

SpareBank 1 Markets acted as financial advisor to SoftOx Solutions in relation to the private placement of new shares conducted by the company in March 2024, and is acting as financial advisor to the company in relation to the subsequent offering of new shares which was announced in connection with the private placement.

#### SOFTX (COMMISSIONED RESEARCH)

### Promising antimicrobial technology - further advancement dependent on sufficient funding

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### **Investment highlights**

SpareBank 1 Markets acted as financial advisor to SoftOx Solutions in relation to the private placement of new shares conducted by the company in March 2024, and is acting as financial advisor to the company in relation to the subsequent offering of new shares which was announced in connection with the private placement.

SoftOx Inhalations Solutions aims to replace the use antibiotics with hypochlorous acid (HOCI) in the treatment of Ventilator-Associated Pneumonia (VAP). VAP is a respiratory infection that occurs during the intubation of patients by circumventing natural airway defenses, heightening the risk of bacterial infection. An estimated 130,000 patients in Europe and the US contract VAP yearly and there is currently no effective treatment on the market as resistant bacteria and biofilms limit the effect of antibiotics. SoftOx has managed to develop medical-grade stabilized HOCI that has showed strong antibiofilm activity against pathogens found in VAP. With proof-of-concept studies in animal respiratory infections the clinical success has a favorable probability. Phase 1 was completed in 2022 and proved the solution to be safe to inhale for humans. Phase 2 aims to demonstrate proof-of-concept in humans and could commence early 2025. However, the company requires funding of NOK50m to take the project through phase 2, and an additional NOK130m for phase 3. In Europe and the US, the estimated market size is NOK18bn. The company targets capturing a 10% market share within the initial 3 years of market approval, with additional growth opportunities stemming from high mortality rates and potential cost savings.

- There is currently limited effective treatments for VAP as antimicrobial resistance and biofilms limits the effects of antibiotics. Antimicrobial resistance is a global concern, causing 1.2 million deaths in 2019 and listed by WHO as one of the top 10 global health threats. Patients contract VAP during ventilator intubation as it circumvents natural airway defenses, heightening the risk of bacterial infection. VAP raises mortality rates in ICUs and, according to SoftOx, intubated patients face a 10-30% risk of developing VAP and increases mortality rates of up to 50%. Studies show that in Europe and the US there is an estimated 70,000 and 60,000 cases each year, respectively, and leads to extra hospital costs of USD47k per patient in the US and USD30k per patient in the EU.
- SoftOx has achieved medical-grade stabilized hypochlorous acid within the therapeutic window. Due to the inherent instability and high reactivity of chlorine-based solutions, most solutions today are unable to maintain a therapeutic level over time. SoftOx Inhalation Solution's HOCI strikes a balance between unacceptable toxicity and insufficient efficacy, with degradation being less than 5% over 2 years. SIS has proven to be effective against bacterial biofilms and respiratory pathogens. With proof-of-concept studies in animal respiratory infections the clinical success has a favorable probability with relatively low study costs. Phase 1 showed the solutions to be safe to inhale for humans, and Phase 2 aims to demonstrate proof-of concepts in humans. SIS is protected by over 90 patents ensuring patent protection for +15 years on vital applications, shielding them from competitors seeking approval for similar products. Should SIS reach market approval, the pathway is well defined. Since VAP is an infection contracted at hospital, the hospital is liable to cover the associated treatment costs without any reimbursement process. VAP comprises a large market with a cost reduction potential of NOK54bn.
- Valuation thoughts: Assuming the company receives sufficient funding and reaches market approval, we estimate NOK1.8bn in revenues and NOK722m in net income by 2030, based a 10% market share and a 40% net income margin. Based on a Price-to-Earnings ratio of 12.5x discounted back to 2024 and equity issuances post-phase 2 of NOK230m in the range NOK0.5-1.5/share, this translates to a fair value of NOK0.53-0.69/share.



