

Preventing and treating chronic infections



SoftOx Solutions AS A Norwegian MedTech Company listed on Merkur, OSE

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The materialization of any of the risk factors listed below or other risk factors could have a material adverse effect on the Company's business, operating results or financial condition

- SoftOx's business is difficult to evaluate because the Company has a limited history and has generated limited sales revenue/profit since its incorporation. Its past performance does not necessarily give a basis for its likely future results.
- SoftOx's success for the foreseeable future is highly dependent upon the commercialization of its product candidates. No assurance can be given as to whether or when these will be successfully developed or commercialized or will generate revenues or whether the Company will be able to develop additional product candidates
- In the event the product candidates are commercialized, SoftOx is dependent on developing relationships with business partners, distributors and key customers or licensees, including attaining sufficient market acceptance of its product candidates among physicians, patients, healthcare payers or the medical community.
- SoftOx's results of operations may be adversely affected by changes in the pricing environment and/or regulations for medical products
- SoftOx is dependent on its key personnel and employees and its ability to recruit skilled personnel for future operations
- Product development may not deliver expected results and may not be indicative of results in later stage trials, or may not result in the Company's pursuit of further clinical trials
- Any failure or delay in completing clinical trials for any of the Company's product candidates may prevent SoftOx from obtaining regulatory approval or commercializing product candidates on a timely basis, or at all, which would require the Company to incur additional costs which may in turn delay receipt of any product revenue
- SoftOx may need to change the clinical programme to meet various health authorities' requirements, as well as to adapt to results from on-going clinical trials and other product improvement metrics. Such change is likely to influence the overall capital requirement and revenue flow of the Company, including the costs and time required to complete the clinical programme
- SoftOx may become subject to burdensome government regulations affecting the industry, which could directly affect the Company's products and product development, which will in turn affect the Company's overall capital requirement, revenue flows and time to commercialization.
- SoftOx may not obtain required marketing authorization from health authorities (domestic og multi-national (EU, etc.) for its products, which is required in order to enter the commercial phase.





- SoftOx may face competition from new as well as from known competing products. If the Company is unable to compete effectively, in terms of its products or prices, it may have to alter the design of its clinical programmes, its overall costs may increase and the Company may be unable to successfully commercialize its products or achieve the expected margins.
- The Company could become subject to liability claims in connection with clinical trials or otherwise in connection with the use or misuse of the Company's products after commercialization
- SoftOx expects to continue to incur substantial expenses related to further research and development of its product candidates, personnel costs, commercializing, support of patent rights, as well
 as administrative functions. It is expected that the currently available funds will not be sufficient to meet the Company's needs or unexpected factors could arise that could increase the Company's
 need for capital, and the Company expects that it will need to seek additional funding bay way of debt or equity capital. The Company may not be able to obtain the required funding or may not be
 able to do so at acceptable cost. A future equity raising will dilute the ownership interest of existing shareholders.
- As of today, SoftOx has several projects that are partially funded by public grants. There is no assurance that SoftOx will continue to have grant applications approved in the future, on the same terms or at all.
- SoftOx's markets are undergoing rapid technological change, and the Company's future success will depend on its ability to meet the changing needs of the industry
- · SoftOx faces risks inherent to international expansion and operating in multiple jurisdictions
- SoftOx is dependent on its intellectual property rights and the Company's methods of protecting its intellectual property rights may not be adequate
- · SoftOx faces risks of claims for intellectual property rights infringement from third parties
- SoftOx depends in large part on its ability to protects its exiting patents and to obtain new patents, maintain trade secret protection, protect its trademarks and operate without infringing on the proprietary rights of third parties. Third parties may have filed patent applications, or hold issues patents, relating to products or processes competitive with those that have been developed by the Company, and this may impair the Company's ability to do business in a particular area. There can be no assurance that the Company sill provide the Company will develop additional products that are patentable, that any patents issued by to the Company will provide the Company will develop additional products that are patentable, that any patents incorporating the Company's methods, or that existing or former employees, consultants or partners of the Company will not allege that they have rights to the Company's intellectual property. Furthermore, there can be no assurance that other companies will not independently develop similar products, duplicate or reverse engineer any of the Company's products or, if patents are issued to the Company, design around the Company's patents. Filed patents that are not granted may cause the development program can be terminated because of lack of market protection
- In the ordinary course of business, SoftOx is subject to credit risk in its contractual relationships with various parties
- SoftOx may not be able to earn the planned revenue or to raise sufficient working capital to fund its operations until its business generates positive cash flow
- SoftOx may face challenges in production of the products which may delay timelines, increase costs or stop the development of the product(s)





