

### Eradicating infections and fighting antimicrobial resistance

Investor Presentation December 2021



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# **Today's presenters**







## Our purpose

### MISSION

Helping the world fighting infections

- Viruses
- Biofilm Resistance
- Antimicrobial Resistance

### VISION

To become a **world-leading developer** 

of antimicrobial technology



# **Investment highlights**



Proven technology that effectively eradicates bacteria and viruses without creating resistance and answers significant unmet needs



Market approval of winning the Norwegian and Swedish public hospital tenders and free to enter the market through The EU Commission's interpretation of the BPR<sup>1</sup>



Experienced research and development team, with support from Bispebjerg Hospital and University of Copenhagen



84 filed patents worldwide and 58 granted patents addressing formulations, uses, methods and devices



Strong medical technology platform developed over 10+ years with numerous opportunities for future development products



# Reinforcing nature's own ability to eradicate unwanted microbes



### Clinical results show significant effect

# Key achievements in the last 12 months

Disinfection	<ul> <li>Established Proof of Sales by winning Norwegian and Swedish public hospital tenders</li> <li>Granted market entry through The EU Commission's interpretation of the BPR<sup>1</sup></li> <li>Secured production capacity at a competitive price with agreement to purchase 50% of Ose Water</li> </ul>
Wounds	<ul> <li>Finalized base technology showing both significant improvement in wound healing and reduction in bacterial burden compared to today's market leader</li> <li>Achieved DKMA approval and started max dose study for infections in chronic wounds and enrolled first patient in the study</li> </ul>
Respiratory	<ul> <li>Finalized preclinical study</li> <li>Achieved DKMA approval to start Phase I clinical trials for inhalation solution and enrolled first patient in the study</li> </ul>
New Cooperations	<ul> <li>Entered a 3-year research collaboration with FFI to adapt the SoftOx technology and products for military purposes</li> <li>Established a pan-European consortium for development of SIS for military purposes</li> <li>Guaranteed NOK 10.6 million in support from The Ministry of Defence over 3 years</li> </ul>



# **Team in brief**

#### **Leadership Team**

Executive management team with a wealth of experience in business development, finance and medical strategy

### Scientific & Research Team

Highly skilled scientific team with 9 PhDs and 3 world-leading professors & researchers on board

### **Commercialization Team**

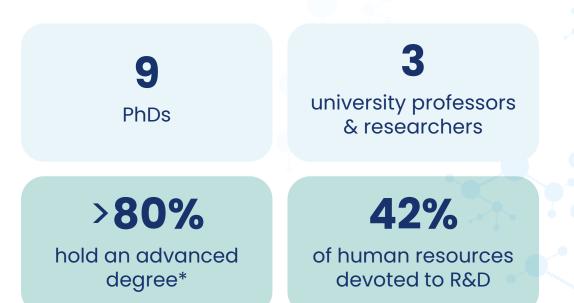
Well experienced and successful team with connections in the MedTech, healthcare, B2B and consumer market segments

### **Board of Directors**

Diverse board with expertise in finance, legal affairs, medical development and brand value

### **Advisory Board**

Advisory board with expertise in chemistry, industrial intellectual property rights, wound healing and bacterial biofilm



