

## **SoftOx Solutions AS**

Norwegian medtech and biotech company listed on Euronext Growth

Presentation Q1 2022 28 April 2022



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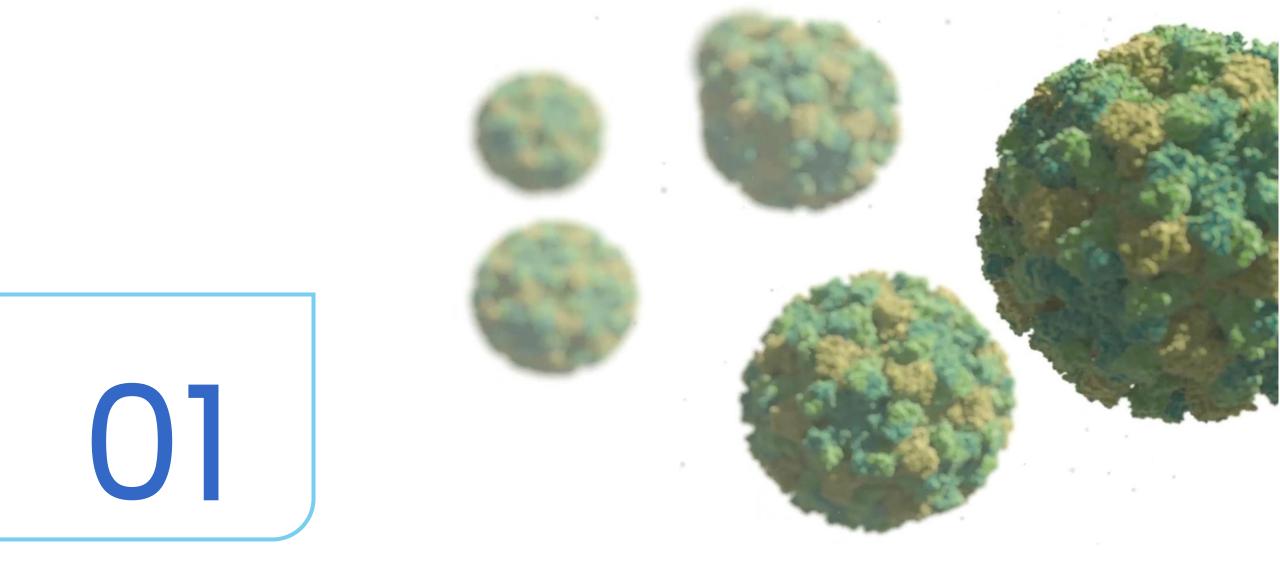
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### **Presenters**







### First quarter highlights and SoftOx in brief

4 | 1<sup>st</sup> quarter results 2022



## First quarter highlights

#### **RESEARCH & DEVELOPMENT**

- SIS-01 is progressing as planned, and the last subject last visit was completed in April
- SBE-01 has improved patient enrolment and advanced to the fourth and final dose-level
- Premarket Notification (510(k)) application submitted to obtain clearance by the US FDA for SWIS as a medical device class II in the US market