SoftOx has discovered a unique combination of natural chemicals proven to have superior antimicrobial effect compared to today's solutions*

- First clinical trial in humans completed successfully
- Secured distribution agreements for hand disinfection (Kiiltoclean/Antibac) and animal health (VESO)
- Cooperation with globally leading universities, and research teams
- Intends to raise NOK 40-75m in equity to finance studies and corporate development

Removing infections – critical for wound healing

*Company information; Filter grown Pseudomonas aeruginosa and Staphylococcus aureus embedded in biofilm



Company background

• Extensive experience from animal husbandry in the European agricultural sphere

• Key observations:

Background

Research

1

2

- » 20% of cows suffer from chronic bacterial infections¹
- » Antibiotic treatments are mostly ineffective in biofilm infections and cause bacterial resistance
- » Hypochlorous acid is also used, but is generally unstable and with limited effect
- Hypochlorous and acetic acid have long histories of use as antiseptics²
- In collaboration with leading researchers in Lund, SoftOx started its research in 2008
- The concept was further developed in 2016, supported by world leading professors at the Copenhagen University
- By combining hypochlorous acid with acetic acid, SoftOx has created a best-in-class non-toxic and clinically proven topical antiseptic

3) Patents

- Intellectual property is protected by a large and strong patent family; first patent granted in 2012
- 20 patent filings; Important patents like composition method and product, NPWT acetic acid and sodium diacetate are granted, others like the biofilm removal still pending.

https://albertamilk.com/ask-dairy-farmer/percentage-cows-suffer-mastitis/
 Kramer A. Consensus on Wound Antisepsis. Skin Pharmacol Physiol 2018;31:28–58 Update 2018



Key personnel



Geir H. Almås, CPA – Chief Executive Officer & Founder

- Extensive experience from business development
- Previously PwC and KLP Asset Management
- MSc Business Administration (BI) and Chartered Accountant (NHH)



Glenn Gundersen, PhD – Director Medical Affairs

- Over 25 years of experience from the pharmaceutical industry, immunology/inflammation and oncology
- Previously Bristol-Myers Squibb Norway, Biotec Pharmacon, Biogen Norway, Roche
- PhD Molecular and Cellular Biology (University of Oslo)



Magnus M. Fazli, PhD – Head of Research

- More than ten years of experience in biofilm research
- Specializing in chronic wound biofilms, biofilm formation and antibiotic tolerance
- PhD Medical Microbiology (University of Copenhagen), and MSc Bio-entrepreneurship (Copenhagen Business School)



Hans Petter Grette – Sales and Marketing Director

- 20 years marketing and executive management background from Lilleborg (Orkla)
- MSc Business Administration (BI) and AGSIM International Management (Arizona, U.S.)



Hans Jørgen Holum - CEO SoftOx Denmark & Head of Animal Health

- Over 20 years' experience with international sales and management positions
- MSc in Business Administration from Copenhagen Business School

Advisory Board

Thomas Bjarnsholt, PhD

- Professor of bacterial and fungal biofilms in chronic infections,
- Ranked as the world leading scientist on biofilms
- · Co-inventor of the technology with financial rights, see Patent and IP
- Works for the company as a consultant
- Member of the Global Wound Biofilm expert panel

Klaus Kirketerp-Møller, MD

- · Since 2007, mainly focused on research on chronic wounds and bacterial biofilms
- · Co-inventor of the technology with financial rights, see Patent and IP
- Works for the company as a consultant
- MD at Copenhagen University and specialist in orthopedic surgery, and chair of Nordic Diabetic Foot Task Force

