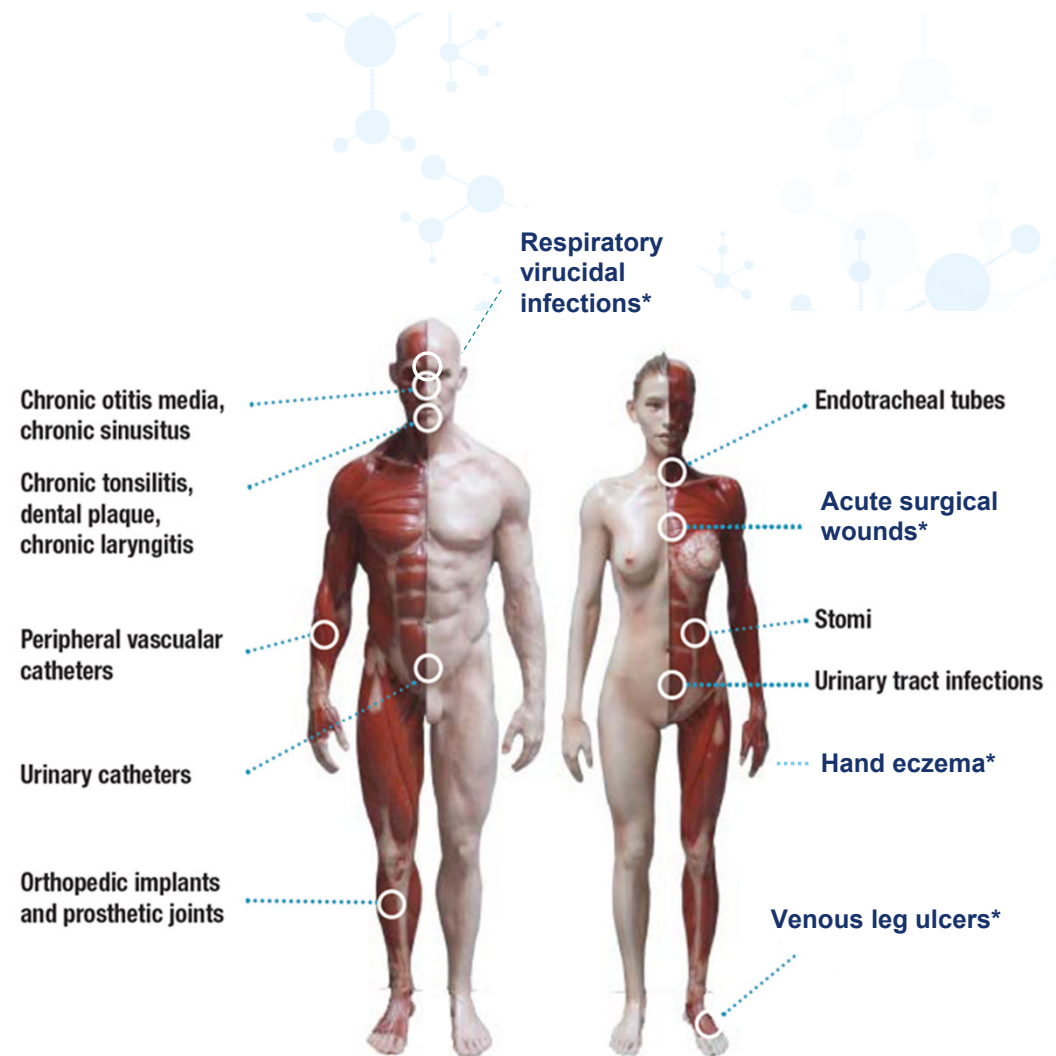
3) Wu, Katherine J. National Geographic Society. April 2020