### **Investment case summary**

- Cutting-Edge Technology SOFTX has pioneered a groundbreaking technology that stabilizes hypochlorous acid (HOCI) with acetic acid (CH3COOH). The stabilized hypochlorous acid can be used to eradicate or inactivate all relevant microorganisms. The core of SoftOx' value proposition is the stabilization of hypochlorous acid, maintaining its concentration within a therapeutic window, which is a balance between unacceptable toxicity and insufficient efficacy. This core technology is fortified by robust patent protection, with over 90 patents granted, leveraging insights from extensive research and development into the immune system's own production of HOCI.
- Targeted Application Leveraging the many potential use-cases of stabilized hypochlorous acid, SoftOx has focused its efforts on enhancing treatment for Ventilator Associated Pneumonia (VAP), recognizing its profound impact on patient outcomes and healthcare costs. VAP presents a critical challenge in intensive care settings, affecting ventilated patients with compromised immune systems. By harnessing the antimicrobial properties of stabilized HOCI, SoftOx aims to address the underlying microbial causes of VAP, potentially revolutionizing current treatment paradigms (antibiotics).
- Progress and Future Prospects The company has successfully completed phase 1 trials, demonstrating the safety and feasibility of aerosolized stabilized hypochlorous acid in human subjects, with no reported Serious Adverse Events (SAEs). Additionally, preclinical studies have shown promising outcomes in the treatment and prevention of Influenza A infection in mice, providing proof of concept for further clinical exploration. Phase 2 trials, slated to commence in early 2025 pending the securing of NOK50m in financing, aim to evaluate the efficacy of SoftOx Inhalation Solution (SIS) in VAP patients, with anticipated enrollment of approximately 250 subjects. The successful execution of phase 2 studies is expected to pave the way for exit opportunities by 2026, potentially unlocking significant value for stakeholders.
- Valuation thoughts With 130k yearly patients in US & EU that develops VAP, high VAP excess mortality rates and additional costs associated VAP of around USD40k per patient, the market for the SoftOx technology solution is large. Under the assumption the total addressable market for SoftOx is 1/3 of hospital cost reductions, we arrive at a market size of around NOK18bn. Given a 10% market share in 2030, coupled with 40% project cash earnings margin and fair P/E of around 12.5x, we arrive at a potential SoftOx Inhalation solutions market cap of NOK9bn in 2030. In addition, the company expects further growth from increase in market share post-2030, which should imply a higher multiple than 12.5x. Given that the company issues NOK50m in equity related to phase 2 study, NOK130m related to phase 3 study to market approval and NOK100m in buffer capital at market approval (our own assumption), we find that there is around 22.2x potential upside in the stock until 2030.
- If we 1) adjust for risk of success of the different phases until market approval based on previous infectious disease- and respiratory studies (18.2% success probability from start of phase 2 to market approval), 2) discount the 2030 cash flows to present with a 15% discount rate and 3) assume future equity issuances prices post-phase 2 study of between NOK0.5-1.5/share we find a fair share price between NOK0.53-0.69/share compared to last private placement of NOK0.2/share and current share price at NOK0.208/share.
- Additional projects The company technology of stabilized hypochlorous acid has, as stated above, many use cases. Within SoftOx Inhalation Solution company, there will also be an ongoing project for employing the technology for military purposes to counteract biological threats. The timeline of this project is that phase 1B is expected to commence in the middle of 2025 and completed in the middle of 2026. Thus, the project is lagging behind the VAP treatment project, but there are some interesting findings from the project: 1) Fully covered funding of phase 1: The budget is around NOK90m and is fully financed by the European Defense Fund and Norwegian MoD. All commercial rights still belongs to SoftOx solution. 2) Synergies: With these financial muscles one optimizes the SoftOx Inhalation Solution (SIS), which they have called SIS 2.0. They optimize and increase dosages and thus, the synergies from these expenditures to the VAP part of the business are expected to be large. 3) Large market potential: One expects to defeat any biological weapons with the technology, and thus the market potential is large. In NATO and partners, Im soldiers can be in service within a few months, and SoftOx expects 3-years stockpiling within NATO + partners. Also, they see a possibility of a civilian spin-off for the civilian population (around 1bn people in NATO and partners) if a terror attack-or the next pandemic with a potential unknown virus occurs, it might also be relevant to stockpile for the civilian population. If successful, the product is expected to be sold directly to military forces.
- Furthermore, SoftOx Skin and Wound Care will become an own privately held company that owners of SoftOx Inhalation Solutions will own before new funding in the company. The company will perform Phase 2 for SoftOx Wound and Skin Care chronic wounds the next 2-3 years, dependent on funding possibilities. The company states that estimated probability of success is statistically above 80%, and according to external valuation report, the value will increase up to NOK4bn after successful phase 2. However, the company needs approx. EUR10m to fund phase 2/3 of the project, and the board is considering a NOK10m funding round to fund planning of the new phase and explore the possibility of licensing out the skin and wound care business to industrial players.