Pål Rongved, PhD,

- Professor Pharmaceutical institute, University of Oslo
- Member of The Norwegian Board of Appeals for Industrial Property Rights
- Works as consultant for the company









Strong international support from key opinion leaders and institutions





Antimicrobial resistance

The ability of bacteria and other microorganisms to resist the effects of an antibiotic/antiseptic to which they were once sensitive

Biofilm resistance

Aggregated bacteria often covered by slime (biofilm matrix), acting as a fortress and protect bacteria from attacks such as antibiotic treatment and the immune system



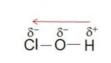
SoftOx reinforces nature's ability to fight antimicrobial resistance (AMR)



A unique combination

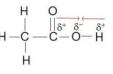
Hypochlorous acid

- The body's natural antimicrobial agent
- Widely used but inherently unstable
- Instantaneous microbial killing effect
- Superior safety profile in efficient concentrations
- Moderate antiseptic effect alone
- Well tolerated, e.g. drinking water



Acetic acid

- Long history of use as an antiseptic
- Potentially effective deep within the wound bed
- Good stability
- Retains antimicrobial activity despite contact with organic material (e.g. blood, tissue)
- Widely used as food additive
- Moderate antiseptic effect alone



The SoftOx Technology – the combination effect

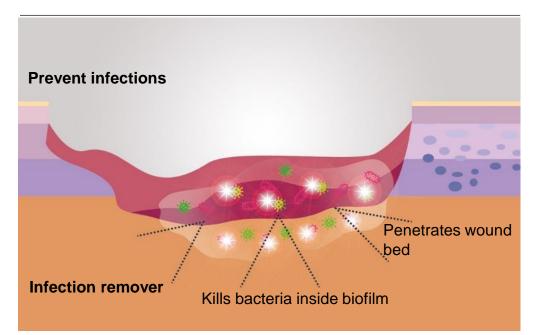
- The combination works synergistically, and shows superior effect on microbes
- Does not induce resistance in bacteria. Effective in antibiotic-resistant bacteria (e.g. MRSA)
- Can be customized for specific purposes;
 - » Higher concentration of acetic acid increases the formula's antimicrobial potency (biofilm eradication)
 - » Lower concentration of acetic acid yields a softer sting when applied to wounds (disinfectant, wound irrigation)
- Effectively stabilizes hypochlorous acid





SoftOx works both on wound surface and beneath wound bed

The SoftOx Wound Model



Success criteria for removal of infections

- Penetrate and kill microbes within the biofilm
- Penetrate and eradicate biofilm also within the wound bed
- Not cause development of microbial resistance to the products
- Well tolerated

Removal of infections \rightarrow critical for wound healing



Pre-clinical experiments show promising effects

In vitro in the lab

9 8 7

6

5

4

3

2

Log10 reduction cfu/ml

- A safe disinfectant with a unique ability to remove hard-totreat microbes embedded in biofilm
- Appears to be significantly more effective than competitors against *P. aeruginosa* and *S. aureus*, the most common bacteria in chronic wounds
- Did not induce resistance or cross-resistance development towards antibiotics

Effectiveness on Pseudomonas aeruginosa¹

1ºlo HAC

tration

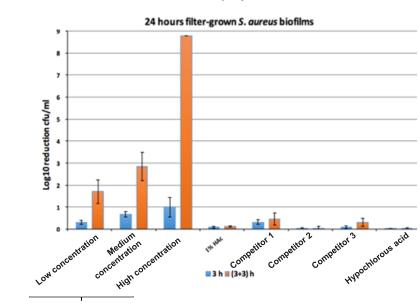
tration

48 hours filter-grown P. aeruginosa biofilms; (3+3) hours treatment

Animal models

- ✓ No negative influence on wound healing
- Well-tolerated in full-depth wounds
- Significant bacterial reduction in wounds