4) Schwab, World Economic Forum, August 2020



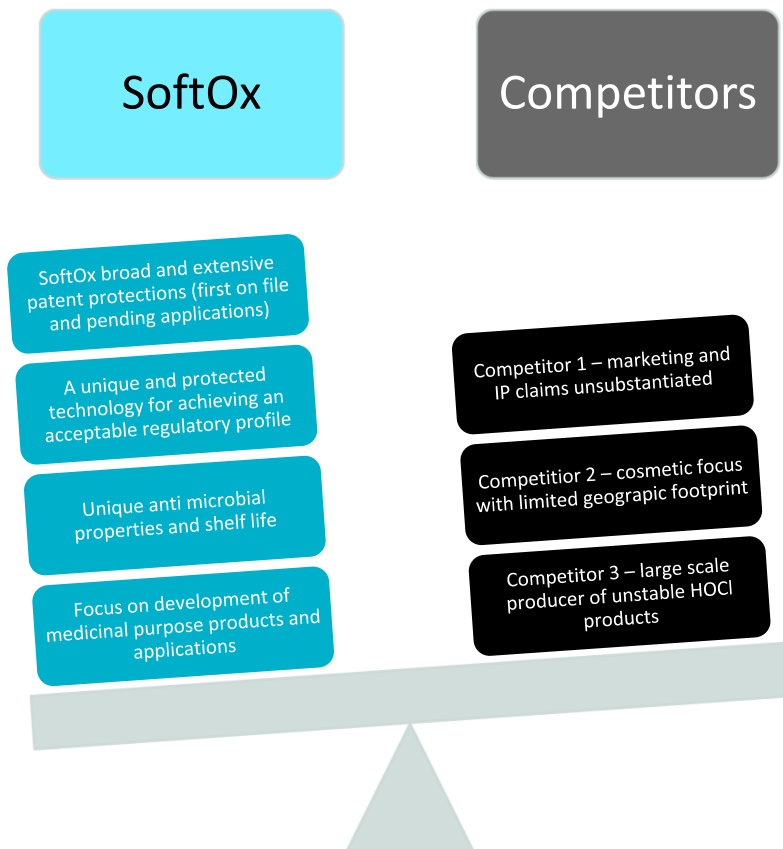
SoftOx Technology Platform

Infection prevention	Infection removal
SoftOx Disinfection (SafeDes®) Hand and surface disinfectant	SoftOx Biofilm Remover (SBE) Infection remover in chronic wounds penetrating and killing microbes within biofilms
SoftOx Wound Irrigation (SWIS) Rinse acute and chronic wounds to prevent infections and biofilm formation	
SoftOx Inhalation Solution (SIS) Treatment of respiratory tract infections caused by viruses and bacteria with an aerosolized form of the SoftOx technology, designed to be safe and effective in the upper airways and in the lungs	



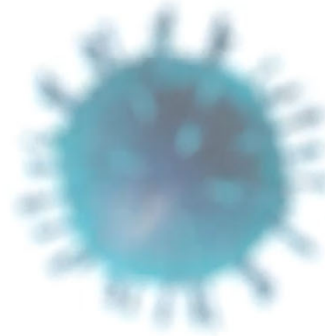
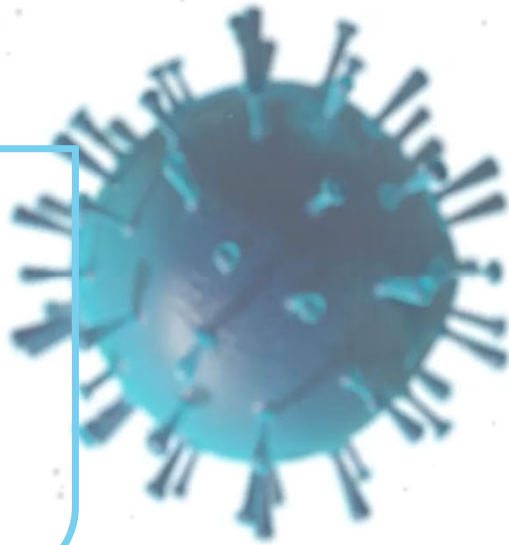
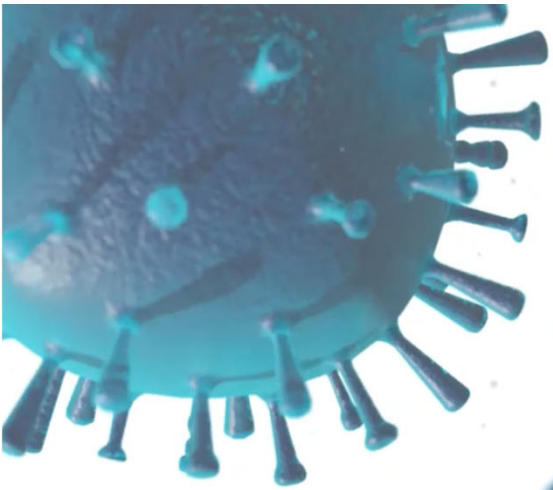
Established a Proof of Concept for a revolutionary way of fighting infections

- SoftOx has a unique and well protected technology
- No IP threats from 3rd parties have been identified



- **Broad and extensive patent portfolio covering:**
 - » formulation
 - » production
 - » storage
 - » route of administration
 - » anti-microbial indications
- **A unique and protected technology for achieving an acceptable regulatory profile**
 - » Two years shelf life in active substance
 - » Avoid building up nonacceptable impurities