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### The new SoftOx

Following the restructuring, SoftOx Solutions will be split into two companies

#### **SoftOx Inhalation Solutions AS**

- **Public company:** Will continue to be listed at Euronext growth.
- **VAP in focus:** Focus on Proof of Concept in Ventilation Associated Pneumonia (VAP).
- **SoftOx Defense Solutions:** SoftOx Inhalation Solutions will control 100% of the company. All commercial rights to EDF project belong to SoftOx Defense Solution AS.
- **Headquarters:** New board and management will be established, with company headquarters in Copenhagen.
- **Funding:** The company will seek funding of NOK50m to finance phase 2 study of VAP. The company has already initiated talks with potential investors who have expressed interest in investing in the company as soon as the company is free of debts and the crawl-out and company-split has taken place.

#### SoftOx Skin and Wound Care Solutions AS

- **Private company:** The company will become a non-listed company continuing with the current board and management.
- Wound care: Focus on Wound Care management.
- **Extraordinary dividend:** Shareholders in SoftOx Solutions AS will receive shares in daughter company SoftOx Skin and Wound Care Solutions AS as extra ordinary dividend.
- **Funding:** Company will seek funding of up to EUR10m to continue development of its wound care business. The board will also recommend a smaller share issue of up to NOK10m to fund the company through the planning of phase 2b/3 and explore the possibility of licensing out the Skin and Wound Care business to industrial players.





### Sources and uses from the debt refinancing

When company is split up, SoftOx Inhalation Solution will finance phase 2 with a new NOK50m equity offering<sup>1</sup>





# No outstanding interest-bearing debt post-refinancing

...But we estimate the company will have a burn rate of ~NOK8m per quarter



#### NOK25m cash post subsequent offering on 1Q24 numbers



#### 7 Source: SB1M, SOFTX Notes: 1) Please note that we assume fully underwritten subsequent offering

#### Post-refinancing, company will have no outstanding IBD





# If the company only finance phase 2 with NOK50m at 0.2/share...

... the existing shareholders will still hold 71.5% of the company



#### Ownership existing shareholders after phase 2 financing sensitivity



0.2 share issue price

0.15 share issue price
0.1 share issue price



### SoftOx's antimicrobial technology

Reinforces the body's own ability to eradicate unwanted microbes



#### HOCI is naturally produced in the body

- The technology is based on a synergistic combination effect between two chemical agents that are naturally produced in the human body, hypochlorous acid (HOCI) and acetic acid.
- HOCI is produced by white blood cells during the body's immune response and acts as a potent oxidizing agent against microbial infections. It kills bacteria by penetrating bacterial cell membranes, causing intracellular damage and death.
- Concentrations and combinations can easily be adjusted to fight different types of infections without inducing new resistance, which de-risk new R&D project's success of accept.

#### SoftOx has solved medical grade stabilized HOCI

- Due to the inherent instability and high reactivity of chlorinebased solutions, most solutions today are unable to maintain a therapeutic level over time.
- SoftOx has managed to achieve medical-grade stabilized HOCI within the therapeutic window, achieving a balance between unacceptable toxicity and insufficient efficacy. The degradation is less than 5% over 2 years and increases reliability and shelf-life.





# **SoftOx Inhalation Solutions (SIS)**

Aims to replace the use of antibiotics in treatment of VAP with Hypochlorous Acid (HOCI)

#### 1. Patients need breathing help



- The function of a ventilator is to help patients breathe by assisting the lungs to provide oxygen and remove CO<sub>2</sub>.
- Many conditions can make mechanical ventilation of ICU patients necessary, including head injury, shock, severe pneumonia, acute respiratory distress syndrome (ARDS) and drug overdose
- Respiratory failure can be lifethreatening, and ventilators are employed to help patients breathe.

#### 2. Some patients develop VAP



- VAP arises from ventilator use, circumventing natural airway defenses and heightening the risk of bacterial infection.
- VAP raises mortality rates in ICUs and, according to SoftOx, intubated patients face a 10-30% risk of developing VAP with mortality rates of up to 50%.
- VAP is difficult to cure as antimicrobial resistance and biofilms limits the effects of antibiotics.

#### 3. HOCI could help cure VAP



- SoftOx hypothesizes that SIS inactivates and kills bacteria, including resistant bacteria and bacteria in biofilms, in the upper and lower respiratory tract, and suggests potential improvements in patient outcomes.
- The hypothesis is proven to be valid in mice. Moreover, results from Phase 1 trial proved that SIS was safe to inhale for humans and showed no signs of resistance developing.