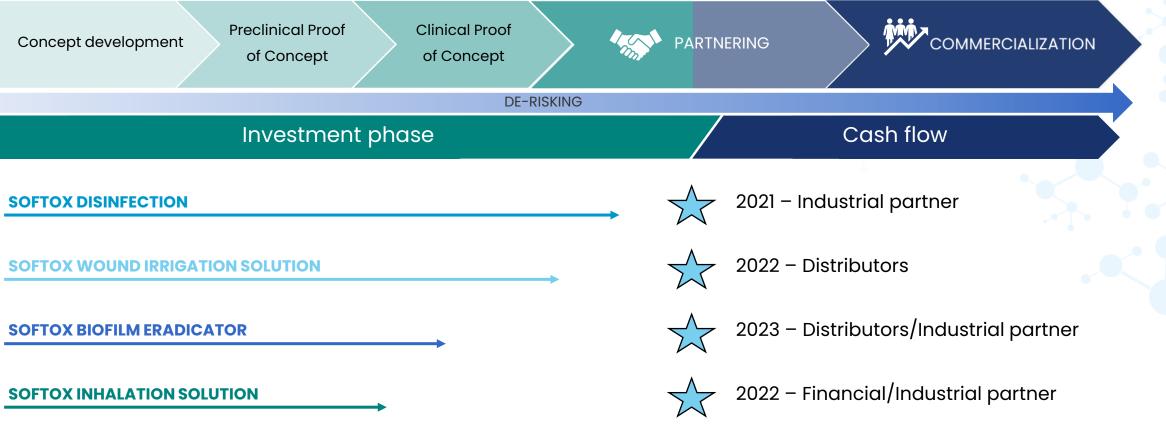


Time for entering commercial talks

# **Planned pathway to market**

# SOFT-OX

# PARTNERS





# **Business segments**



# Disinfection

Infection prevention solutions for hands and surfaces



# Wounds

Infection prevention and treatment for acute and chronic wounds

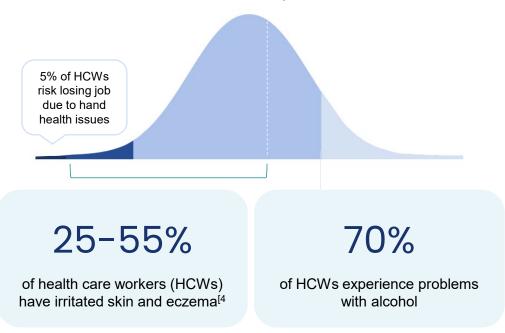


Infection treatment for viral infections

## Health care workers demand new solutions



Distribution of hand eczema among 59 million health care workers worldwide<sup>1</sup> (31 million in Europe and US<sup>2,3</sup>)



«Provide **alternative hand hygiene products for HCWs** with confirmed allergies or adverse reactions to standard products used in the health-care setting»<sup>[4</sup>

Expert panel (Kaiser Permanente, Mayo Clinic, NICE) <u>acknowledged a great need for</u> <u>more skin friendly solutions</u> and recommends SoftOx as a strategy for replacing Alcohol-Based Hand Rub

Established a separate class for alcohol-free hand disinfectant.

SoftOx won the tender based on top scores due to excellent quality and competitive price.

### SoftOx delivers Proof of Sales

Investor presentation

World Health Organization – The World Health Report 2006 (2006)
 Eurostat - Majority of Health Jobs Held by Women (2020)
 Kaiser Family Foundation – Total Health Care Employment (2020)
 World Health Organization – Guidelines on Hand Hygiene in Health Care (2009)



# **Unique market opportunities**



### **Main Benefits**

### **Skin Friendly**

Avoid skin irritation and eczema

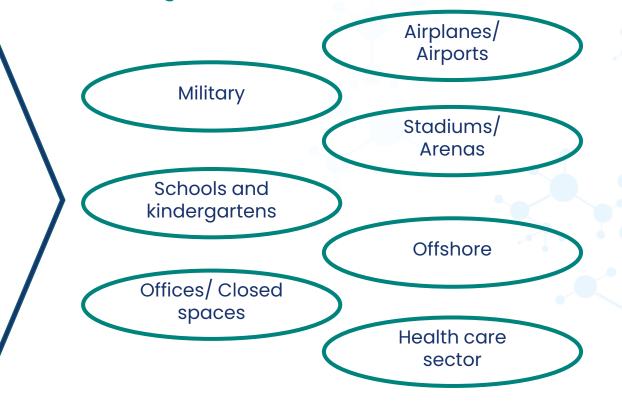
### Effective

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

### Safe usage in critical areas



SoftOx's skin friendliness, effectiveness and safety provide opportunities for cross-selling



# Commercialization (EU and RoW) Market opportunity – compromised skin

### **Potential customer share:**

Unique value proposition towards 20% of the market<sup>1</sup>

**Estimated global number of HCWs with compromised skin:** 12 million health care workers (6 million in the US and Europe)

**Gross profit margin:** 80-90% (achieved in Norwegian hospital tender)

### Customer savings:

\$1,080 per HCW<sup>2</sup>

\$265 estimated yearly price per health care worker based on price achieved in market<sup>3</sup>

### Actively seeking international partners



Investor presentation

1. Conservative estimate of HCWs with irritant contact dermatitis

2. 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" (2019)

3. Based on SoftOx's numbers and approved tenders



# Planned commercialization activities (US)



2021	2022	2023-24	
<b>Proof of Sales</b> from Norwegian and Swedish Hospital Tenders	Supplement clinical documentation for FDA approval	Enter the US market as a drug with medical claims	
Ongoing application process with request from FDA for further clinical documentation in order to assess classification as drug	Start talks for establishing partnerships for commercialization	added to our disinfectant products	