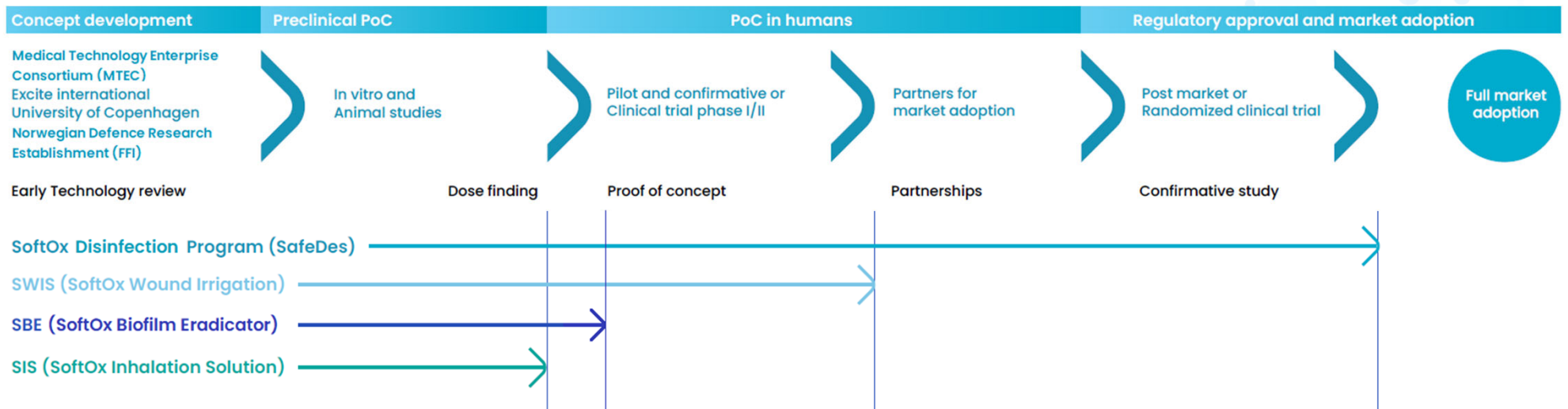
Currently, the Company has 57 issued patents and 85 pending applications



02

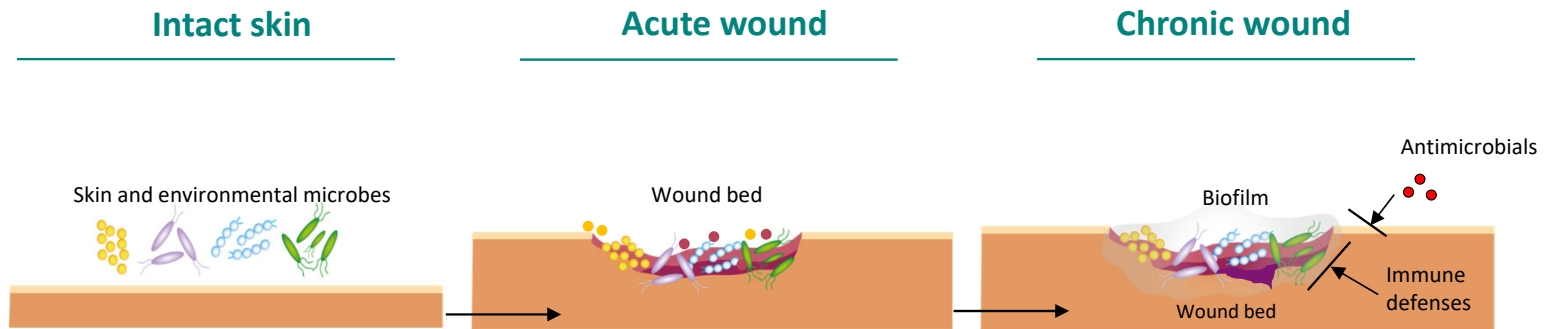
Product Development

SoftOx Product Development Methodology



Same Technology - Tailored Concentrations for Different Use

Skin and Wound Challenges



SoftOx Solutions

SafeDes® hand disinfection

SoftOx Wound Irrigation Solution (SWIS)

SoftOx Biofilm Remover (SBE)



SoftOx Wound Irrigation Solution (SWIS) – clinical study finalized

Status of the project

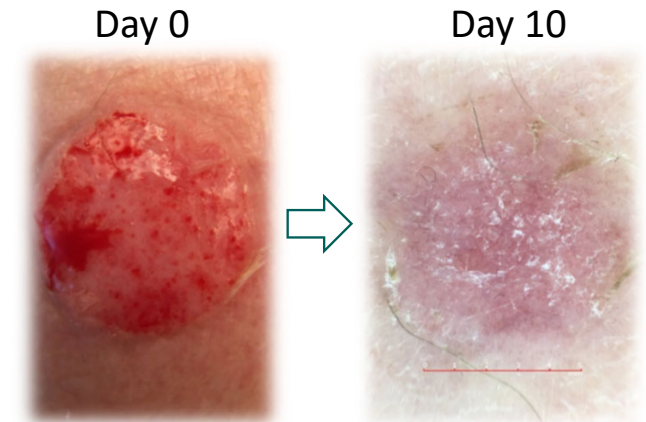
Final confirmatory clinical investigation (SWIS-02 trial) has successfully been completed and finalized study report.