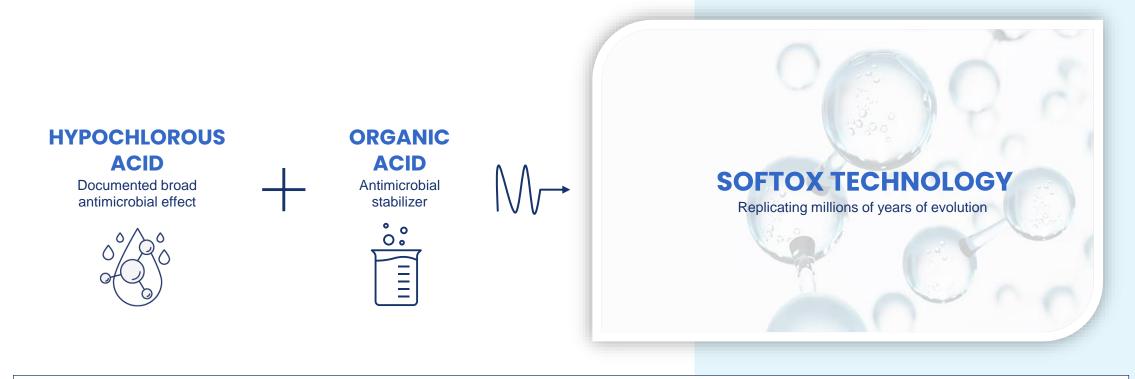
#### COMMERCIAL

- Signed NDAs and started talks with several potential international partners
- Started to deliver disinfection products to Hospital Purchasing (HINAS) in Norway and other companies within and outside the health sector.

#### FINANCE

• Q1 result of NOK -24,3 million (NOK -22,5 million)

# Reinforcing nature's own ability to eradicate unwanted microbes



A base technology tailored for different indications and uses



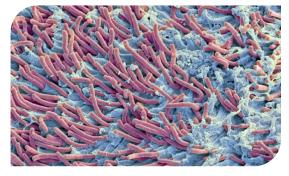
## Helping the world fighting infections

#### VIRUS



Respiratory infectious diseases are among the **leading causes of death**<sup>[1</sup>

#### **BIOFILM RESISTANCE**



**1-2% of the population** are projected to experience a chronic wound during their lifetime in developed countries <sup>[2</sup>

#### **ANTIMICROBIAL RESISTANCE**



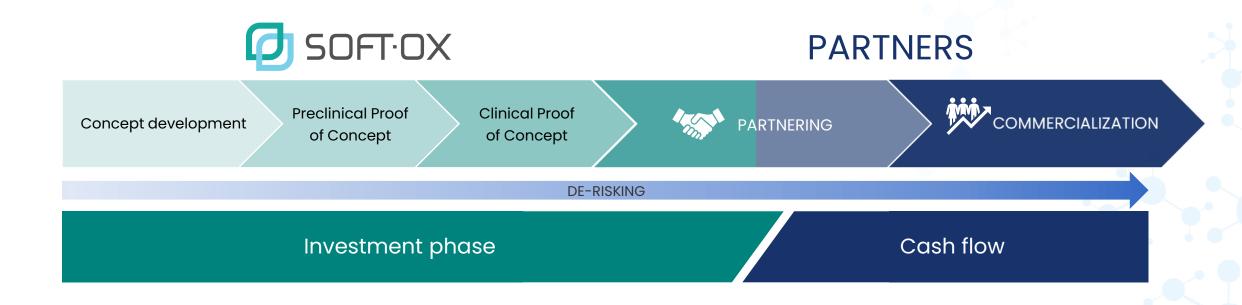
AMR is regarded as one of the **biggest threats** to global health <sup>[3]</sup>

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

Forum of International Respiratory Societies (2019). The Global Impact of Respiratory Disease – Second Edition. Sheffleld, European Respiratory Society.
 Sen, C.K. et al. (2009) Human Skin Wounds, *Wound Repair Regen*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2810192/
 IACG (2019). No Time to Wait, WHO. https://www.who.int/antimicrobial-resistance/interagency-coordination-group/IACG\_final\_report\_EN.pdf?ua=1



## **Business strategy**



#### SoftOx's core activities involve research and development before partnering up



## **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

## Project updates

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10 | 1<sup>st</sup> quarter results 2022

02



## **Competitive advantage**

1. Unique chemical stability and quality

- 2. Strong antimicrobial effects
- 3. Non-toxic, excellent tolerability
- 4. Does not induce microbial resistance
- **5.** Technology protected with extensive patent portfolio
- 6. Technology platform suitable for several needs