Effectiveness on Staphylococcus aureus¹



1) Company information

SoftOx

Effect

on

bacteria

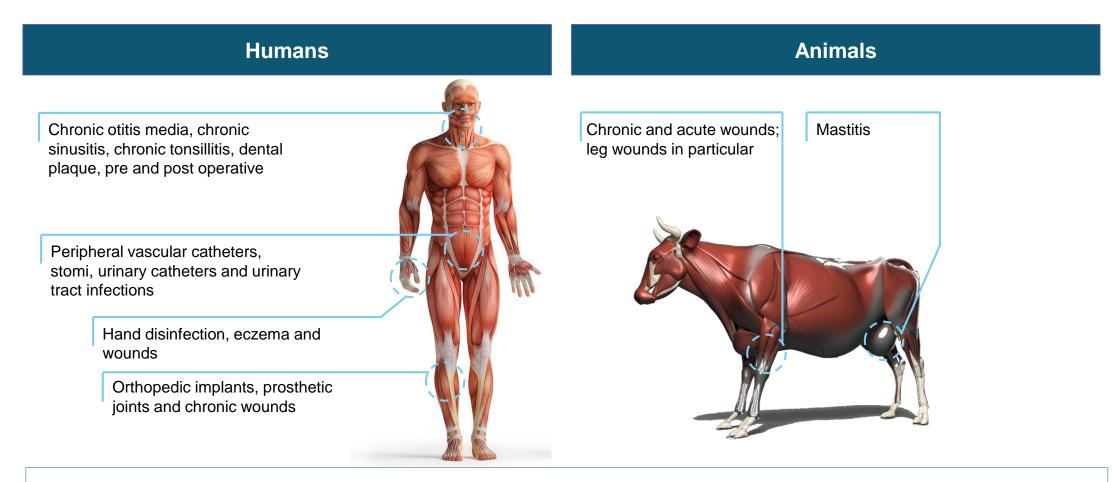
in

biofilms

SoftOx



Multiple areas of use – current focus on hands and wounds



SoftOx is effective against bacteria (also in biofilms), virus, fungus and spores



Conducted preclinical and clinical studies

Study	Objectives	Results	Cost (NOK)	Completed
Laboratory in vitro	Costerton Biofilm Center: Multiple experiments on surface biofilms to define optimal concentrations of SOX. Comparison with competitors.	Superior antimicrobial effect documented for a range of concentrations (HOAc: 0.25%-4%, HOCI: 100-1000ppm). Tests showed significantly better killing than all competitors. <i>Pseudomonas aeruginosa</i> seems more sensitive than <i>Staph aureus</i> .	2m	2018
Animal (Horses) Wound healing, infected wounds	Dept Veterinary Clinical Sciences, Univ of Copenhagen: To test SOX in established biofilm-infected horse legs to explore wound scores/healing, antibacterial effects and safety.	SOX exerted no harmful effects and was well tolerated. Wound score improvement. Significantly reduction of <i>S.aureus</i> (day 12 and 20). Proves that SOX works in infected wounds <i>in vivo. (Proof of Concept)</i>	0.6m	Jul 2018
Animal (minipigs); wound healing	<i>CITOX Labs.</i> GLP study to demonstrate tolerability and toxicity of SOX on wound healing.	All SOX-formulations were documented to be well tolerated, i.e. did not impede wound healing.	0.8m	Aug 2018
Animal (minipigs); wound healing	<i>RTC (Italy):</i> Preliminary test of 4 SOX for toxicity (higher doses than before to approach MTD).	All four SOX formulations confirmed to be well tolerated, limited irritation in wound tissue. These results will be further exploited in the main study (Q2-2020).	0.4m	Sep 2019
Clinical study (SWIS-01) Pilot study (first in human) to explore SWIS safety and performance in human patients with Split Skin Graft Donor sites (acute wound model), n=12.		SWIS was confirmed to be safe and well tolerated. It also showed antimicrobial effects and good wound healing results. User and patient feedback was favorable. The pilot study will serve as an important source for optimal design of next study (SWIS-02). (<i>Proof of Concept in</i> <i>humans</i>)	10m	Sep 2019



Human pilot study on safety in 12 patients with acute wounds

Primary Objective

The primary objective of this clinical investigation is to document **safety** of the SoftOx Wound Irrigation Solution when used on split skin graft donor sites¹ in an adult population