Major results:

- Excellent wound healing properties
- Profound antibacterial effect, significantly better than saline at all measures
- Usability: 100% scored Acceptable or Perfectly acceptable
- No product related adverse events

Features

- **Safe to use:** just as safe as sterile salt water (saline)
- **Added value:** Profound **antimicrobial effect** with favourable early **wound healing** properties



Proof of Concept of SoftOx technology in humans



SoftOx Infection Remover (SBE) – slight delay due to strike

Status of the project

Clinical Trial Application (SBE-01 phase I study) gained approval from DKMA and Ethics Committee NVK, Denmark

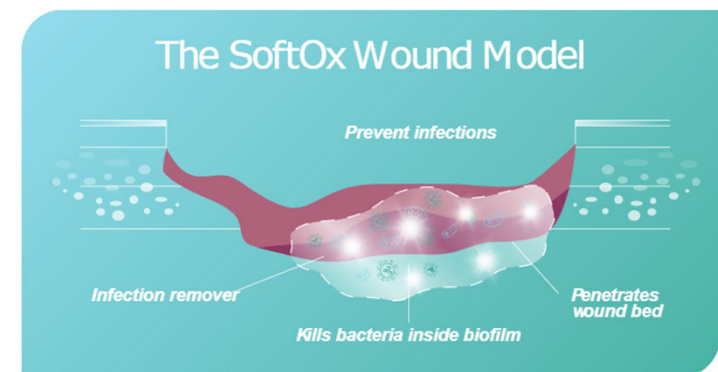
Study site inspected by DKMA with satisfactory outcome

Study site activated.

Recruitment has been affected by nationwide nurse strike in Denmark. The strike was terminated last week

Features

- SBE is a stronger antimicrobial solution than SWIS that aims to treat established (biofilm) infections
- Penetrates deep into the wound bed
- Animal data indicates excellent local safety and tolerability with no systemic exposure
- Kills antibiotic resistant bacteria and does not induce new resistance





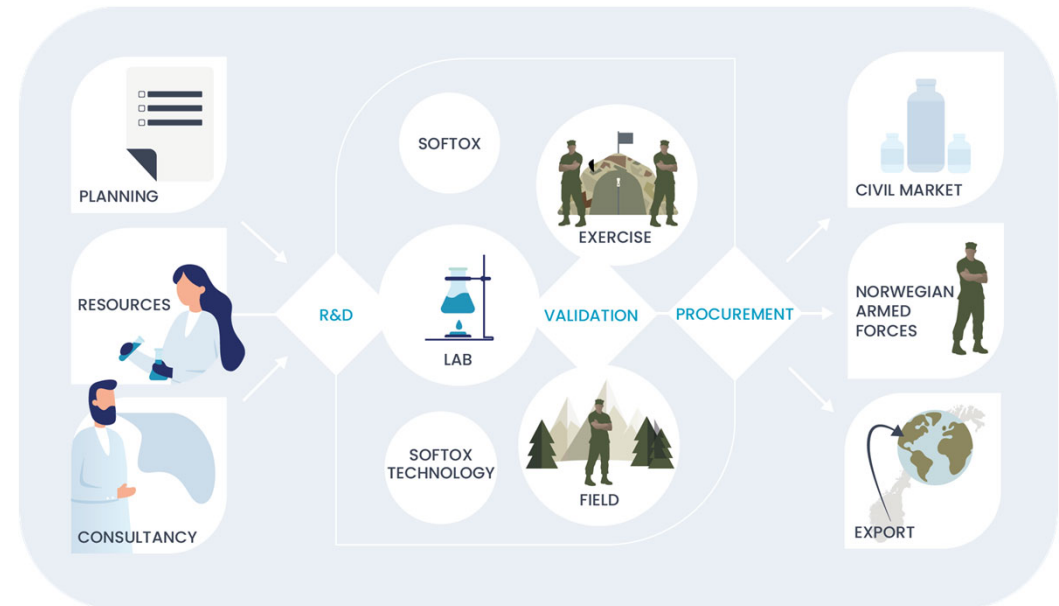
Collaboration agreements – defence sector and SoftOx wound segment

Norwegian Defence Research Establishment (FFI)

- Cross-disciplinary research and development partnership with the Norwegian Armed Forces and the Norwegian Defence Research Establishment.
- The aim is to adapt civilian products manufactured by SoftOx for military purposes.
- The recent SWIS findings have cemented our proof of concept. SoftOx Defense Solutions, a subsidiary, was established to facilitate the development of the military segment.
- Our target is to develop a multi-purpose product for the defence sector.

US Navy – Naval Medical Research Center

- Award granted by the Medical Technology Enterprise Consortium (MTEC) for the clinical development of a broad spectrum, topical antimicrobial wound irrigation solution – SoftOx Infection Remover (SBE).
- The project is a research and development collaboration focusing on chronic wounds and biofilm infections.