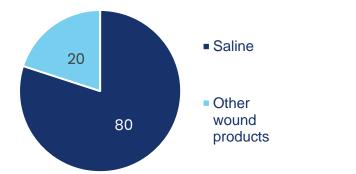
## **Unmet need in wound care**

#### ACUTE WOUNDS

180 million

Individuals have skin wounds worldwide each year<sup>[4</sup>

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



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

1-2%

of population are projected to have a chronic wound in developed countries<sup>[5</sup>

**Biofilm resistance**: Aggregated bacteria often covered by slime (biofilm matrix), which acts as a fortress and protects bacteria

Before healing, infections must be removed

CHRONIC WOUNDS

40 million

Chronic wounds worldwide<sup>[4</sup>

Today's recommended solution removes **only 90%** of the bacteria and includes surgical removal of the wound bed



## Wound care – Q1 updates

#### PREMARKET NOTIFICATION (510(k))

Submitted the Premarket Notification (510(k)) application to the US FDA to obtain clearance for SWIS as a medical device class II

#### SWIS-02 PUBLICATION & PRESENTATION

Accepted for publication in the international medical journal, *Acta Dermato-Venerologica*, and the SWIS-02 study will be presented at EWMA-CICA 2022 Conference in Paris, May 2022

#### SBE-01 STUDY AIM

Establish tolerable dose and treatment schedule for SBE to develop an effective infection treatment solution in problematic, non-healing wounds

#### SBE-01 ENROLMENT

Completed first three study cohorts of single ascending dose stage Nearing completed patient enrolment of SAD stage and moving into multiple ascending dose stage



#### SoftOx Wound Irrigation Solution (SWIS)

- » Well tolerated in wounds
- » Skin friendly
- » Excellent wound healing
- » Bacterial reduction
- » Does not induce microbial resistance

#### SoftOx Biofilm Eradicator (SBE)

- » Treat (biofilm) infections in chronic wounds
- Animal data indicate excellent local safety and tolerability with no systematic exposure
- » Kills antibiotic resistant bacteria and does not induce new resistance



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

Influenza

Influenza Waterfall Chart OTC products focused on reducing symptoms, but not: 100% **Unmet Need**  curing disease, shortening the duration of disease, 25% Percentage of patients with flu-like symptoms (%) altering the course of the disease, or reducing disease transmission 20% **OTC** product market 15% Influenza approved drugs have demonstrated specific antiviral 10% activity but: · clinical efficacy is limited to earlier **Approved Influenza drugs** 5% resolution of symptoms (approx. 1 day) in treatment of uncomplicated influenza within (on/off-label) market 48 hrs of symptom onset. 0% documented cross-resistance to Flu-like Medical Tested for Lab Hospitalised neuraminidase inhibitor drug class Confirmed Visits Influenza symptoms

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







## **Respiratory – Q1 updates**

#### SIS-01 STUDY AIM

Explore the safety and tolerability of single and multiple ascending doses of the inhaled nebulised SIS in healthy volunteers

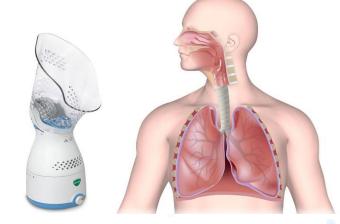
#### SIS-01 ENROLMENT

Progressed as planned and the completion of the last subject last visit was announced in April

#### SIS-02 PREPARATIONS

Preparing phase 2 documentation and engaging experts for scientific advice and input into the clinical trial design





#### SoftOx Inhalation Solution (SIS)

- » Aerosolized form of SoftOx technology
- » Designed to be safe and effective in upper airways and in lungs
- Current focus on treatment of COVID-19 patients and upper respiratory tract infections
- » Suitable for many infectious disease indications



## **Disinfection – Q1 updates**

#### 25-55%

of health care workers (HCWs) have irritated skin and eczema<sup>[6</sup>

#### Major cost drivers of HAIs

Direct relationship between hand hygiene compliance and HAIs<sup>[7</sup>

#### **PROOF OF SALES**

Norway – HINAS tender period began January 2022

Sweden – Tender period is valid from April 1, 2022 and the first order has been received