Competitive position as new molecular entity & exclusivity with medical claims



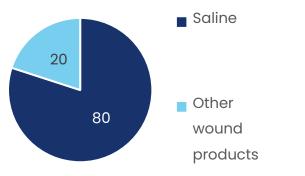
# Unmet need in wound care

### ACUTE WOUNDS

180 million

Individuals have skin wounds worldwide each year<sup>1</sup>

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



CHRONIC WOUNDS

40 million

Chronic wounds worldwide<sup>1</sup>

1-2%

of population are projected to have a chronic wound in developed countries<sup>2</sup>

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

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

Investor presentation

1. MedMarket Diligence - Wound prevalence and wound management (2011) 2. Sen, C.K. et al. -Human Skin Wounds, Wound Repair Regen, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2810192/ (2009)





# Wound care product plan

Project	<b>Regulatory class</b>	Planned entry into commercial partnership talks	Partner type	Expected first delivery to partner
<b>SWIS – Acute wounds</b> Wound rinse product	US: 510(k) EU: MDR cl. III	2022	Distributors/ Industry	2023
<b>SBE – Chronic wounds</b> Infection remover claim	US: Drug EU: Drug	2023	Distributors/ Industry	2025

### US

FDA approval – 510(k) Premarket Notification

- Classification as a medical device
- No auxiliary medical claim

### Europe

**CE-mark Class III** 

- Main claim: mechanically wound rinse
- Auxiliary claim: antimicrobial effect

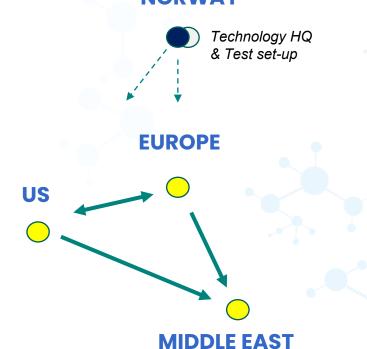
**Commercial strategies – medical devices** 

### **Our aims:**

- partnering with industry players or major distributors
- offering a branded portfolio for proof-of-sales via distributors, to stay cash-flow independent from fluctuations in industry interest (dual strategy)
- targeting the best commercial opportunities for wound care: US, Europe and Middle East
- relying on industry or distributors for **Mass Marketing**
- utilizing external production unit for Mass **Production** ramp-up