Process diagram illustrating the project between SoftOx and FFI



SoftOx Inhalation Solution (SIS) – on track

Features

- Antimicrobial inhalation solution for respiratory tract infections
- Broad spectrum including virus and antibiotic resistant bacteria

Results from preclinical studies with SIS

- Antiviral and antibacterial effects demonstrated *in vitro*
- Tolerable & safe concentration range established in minipig model (*in vivo*)

Status of the project

Approved by Nat. Ethics Comm (NVK) in Denmark

Received conditional approval from Danish Medicines Agency (DKMA)

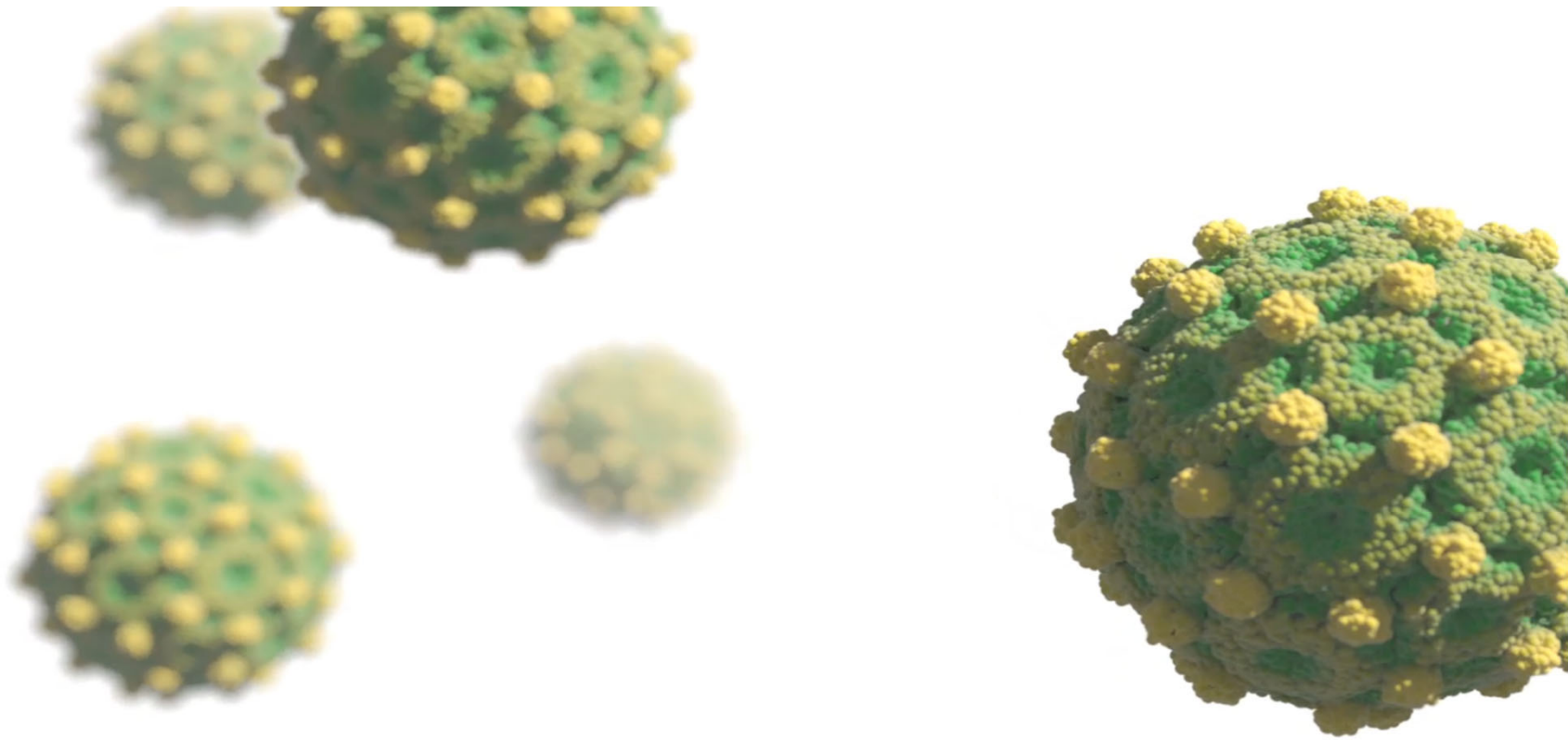
- SoftOx is currently working on meeting the conditions for final approval