#### INTERNATIONAL PARTNERS

Ongoing talks with international players for potentially entering partnerships for both our disinfection and wound care products

#### **BIOCIDAL PRODUCTS REGULATION (BPR)**

Awaiting a response on the marketability of multipurpose products in the Norwegian market from the Norwegian Environment Agency





#### SoftOx Disinfectants SafeDes<sup>+</sup> & EffectDes<sup>H</sup> (Norway)

#### **Skin Friendly**

Avoid skin irritation and eczema

#### Effective

Full effect on all viruses and effective towards biofilm

#### No health concerns

- » Safe and non-flammable formula
- » Prevents alcohol poisoning
- » Safe transport and storage
- » No increase in VOCs observed

 Tomczak, H. et al. (2019). The role of Staph aureus in atopic dermatitis. Adv Dermatol Allergol; XXXVI (4): 485–491
 MedValue+, Radboud 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"

## Financial update

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18 | 1<sup>st</sup> quarter results 2022

03



## **Financial highlights**

Profit and loss statement Accounts for Q1 and FY 2021

SoftOx Solutions Group NOK 1,000	Q1 2022	Q1 2021	Change	FY 2021
Operating revenue	50	412		1 788
Grants	999	1 071		6 113
Total operating revenues	1 049	1 483	-29%	7 901
Personnel expenses	6 538	5 847	13%	21 113
Other operating expenses	17 795	17 554		69 107
Depreciation	906	722		3 784
Total operating expenses	25 238	24 124	5%	94 004
Operating result	-24 189	-22 641	7%	-86 102
Net financial items	-87	141		-189
Net result before taxes	-24 276	-22 500	8%	-86 291
Тах				20 888
Net result after tax				-65 403

#### **Operating revenue**

Low operating income due to low sales

#### **Operating expenses**

- Operating expenses on the same level as 2021 in Q1
- Increase in 2022 due to high levels of activity in R&D projects, such as two ongoing clinical trials



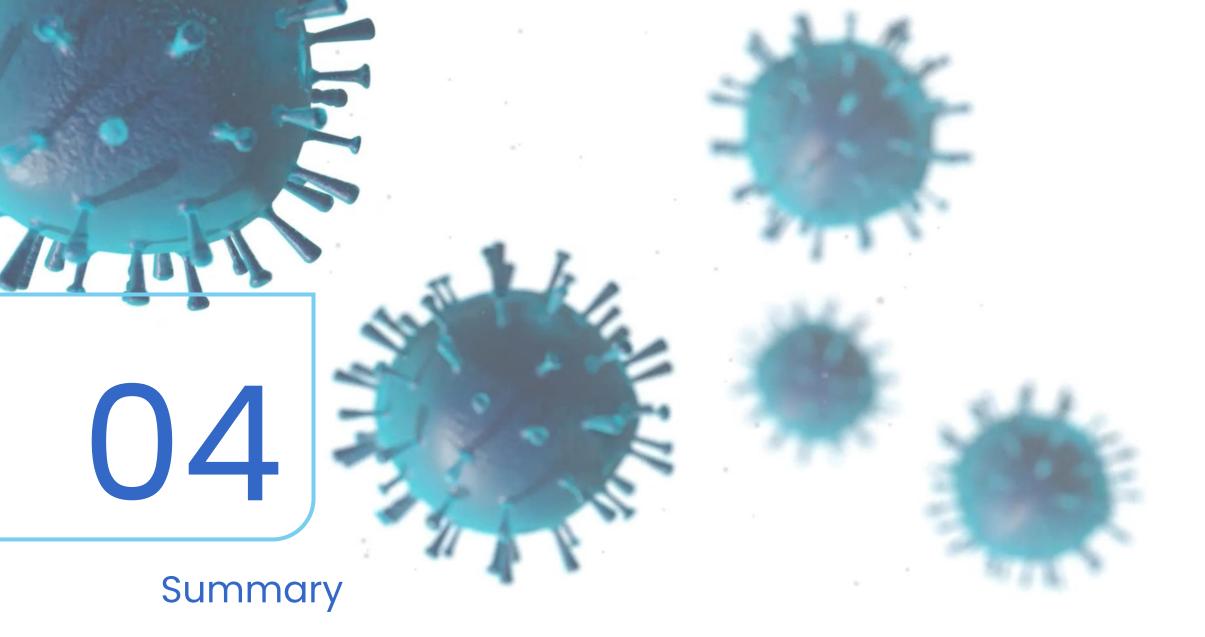
20 | 1<sup>st</sup> quarter results 2022