Secondary Objectives

The secondary objectives are to document the SoftOx Wound Irrigation Solution capability to provide clean wounds for optimal reepithelization (including microbiological control), and subject/user satisfaction when used on split skin graft donor sites in an adult population

Results: No serious adverse events | Well tolerated | Bacterial reduction confirmed | Excellent wound healing



Study confirms safety and bacterial reduction



Clinical studies in progress/to be conducted

Study	Objectives	Cost (NOK)	Expected to be ready
Animal (minipigs); MAX dose; wound healing	RTC: Local tolerance, systemic effects and pathology in minipigs after repeated dosing (continuously for 28 days) with increasing SOX-strengths. Aiming to achieve maximal tolerable dose.	4m	Q2-3 2020
Biocide (SafeDes) Skin Tolerability	Clinical testing of SafeDes hand disinfectant on healthy and experimentally induced eczema with respect to skin barrier functions. Comparison with alcohol-based products.	1.5m	Q3-2020
Clinical Study Medical Device (SWIS-02)	Pivotal, confirmatory, comparative trial in subjects with superficial (blister) and full depth (biopsy) wounds to demonstrate safety and performance, with focus on wound healing. n = est. 40 (tbd).	10m	Late 2020 (if start in Q2-20)
Phase I / II drug study	To test drug candidates in relevant patient population (infected chronic wounds), dose escalation, safety and efficacy measures (i.e. proof of concept). n = test. 30 (tbd).	25m	TBD, 2021
Phase III drug	Confirmatory study in target population (chronic wounds). Preferentially together with a partner.	>50m	TBD



Product development plan

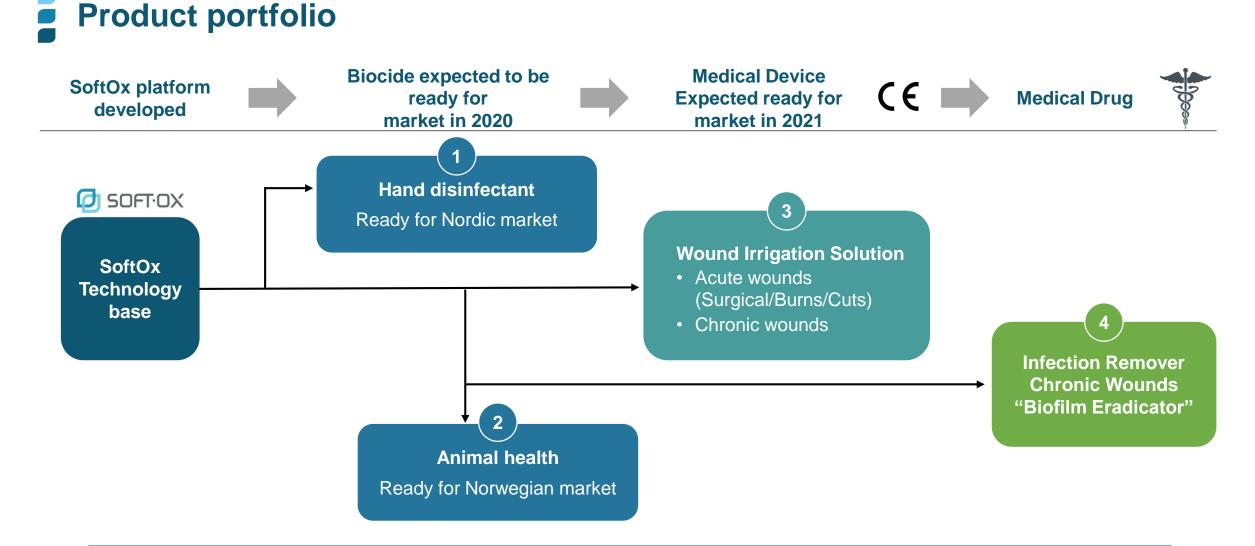
Hand Disinfection	In vitro/EN studies	Preclinical/EN studies	Application market approval	Market introduction Nordic region	Voluntary post market studies
SafeDes				1H2020	2020

2 Animals	In vitro/EN studies	Preclinical/EN studies	Pilot/PoC	Market introduction	Voluntary post market studies
Infection prevention				1H2020	N/A
Infection treatment			1H2020	2H2020	2H2020