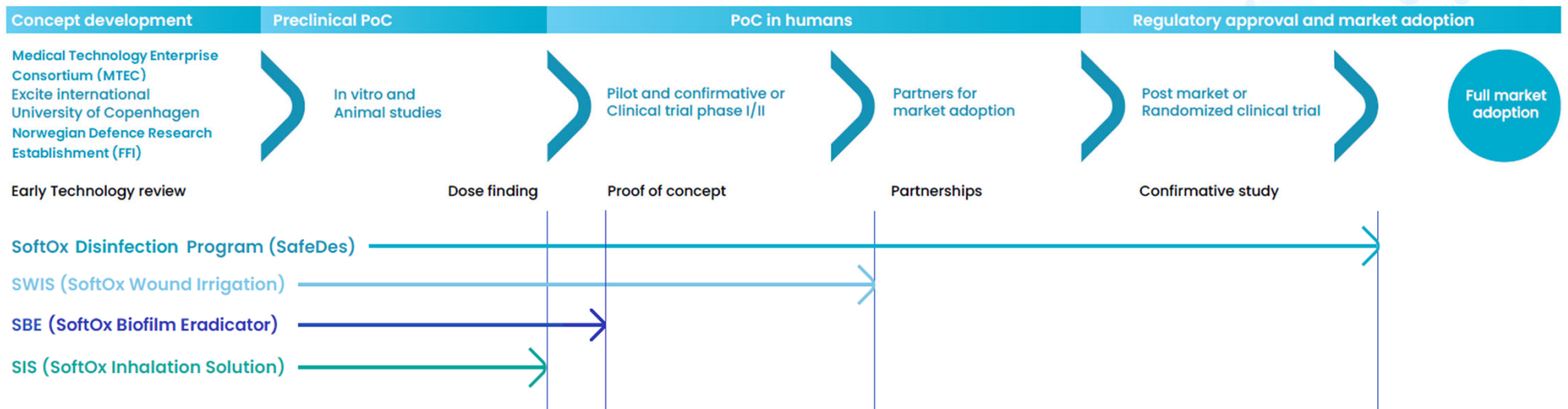
Answering the unmet medical need of treating respiratory tract infections

03

Market adoption



SoftOx Product Development Methodology





SoftOx – a Paradigm Shift in Disinfection

Challenges answered by SoftOx

- Skin friendly alternative to 25-55% of healthcare workers (HCW) have skin problems on their hands^[1]
- Alternative to for 70% of HCW experience problems with alcohol
- Full effect on all viruses incl. 15sec effect on enveloped viruses
- Effective towards biofilm (hand eczema)
- No health concerns
 - » No burning sensation
 - » Not toxic for eyes and drinking
 - » Non-flammable

Economic impact



31.5 million HCWs in the EU and the US^{[2][3]}
Whereof 10 million have irritated skin and eczema^[4]



USD 1,080^[5]
Value of effective prevention of hand eczema per HCW



1 mill HCWs in EU and US at risk of losing their job
If so, 2/3 of them risk ending up on disability benefits

SoftOx disinfection, SafeDes®, is as mild as saline and effective as alcohol

1) World Health Organization – Guidelines on Hand Hygiene in Health Care

2) Eurostat- Majority of Health Jobs Held by Women (2020)

3) Kaiser Family Foundation – Total Health Care Employment (2018)

4) National Eczema Association – Hand Eczema Common Among Health Care Workers

5) MedValue+, Radbound University Medical Center and Exite International's Panel of 11 KOL/experts – “2019 Health Technology Assessment; SoftOx Hand-wash for Health Care Workers with Eczema”



Leading Players Emphasise Need for an Alternative to Alcohol

Healthcare sector - Norwegian Hospitals (Helseforetakenes Innkjøpsservice AS (HINAS))

- Established a separate class for alcohol-free hand disinfectants
- SafeDes® **won** the category with top scores in the evaluation criteria of “properties on skin” and quality, in combination with a competitive price.
- All 70 public hospitals in Norway can now purchase SafeDes® for the next 4 years, starting from October 2021.
- As a pilot customer, Norwegian hospital market is not expected to provide profitability during the first years but will provide valuable home market recognition, references and KOL support for the international market.
- The product has been assessed by the country's foremost professional expertise on efficacy and safety in disinfection.
- A confirmation of SoftOx's base technology.

Business-to-Business sector – Transportation and education sectors

- Signed an agreement with a Norwegian airline company
- Plans to expand within the transportation sector and also for use in schools and kindergartens

SoftOx is answering an unmet need in a \$6 bn market in US and EU^[1]

1) Company own estimates



Regulatory process

Regulatory process – BPR approval

- The Swedish Chemicals Agency rejected the application for approval of SoftOx disinfection products and has requested additional testing data
 - » SoftOx will present the data KemI has demanded prior to a renewed submission later this year
 - » SoftOx intends to contest and submit an administrative appeal in Sweden.
 - » SoftOx has submitted an appeal in Norway.