### Why focus on Ventilator-Associated Pneumonia?

A hospital acquired condition with no effective treatment and costs EU&US hospitals USD4bn yearly

#### Pathway to market is short and well-defined

- Treatment: VAP has a high mortality rate and there are currently limited effective treatments on the market.
- Administration: Patient group is well-defined and enrolled into ICU. The targeted delivery of SIS is through already present tubes that will be handled by health personnel without the need for any additional equipment.
- **Pathway to market:** Since VAP is an infection contracted at hospital, the hospital is liable to cover the associated treatment costs without any reimbursement process. VAP comprises a large market with cost reduction potential of USD4bn.
- Cost saving potential:



#### SoftOx Inhalation Solution protected by patent family

- Probability of success: SIS has proven to be highly effective against bacterial biofilms and respiratory pathogens. With proofof-concept studies in animal respiratory infections the clinical success has a favorable probability, and study costs are relatively low.
- **Patents:** Protected by over 90 patents ensuring patent protection for +15 years on vital applications.
- **Competition:** Competitors have not been able to a develop stabilized HOCI within the therapeutic range. Moreover, patent family shields competitors from seeking approval for similar products.





### SIS preclinical efficacy studies supports high probability of success

SIS eradicates all relevant microorganisms and demonstrated proof of concept for treatment in mice

#### Key insights

- **Pulmonary pathogens:** P. aeruginosa and S. aureus are among the most common pathogens in VAP and often present as biofilms. SIS shows strong antibiofilm activity against such pathogens.
- Influenza A in mice: Twice daily SIS-treatment resulted in a 90% reduction of viral titers on post-infections days 1 to 3 and demonstrated proof of concept.
- Sendai virus in mice: SIS treatment prevents infection in mice after exposure and stops virus from spreading further.

#### Effective treatment of Influenza A in mice



#### SIS tested against biofilms grown for 24h with 1h contact



#### Prevents virus from spreading in mice





### **Successful SIS Phase 1 trial**

Showed the solution to be safe and tolerable to inhale for healthy individuals

#### Eligibility

- **Subjects:** Conducted on 56 subjects randomized to receive SIS or placebo in a 3:1 ratio, where 42 received SIS and 14 placebo.
- **Inclusion criteria:** The volunteers were healthy adults between the ages 18 and 55 with a BMI ranging from 18.5 to 30 kg/m<sup>2</sup>.
- **Exclusion criteria:** Recent participation in other trials, blood donation, medical condition or drug sensitivity, user of concomitant medication, positive drugs of abuse test.

#### Outcomes

- Actual study start was October 8, 2021, and primary completion date April 13, 2022.
- Demonstrated safety of up to 4 doses of 5 mL 100µg/mL SIS per day for five days, with no serious adverse effects.
- Still, mild adverse effects were present in 27.9% of SIS recipients and 21.4% for placebo.

#### Design

- **Design:** Subjects were enrolled into one of three single dose groups or into one of four multiple dose groups.
- **Dosages:** 1<sup>st</sup> two multiple dose groups OD for 5 days. 2<sup>nd</sup> two multiple dose groups BID for 4 days plus day 5 morning dose or QID for 4 days plus morning dose day 5<sup>1</sup>. Max SIS concentration was 100 ug/ml administrated four times daily.
- Administration: SIS administered via a jet nebulizer and inhaled through a mask over a period of up to 15 minutes.

#### Dr Bjarnsholt, Chief Scientific Officer, receiving SIS<sup>2</sup>





### SIS Phase 2 could commence early 2025

But is dependent on funding of NOK50m to sustain operations throughout the phase

#### Lack of funding is a major concern

- Preparations: SoftOx is currently in discussions with hospitals in Denmark to kickstart phase 2 trial, with available slots slated for 2025. All essential documentation has been gathered to facilitate the Clinical Trial Application process, and regulatory approval is anticipated within 2-3 months following submission.
- **Funding:** Phase 2 is not possible before funding is secured. Although discussions with hospital stakeholders suggest a possible early 2025 start, lack of funding will result in delays.
- **Cash:** The company stipulates a requisite funding of NOK50m to sustain operations throughout Phase 2. However, the current quarterly cash burn post-refinancing is NOK10m. Unless cash burn is reduced, this translates to NOK80m in needs the next two years.