	Device & Drug	In vitro/EN studies	Preclinical/EN studies	Pilot/PoC	Pivotal/phase 3	Market introduction
3	SWIS				2020	2021/2022
4	Infection treatment		1H2020	2020/2021	To be decided	To be decided







Product development plan based on the SoftOx platform



Go-to-market strategy: 1 Hand disinfection

Sales channels and target market

- Sales through distribution partners
 - Nordics/Baltics: Kiiltoclean (Antibac), market leader in the region (est. >50% market share)
 - Rest of Europe: In progress
- Premium product, aimed at healthcare workers
- 25-50%⁴ of healthcare workers (HCW) have skin problems on their hands
- Does not cause dry skin with same antimicrobial effect as alcohol
- Planned to be made available in pharmacies, sold directly to large clients and through consumer channels

Market size

- N

18.8 million HCWs in the EU and the US^{1,2} Whereof 13.3 million have irritated skin and eczema¹

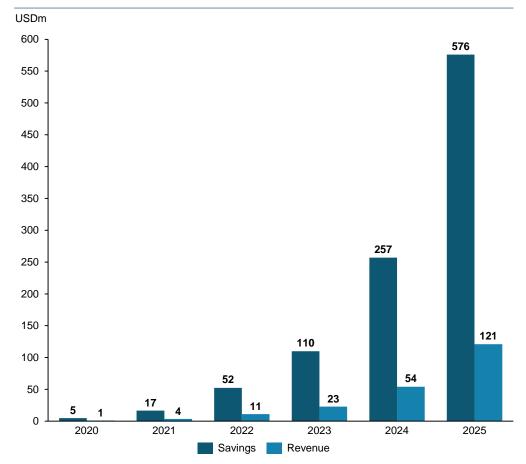


USD 1,080³ Value of effective prevention of hand eczema per HCW

19

USD 20.2 bn³ Value of hand health market in Europe and the US

Healthcare savings and revenue scenario



Market share assumptions for each market entry: Y1 (1%), Y2 (2%), Y3 (3%), Y4 (5%), Y5 (7%)

1) ec.europa.eu/eurostat/Healthcare_personnel_statistics_-_nursing_and_caring_professionals 2015 & Presentation Prim. Univ.-prof Dr. Robert Strohal, Hospital Fledkirch

2) Center for Disease Control and Prevention (CDC) homepage https://www.cdc.gov/niosh/topics/healthcare/default.html

3) 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"

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



Go-to-market strategy: 2 Animal wound- and disinfection market

Sales channels and market entry

- First distribution agreement with VESO, a strong distributor to the Norwegian veterinary healthcare market
- Planned launch of first products in 2020
- Will seek strong strategic partnerships for entry in the rest of Europe and the US
- Large potential for future line extensions

Market size

1-1

Dairy cows: 23 million (EU) & 9.5 million (US) 20-35%¹ and 47-71%² reported prevalence of clinical mastitis across EU. Est. cost per case varies from USD 70-300³. Est. cost in EU as high as USD 1.2-2 bn



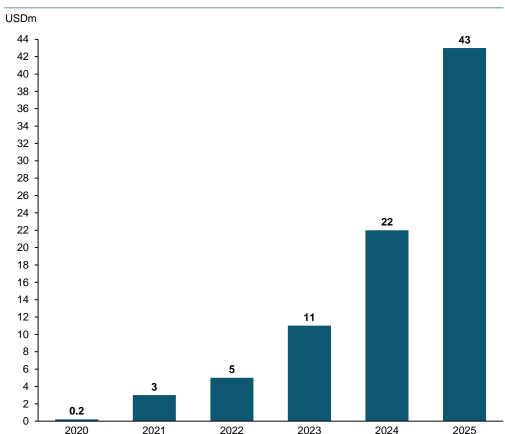
Cats and dogs: 160 million (EU) & 185 million (US) EU companion animal wound treatment market incl horses is est. at USD 221 million with a CAGR of 6.5%⁴