An updated biocidal application for Norway submitted

- » The application addresses the objections raised in the first application.
- » Change of active substance.
- » Certain unsolved regulatory issues at government level.
- » The application is currently being assessed by the Norwegian Environment Agency.
- » Several alternative solutions to keep our disinfection product in the market on the table

SoftOx are in a good dialog with authorities and confident on success



Production at Ose Water AS – secures production at a competitive price

Ose Water AS – the agreement

- SoftOx has entered into an agreement to purchase 50 % of the shares
- Strategic collaboration for growth and competitive production
- Competent environment within production and bottling
- Disinfection production moved to Ose
- Reliable production and delivery both nationally and internationally secured



Production and location

- Located in Bygland Setesdalen
- Port of Kristiansand is one hour drive away
- New in-house production line gives increased flexibility
- The factory has a large capacity and several production lines
 - » Focus on bottling and flexibility in bottle size and shape
- Ose Water is bottled directly from the pure and natural mineral water source OseKilden in Setesdalen

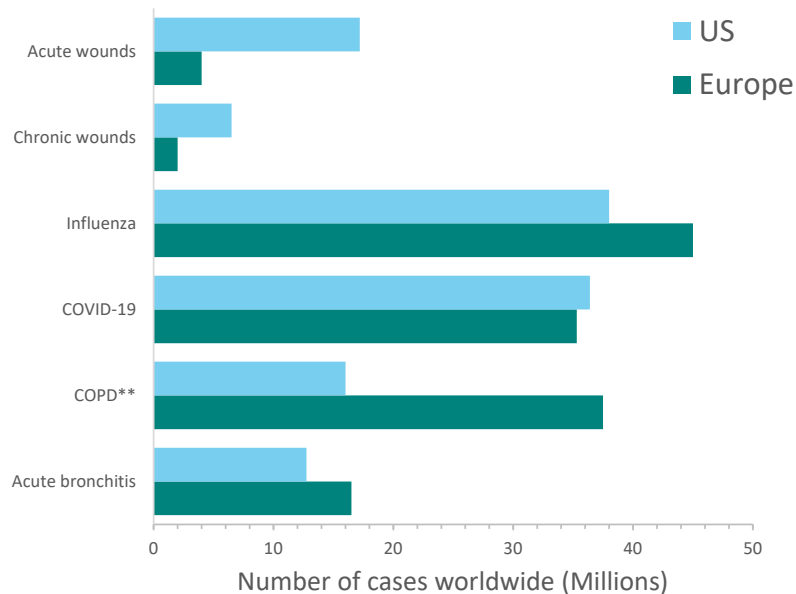




Total adressable market (TAM) - SoftOx products under development

The SoftOx products in development aim to treat prevalent and costly health conditions that affect the lives of many. The global market size of these conditions reflect the growing need and value of these treatments.

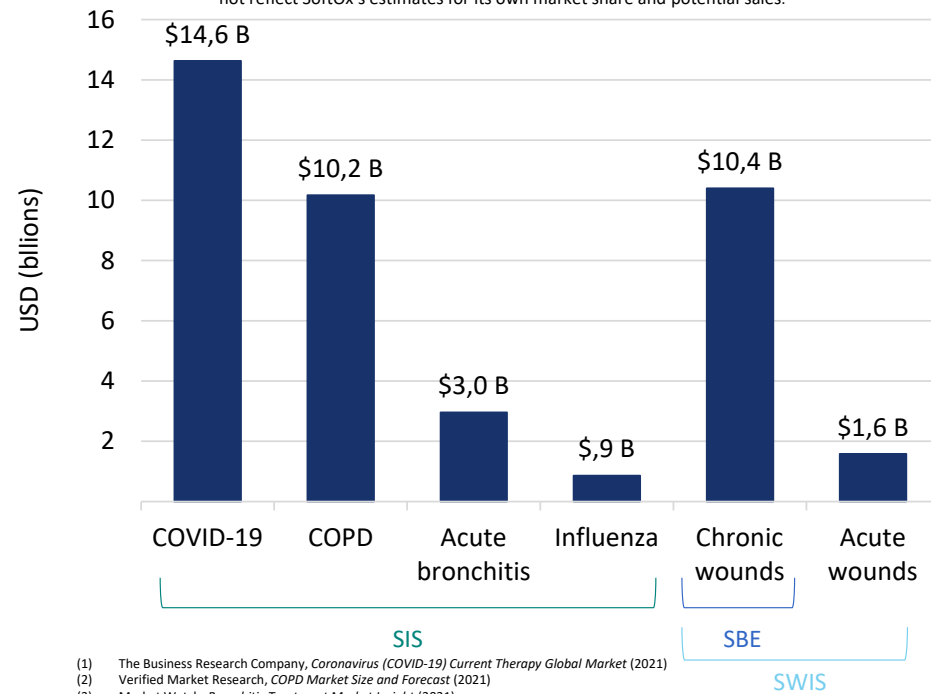
Condition prevalence (by region)