#### High probability of Phase 2 success

- The study will comprise 250 ICU patients diagnosed with VAP to assess the efficacy of SIS. 200 patients will receive the solution, while the remaining 50 patients will be administered a placebo.
- Rigorous monitoring protocols will be implemented due to the critical condition of ICU patients, ensuring prompt identification of any serious adverse events.
- Given that SoftOx receives the required funding, Phase 2 should be completed by the end of 2025. According to Chief Scientific Officer the probability of phase 2 success is at least 50%.



### The company should have sufficient funding until 2Q26

With a quarterly cash burn of ~NOK8m







### **Company anticipates SIS approval faster than the industry average**

SIS product category on lower end of duration relative to other Biotechnology R&D projects



Total duration is around 10 years for SIS product category



### In Europe and the US, total VAP market amounts to NOK18bn

Based on a cost savings potential of NOK54bn where 1/3 is allocated to supplier

#### 130k yearly VAP cases and NOK54bn in extra costs

- Hospital costs: Studies report 70,000 and 60,000 yearly cases of VAP in Europe and the US, respectively. Estimates show that it leads to extra costs of USD47k per patient in the US and USD30k per patient in the EU<sup>1</sup>.
- **Revenue potential:** Common practice during the patent period for companies is to charge hospitals based on the cost reduction provided by the product. Typically, the industry standard ranges from 20-40%. Hence, revenue potential is based on assumption of charging 1/3 of the cost savings.

#### If SIS is approved, we assume a 10% market share by 2030

- **Patent protection:** SIS is protected by its patent family from competitors getting approval of similar products.
- **20/80 rule:** Generally, 20% of the largest companies account for 80% of the market. Assuming the 20% largest hospitals are similar in size, SIS would only need to penetrate a fraction of these hospitals to achieve substantial market presence.
- **Growth potential:** The company expects continued growth beyond 2030, driven by both high mortality rates and significant cost savings potential. However, we believe a 10% market share is fair.





#### SIS revenue potential





### SIS income margin 40% as sole focus is providing hospitals

We use peers' EBITDA post-tax as benchmark given anticipated focus on expanding market shares and product use once approved, rather than further investments



#### Potential cash earnings



#### SIS margins should be higher than that of peers

- Peers allocate significant R&D expenditure to new products in early stages, with low probability of success, leading to the recognition of these costs as opex.
- Furthermore, SoftOx will sell their product directly to hospitals, which means that marketing costs will be low. The net income margin should thus align with the product margin.



# Fair P/E of 12.5x on 2030 earnings with a 15% discount rate

Given that the project is successful

#### Median P/E 2010-20231



#### Fair P/E 12.5x as low capex reduces growth potential

- **Capex:** If SIS enters the market, there is room for growth without further capex based on market share potential of 10% and the use of product as both treatment and prevention.
- **Growth:** Given the assumption of no maintenance/growth capex needed, growth should align with inflation, and thus 14-15x seems like a fair multiple. However, growth variations affect multiples, and a reasonable range is [10,20], and as lower investments reduces the growth potential we argue for a more conservative valuation between P/E 10-15x.

#### Peers rNPV discount rates



#### 15% discount rate after risk adjusting

- **Methodology:** Utilizing the risk-adjusted NPV method involves the adjustment of NPV by incorporating corresponding probabilities. This method is widely used in valuing binary cases and is generally seen as a more precise estimate than adjusting for the risk of failure solely in the discount rate.
- **Discount rate:** According to studies the rates for products in mid-stage development is 10-22%. Given the high probability of SIS not being unsuccessful, we argue that 15% is fitting.



# There is a 18.2% likelihood of success from phase II to market approval according to study on clinical development success rates

SIS product category has high to median probability of transition relative to other Biotechnology R&D projects



Phase I to II

#### Phase III to NDA/BLA



#### Phase II to III



#### NDA/BLA to Approval





# SoftOx believes that probability of phase 2 success is high

The probability is expected to be higher than what is generally seen across the market





### **Shares outstanding development**

If Phase 2 is successful, we assume SoftOx will be able to issue new shares far above current share price



#### Based on an issuance price of NOK1/share, the company would have a total of 1.108m shares outstanding



### Fair value range of NOK0.53-0.69/share...

... when we assume different equity issuance prices between NOK0.5-1.5/share post-phase 2 study

Calculations 2024	NOKm	Assumptions	
		Market size (NOKm)	18,040
Revenues	1,804	Market share	10 %
Net income	722	Net income margin	40 %
Equity value	9,020	Fair P/E multiple	12.5x
Risk adjusted	1,637	Probability of Phase 2 to approval	18.2 %
Discounted	708	Discount rate	15 %
Implied share price	0.64	Shares outstanding	1,108

#### Implied value given future equity issuances at NOK1/share

### Comments

- Under the assumption of a NOK130m issuance at NOK1/share following a successful phase 2 study and NOK100m issuance at NOK1/share after market approval (these equity issuances should differ in price due to differences in risk – but we employ the same price for simplicity), there would be 1,108m shares in the company.
- With an equity value of NOK708m, this gives us a price of NOK0.64/share, or 3.2x the last private placement at NOK0.2/share.