20

Horses: 6,4 million (EU) & 9 million (US) 6-9 times higher spending on horse wound treatment than on cats

6-9 times higher spending on horse wound treatment than on cats and dogs⁴



Animal care revenue scenario – gross market

1) https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2009.1143r

2) https://ec.europa.eu/eip/agriculture/en/content/mastitis-control-organic-dairy

https://www.independent.ie/business/farming/dairy/mastitis-cases-can-cost-up-to-300-per-cow-35338174.html

4) FIOR - Europe animal wound care market report 2019-2026



Go-to-market strategy 3 Medical device (SWIS) 4 Infection remover (drug)

Market access and sales strategy

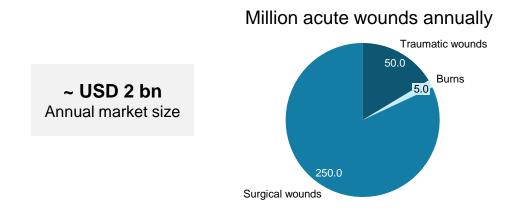
- To secure market access
 - Clinical development plan
 - Excite International
 - KOL University of Copenhagen
 - Reimbursement
 - Regulatory
 - Infection prevention medical device
 - Infection remover drug
- Partnering to secure total wound care solution and distribution

External health economy assessment report

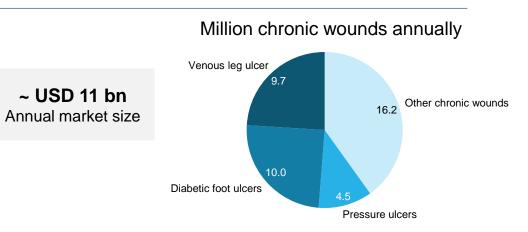
 Est. cost reduction by using SoftOx-technology on venous leg ulcers (VLU) and diabetic foot ulcers (DFU) below¹:

Treatment	Prevention
VLU – USD 4,969	VLU – USD 643
DFU – USD 2,030	DFU – USD 2,692

Infection prevention market size²



Infection remover market size³





"MedValue health economic decision modelling; Decreased time to ulcer healing and prevention of clinical infections in diabetic foot and venous leg ulcers"
 Wound Irrigation Solutions Market to 2027 - Global Analysis & Forecast by Product, End-user and Geography - ResearchAndMarkets.com
 Wound prevalence and wound management, 2012-2020, Med Market Dilligence, 2013

Existing products shall cover overheads and indirect costs

1)

Hand hygiene - Antibac

- Distribution agreement with Kiiltoclean the market leader in disinfection for healthcare industry
- Antibac-brand strong brand recognition
- Premium non-alcoholic antimicrobial hand disinfection
- Provides access to pharmacies and whole stores
- Targeted sales channels: online stores, direct sales to large corporates and non-medical chain stores
- > Expected market entry in 1H 2020.

2

Animal health - VESO

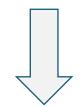
- Market leader on pharmaceutical products for animal and veterinarian industry in Norway
- Sale and distribution of SoftOx through VESO's platform incl. veterinarians, webshop and pharmacies
- Intentional agreement for future JV on further product development for aqua culture and farming industry
- > Expected market entry in 2H 2020.



Wounds - medical device & drug

- Clear plan to conduct further clinical trials to achieve classification as medical device and medical drug, such as toxicity tests and RCT-studies
- > Expected market entry in 2021 (US) as a medical device.

Revenue from sale of hand disinfectant and wound-solution for animals is intended to finance further clinical development



Clinical trials are intended to be conducted to achieve status as medical device and drug



Intended use of proceeds – cash positive on operations

	1	Enter the hand disinfectant market – NOK 10 mill
	2	Enter the animal health market – NOK 8 mill
SOFT-OX	3	Increase production capacity – NOK 2 mill
	4	 Infection remover – NOK 25 mill Conduct phase 1 and phase 2 trials (PoC) on infection remover wounds (medical drug)
	5	Finish clinical development SWIS – NOK 10 mill Conduct confirmative study (medical device)
	6	General corporate purposes – NOK 20 mill including repayment of NOK 3 in debt to shareholders and transaction fees