Actively seeking distributors for sales in early 2023



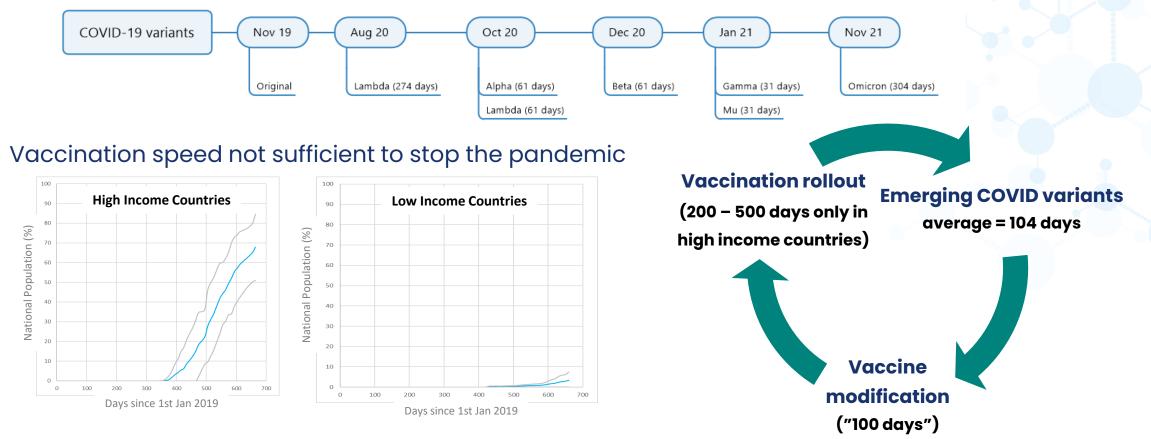










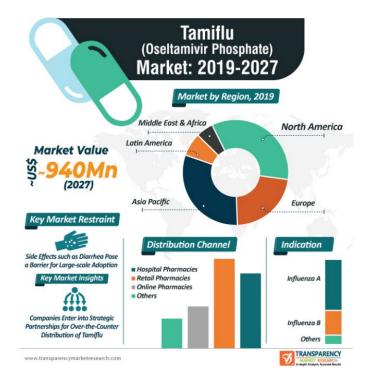


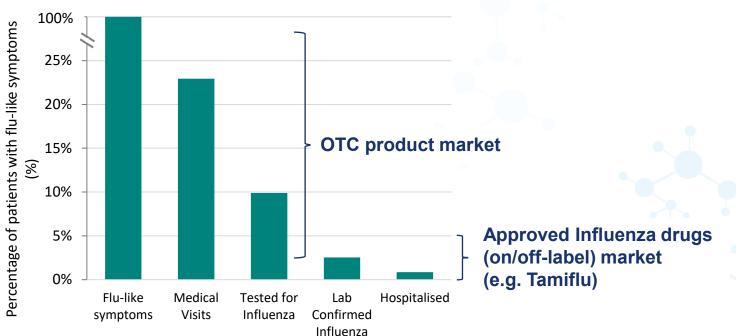
Vaccine development and roll out cannot keep up with the emergence of new COVID-19 variants, ultimately leading to failure to gain control of this pandemic



# SIS targets the OTC product market







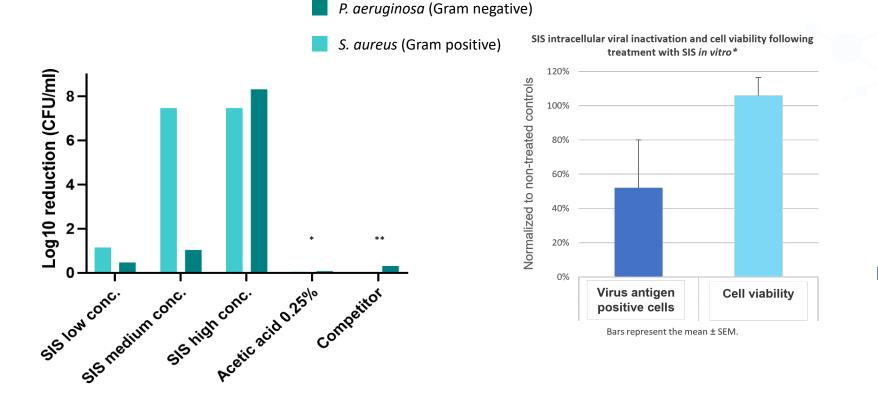
Influenza Waterfall Chart

a. Lancet Respir Med 2021; 9: 251–59. b. Infection (2021) 49:149–152; c. ec.europa.eu/Eurostat; d. statens serum institute: <u>Annual reports on disease incidence</u> - Influenza season 2018-2019; e. CDC; f. World Bank

### Tamiflu targets only 3% of the market and has a market value of USD 940 million<sup>1</sup>



# Cheap, effective antiviral treatment is necessary to break the cycle



Handheld solutions will aim to be made available for self medication at an early stage

Demonstrates effective virucidal activity in vitro and is currently in Phase 1 clinical development