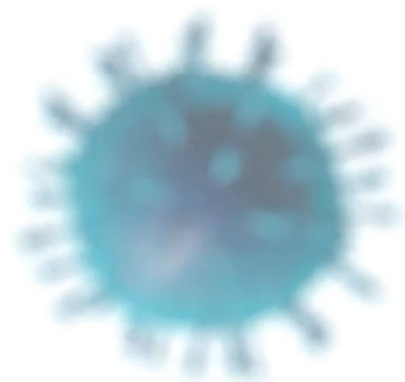
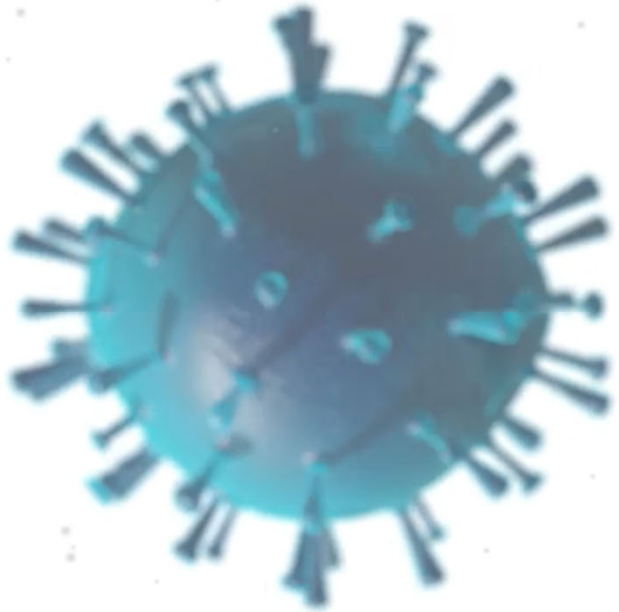
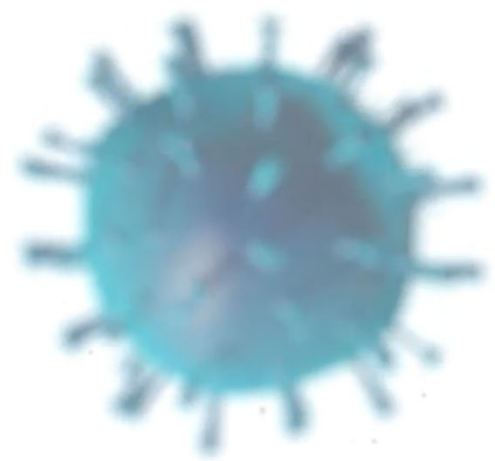
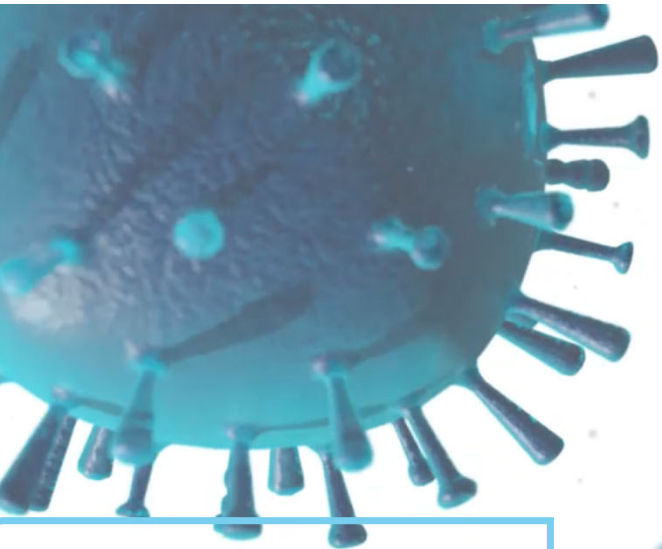
**COPD is considered to be globally underestimated and underdiagnosed

Global Market Size (B USD)

These global market size estimates represent the total value of the markets and do not reflect SoftOx's estimates for its own market share and potential sales.



- (1) The Business Research Company, *Coronavirus (COVID-19) Current Therapy Global Market* (2021)
- (2) Verified Market Research, *COPD Market Size and Forecast* (2021)
- (3) Market Watch, *Bronchitis Treatment Market Insight* (2021)
- (4) Allied Market Research, *Influenza Treatment Market* (2020)
- (5) Verified Market Research, *Global Chronic Wound Care Market Size* (2021)
- (6) Research and Markets, *Wound Irrigation Solutions Market to 2027* (2019)
- (7) WHO, *The Global Impact of Respiratory Disease* (2017)



04

Summary

Investment highlights



Solid progress on all R&D projects targeting **\$40bn+ TAM**



+80%
Gross margin target²
+35%
EBITDA²



Proven effect
Successful clinical trial in humans



MTEC and FFI



57+ patent filings
Strong patent family protecting IP



SafeDes[®]
Breakthrough agreement with HINAS



Collaboration with **world-leading** scientists



No antimicrobial resistance

1) Calculated by adding the potential markets
2) Company estimate



*New ways of eradicating infections and
fighting antimicrobial resistance*