Key assumptions for market penetration – first two products*

Targets	2020	2021	2022	2023	2024	2025
		Hand	disinfection			
No. of users	3,500	14,000	37,000	75,000	180,000	360,000
Target market share	0.5%	2%	1.3%	1.2%	2.1%	4.2%
Markets	N, S, DK, IS	N, S, DK, IS	N, S, DK, G	N, S, DK, G, UK, F	N, S, DK, G, UK, F, I, SP	EU

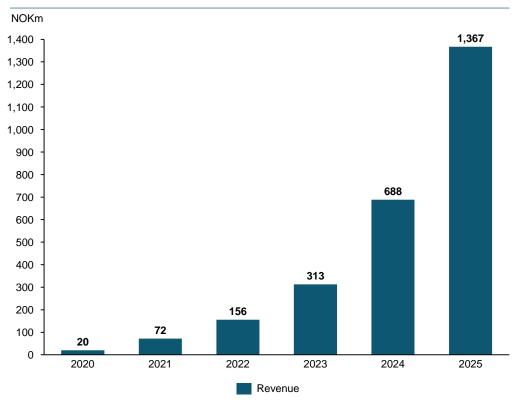
Animal						
Target market share	4%	0.6%	0.7%	3.1%	3.1%	6.2%
Markets	N, DK	Europe	US, Europe	US, Europe	US, Europe	US, Europe

Revenue target scenario

Revenue scenario based on following key assumptions

- First two years' budget income are independent of costs
- Profit sharing with pilot partners assumed initially, later 60/40
- Price estimated to be 10% of target costumers cost savings
- Market approval according to company's aspirations
- For hand disinfection, we target the 25% with the most severe hand eczema
- Revenue from acute and chronic wounds products not included in this scenario

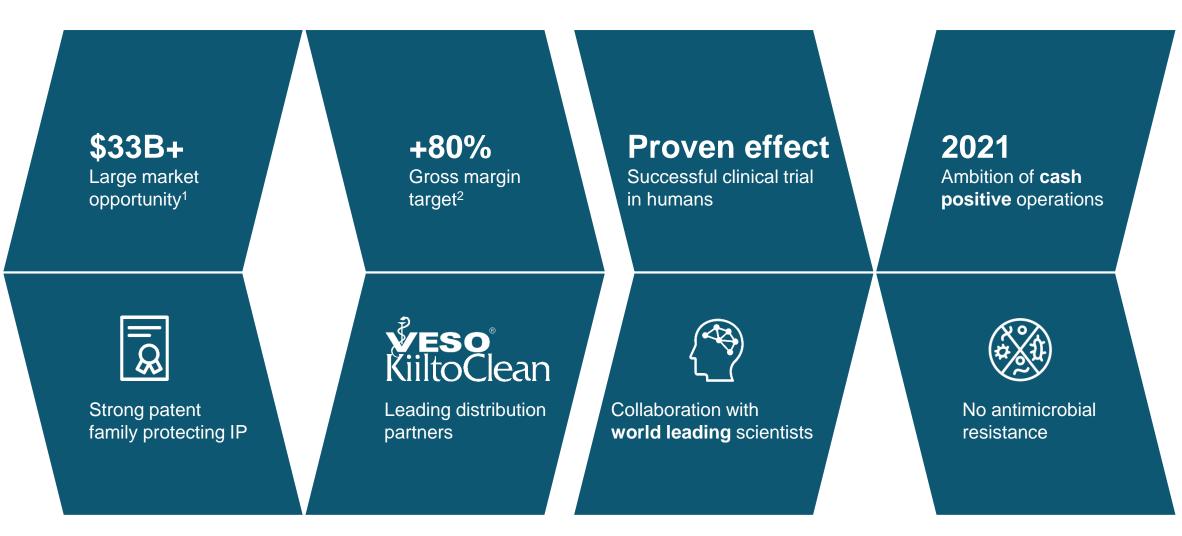
Preliminary sales projections

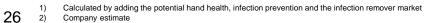


Potential for solid gross- and EBITDA margins



Investment proposition









Thank you for your attention!

Index and References