Respiratory

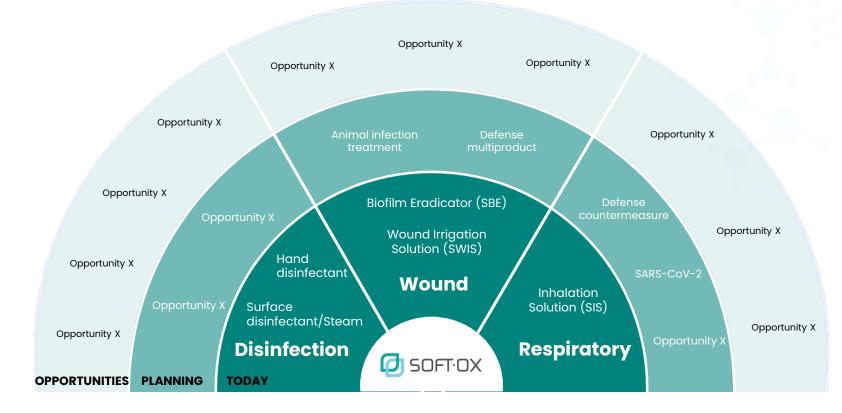


# News flow – value drivers and targeted milestones

	2021	1H 2022	2H 2022	1H 2023/2H 2023
Disinfection (EU & ROW)	Won Norwegian and Swedish hospital tenders	<ul> <li>Partner discussions Hand disinfectant EU and ROW</li> </ul>	Start sale in major EU markets	<ul> <li>Start sale in major ROW markets</li> </ul>
Disinfection (US)	Response from FDA on classification as drug	Partner discussions     Hand disinfectant US	<ul> <li>Preclinical work Hand Disinfectant US</li> </ul>	Initiation of clinical program for Hand disinfectant US
Wound Irrigation Solution	SWIS-02 showed superior improvement in wound healing and confirmed SoftOx's base technology	<ul> <li>Apply for US and EU approval</li> <li>Start talks with major distributors</li> </ul>	Establish GMP production line	<ul> <li>Start sale in the US market and achieve EU approval</li> </ul>
Infection Remover	Phase Ia initiation with first patient enrolment	• Finish phase 1	<ul> <li>Initiation of first patient in phase 2</li> </ul>	<ul> <li>Initiation of phase 3</li> <li>Start commercial talks</li> </ul>
Inhalation Solution	Phase Ia initiation with first patient enrolment	<ul> <li>Finish phase 1</li> <li>Financial partner</li> </ul>	<ul> <li>Initiation of first patient in phase 2</li> </ul>	<ul> <li>Initiation of phase 3</li> <li>Start commercial talks</li> </ul>



# Multiple opportunities for development of products based on SoftOx technology



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



# Key takeaways



# **SOFT**OX

Unique and highly efficient solution for eradicating infections and fighting antimicrobial resistance

### Contact Information: ir@soft-ox.com







Kristine Mundal Rød Chief Financial Officer



# **Board of directors & scientific advisory board**

#### **Board of Directors**



**Melvin Teigen** Chairman

- Listing Department Leader, Oslo Stock Exchange Investment banking &
- asset management industry MSc economics (BI)



**Olav Jarlsby** Non-Executive Director

- General Counsel & Attorney-at-law, Elopak AS
- LL.M. law (UiO)

#### Scientific Advisory Board



#### **Dr Pål Rongved** Professor, UiO

- Professor at School of Pharmacy, UiO
- Senior Consultant in Board of Appeal Industrial Intellectual Property Rights (KFIR)
- Cand.scient. organic chemistry, PhD medicinal chemistry (UiO)



#### Dr Kari Myren **Non-Executive Director**

- 10+ years in biotech & pharma industries
- Specialist in medical affairs management and drug development Cand.med. (UiO)

#### Claus Seeberg **Non-Executive Director**

- 20+ years in communication and building consumer brands
- Specialist in managing business processes and brand value strategies
- Marketing (GWU & Fagskolen Kristiania)



#### Dr Klaus Kirketerp-Møller **Principal Investigator**

- Co-inventor of the SoftOx technology with financial rights and company consultant
- Since 2007, research focus on chronic wounds and bacterial biofilms
- Medical Doctor, PhD at Copenhagen Wound Healing Center, Bispebjerg Hospital Denmark





# **Management and financial team**

#### Organization leadership



#### Geir H. Almås Chief Executive Officer & Founder

- Extensive experience from business development in Norway and Poland
- Previously PwC and KLP Asset
   Management
- MSc in business administration (BI) and Chartered Accountant (NHH)



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#### Kristine Mundal Rød Chief Financial Officer

- 14+ years of experience in financial and non-financial reporting, auditing, forecasting, and strategy
- Previously EY and Fretex Miljø/ Salvation Army
- State Authorized Public Accountant and Master of business administration in economics (NHH)



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#### Trine Hasselknipe Olsby HR & Office Manager

- 14+ years of experience with personnel management, recruitment, labor law, and HMS
- Previous experience from legal and financial sectors
- Bachelor in HR management and Master Program in Norwegian labor law (BI)



#### Ingrid Juven Project Manager

- 25+ years of consulting and management expertise within a variety of industries
- Previously Director at EY and Partner at Frost Nordic
- MBA in management and marketing (BI)



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#### Hans Jørgen Holum CEO SoftOx Denmark

- Responsible for development of veterinary products and biocidal regulatory affairs
- 25+ years of experience with sales, management, and business development in various industries
- MSc economics/ Cand.merc
   (Copenhagen Business School)



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#### Rune Jomaas CEO SoftOx Defense Solutions