## **Financial highlights**

Cash flow statement	Q1 2022	Q1 2021	FY 2021
SoftOx Solutions Group NOK 1,000			
Cash flow from operating activities	-21 141	-20 410	-72 561
Net result before taxes	-24 276	-22 500	-86 291
Depreciation	906	722	3 784
Change in current assets	865	3 285	3 061
Change in current liabilities	1 364	-1 917	6 886
Cash flow from investment activities	-847	-357	-4 596
Investments in non-current assets	-847	-357	-4 596
Cash flow from financing activities	-809	40 962	99 339
Proceeds from equity issues	0	41 209	89 018
Other financing activities	-350	0	10 355
Translation differences	-460	-248	-34
Net change in cash and cash equivalents	-22 797	20 196	22 182
Cash and cash equivalents at end of period	34 187	54 998	56 984

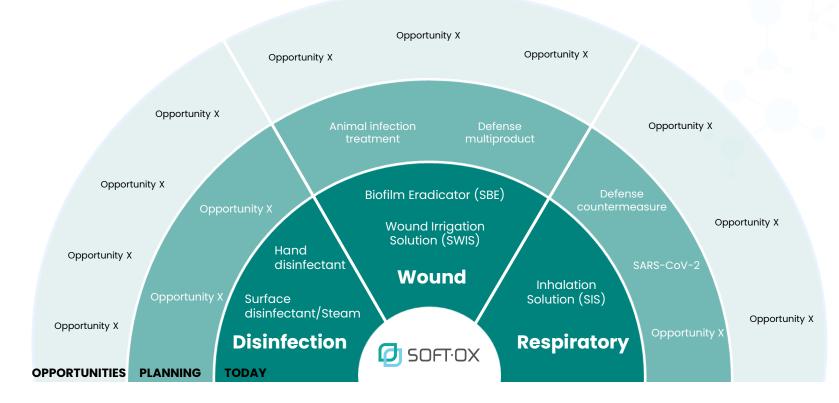
## Net change in cash and cash equivalents

 Strong focus on the product development and commercialisation processes while managing cash situation carefully





# Multiple opportunities for development of products based on SoftOx technology



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

22 | 1<sup>st</sup> quarter results 2022



## **Expected news flow 2022**

#### SoftOx Wound Irrigation Solution (SWIS)

- Talks with major distributors
- GMP production line
- Establishing a QMS for medical devices
- Achieve a 510K clearance for the US market

#### SoftOx Biofilm Eradicator (SBE)

- Complete patient enrolment of the SBE-01a single dose study
- Proceed to the multiple dose study (SBE-01b)
- Initiation of phase 2

#### SoftOx Inhalation Solution (SIS)

- Complete data analyses and study report (SIS-01)
- Initiation of phase 2
- Financial partner

#### 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



Well known & well tolerated by human body

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#### Strong platform

with great potential for many products/segments,



58 granted patents

Strong patent family protecting IP





#### Collaboration

with world-leading scientists



## Huge unmet medical need

and no antimicrobial resistance

# **SOFT**OX

New ways of eradicating infections and fighting antimicrobial resistance

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