- 30+ years of experience as head of different military and civilian organizations
- Previous experience of 9 years as strategic advisor and served as director in the Ministry of Defence
- MA in defence studies from King's College London University, Master in management (BI)

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# **CMC, quality & commercialization teams**

### Chemistry, Manufacturing and Controls (CMC) and Quality Management



#### **Hanne Grøgaard CMC** Scientist

- Broad startup experience and strong network within pharmaceutical, supplement, cosmetics and life science startup industries
- Specialties in analytical chemistry and health-related topics
- MSc in biotechnology(NTNU)



#### Kent Ghose **Quality Manager**

- Nearly 20 years' experience in GMP regulatory affairs within pharmaceutical drug production
- Previously Quality Manager at Diatec Monoclonals AS and Owner and CEO at LabSupport
- Engineering degree in chemistry (Oslo Engineering University College)



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#### Elisabeth A. Ohlsen **QA & Regulatory Affairs Manager**

- Several years of experience working in the pharmaceutical industry and healthcare sector
- Expertise of how to operate a Quality Management System, Good Manufacturing Practice and regulatory standards
- Civil Engineer in pharmaceutical design and engineering (Technical University of Denmark)

### Commercialization



#### **Annette Hjulstad** Sales Manager - Health Care Sector

- Certified nurse and sales representative both in the Pharma and MedTech industries
- 15+ years experience as Key Account Manager in a leading pharmaceutical company and expertise in wound care and infection control project sales
- Bachelor in nursing (Hedmark University College)



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#### Dag Abrahamsen **Communication Director**

- 20+ years' experience working with Pharma-, Bio Tech- and health sectorrelated companies and organizations
- Specialist in Market Access, **Reimbursement and Business** Development within this industry
- Law studies (University of Bergen), as • well as international business management and international business strategy (Norwegian Business School)



#### **Finn Ketler Chief Sales Officer**

- 20+ years' experience in Medtech, former SVP at Coloplast (DK, DE), CEO at Vigmed AB (SE), VP at Biotech Pharmacon (NO) and Selection Committee Member at BII, a Novo Nordisk Foundation initiative
- Managing Partner and Founder of Coopmed where mission is to ensure more MedTech innovations reach market and help patients by supporting startups commercializing innovations

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# Scientific and research team

#### Science and Medical Research



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Dr Glenn Gundersen Chief Medical Officer

- 25+ years of experience from the pharmaceutical industry with focus on immunology/ inflammation and oncology
- Previously Bristol-Myers Squibb Norway, Biotec Pharmacon, Biogen Norway
- PhD in molecular and cellular biology (UiO)



 More than 8 years of experience in pharma and health sector related companies

> MSc in medical biotechnology (Technical University of Berlin); PhD in molecular biology (UiO)



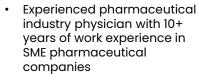
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#### Aina Kristin Pham Industrial PhD Candidate

- Formulation scientist and industrial PhD researcher
- Experience from the pharmaceutical field, previously working at the Norwegian Medicines Agency and as a pharmacist for Apotek1 Gruppen AS
- Master of pharmacy (UiO)

### SIS Project Leads

#### Dr Christopher Burton Chief Medical Officer - SIS



- Previously Sr Clinical Director at Savara Pharmaceuticals and Sr Medical Advisor at Novo Nordisk
- MA in medicine (Cambridge University); PhD (Copenhagen University)

### SBE Project Leads



#### Dr Magnus M. Fazli Director of Science & Research

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- 15 years of experience in biofilm research
- Specializing in chronic wound biofilms, biofilm formation, and antibiotic resistance
- PhD in medical microbiology (University of Copenhagen); MSc in bio-business and innovation (Copenhagen Business School)



#### Dr Edwin den Braber SBE Project Manager

- 20 years' experience as Medical Director (regional and global) and VP of R&D, Clinical Affairs, Medical Affairs, Regulatory Affairs, QA and Compliance.
- Broad experience within pharmaceutical, medical devices, combination products and ATMPs
- Clinical Toxicologist
- Doctorate in medicine (Radboud University and Clemson University)





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#### Dr Thomas Bjarnsholt Chief Scientific Officer

- Expert in the role of bacterial and fungal biofilms in chronic infections with over 135 peer reviewed publications
- Co-inventor of the technology
   with financial rights
- Member of the Global Wound Biofilm Expert Panel
- Professor at the Costerton Biofilm Center, Department of Immunology and Microbiology (University of Copenhagen)