#### Share price sensitivity





### **Sensitivities**

The company is highly sensitive to market share and probability of success in phase 2

#### Assumptions

Assumptions	
Market size (NOKm)	18,040
Market share	10 %
Net income margin	40 %
Fair P/E multiple	12.5
Discount rate	15 %
Phase 2 equity funding need	50m
Equity funding neeed ex phase 2 funding	230m
Equity issuance price post phase 2 success	NOK1/share
Probaility of phase 2 transition	30 %
Probaility of phase 2 transition, SoftOx estimate	50 %
Probaility of phase 3 transition	65 %
Probability of phase NDA/BLA to approval	95 %
Probability of phase 2 to market approval	18 %

#### Highly sensitive to market share assumption of 10%



### Compared to last private placement, the stock seems attractive despite a scenario of additional funding need for completion of phase 2 at NOK0.2/share



### Given SoftOx estimate of +50% probability of phase 2 success, and no additional funding need above the estimated NOK50m, we find a 5.3x candidate



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### **Sensitivities**

#### Assumptions

Assumptions	
Market size (NOKm)	18,040
Market share	10 %
Net income margin	40 %
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Discount rate	15 %
Phase 2 equity funding need	50m
Equity funding neeed ex phase 2 funding	230m
Equity issuance price post phase 2 success	NOK1/share
Probaility of phase 2 transition	30 %
Probaility of phase 2 transition, SoftOx estimate	50 %
Probaility of phase 3 transition	65 %
Probability of phase NDA/BLA to approval	95 %
Probability of phase 2 to market approval	18 %

#### **Discount rate sensitivity**



### Post phase 2 success, we assume NOK130m in funding to come to market approval, and NOK100m in buffer funding post market approval



#### P/E Multiple sensitivity





### Scenario: SIS is owned by a sole proprietor post-phase 2...

... Using NOK230m of own funds to finance development, the expected value of SIS could be NOK3bn in 2026



#### 2026 value of company given phase 2 study success

#### Present value phase 2 risk sensitivity



#### Current market cap implies 10% success rate for phase 2

- Studies indicate a phase 2 study success rate of 30% (average of infectious disease and respiratory), this implies a fair present value of NOK685m, compared to a market cap of NOK176m post NOK50m equity issuance at 0.2/share.
  - However, given SCO's belief in >50% probability, fair market value of the company can be above NOK1,091m. Current market cap at NOK176m implies a 10% probability of phase 2 success.
- NOK130m in 2026 plus a buffer of NOK100m in 2030, expected fair 2026 value after risk adjustments would be NOK3,019m, compared to a market cap of NOK176m (at 0.2/share post NOK50m equity issuance from external investor).

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### Scenario: SIS is owned by a sole proprietor post-phase 2...

... Using NOK230m of own funds to finance development, the expected value of SIS could be NOK3bn in 2026

#### **Calculations & Assumptions**

Calculations	NOKm	Assumptions 2030	
		Market size (NOKm)	18,040
Revenues	1,804	Market share	10 %
Net income	722	Net income margin	40 %
Equity value	9,020	Fair P/E multiple	12.5x
Less buffer capital	<i>8,920</i>	Buffer capital	100
Discounted back to 2026	5,100	Discount rate	15 %
Less investment phase 3	4,970	Investment Phase 3	130
Fair value, risk adjusted	3,069	Market approval post phase 2	61.75 %
Expected value loss of Phase 3 investment	-50	Failure to meet approval	38.25 %
Fair value 2026	3,019		
Discounted back to 2024	2,283		
Risk adjusted	685	Probability of Phase 2 transition	30.0 %
Fair value 2024	685		



### When adding the 4 different outcomes...

... the expected value yields a fair value of NOK635m, based on our assumptions





# **European Defense Fund project**

Large market potential with a counteracting product to biological threats



EDF project phase 1 expected to be finalized in mid2026

The company technology of stabilized hypochlorous acid has many use cases. Within SoftOx Inhalation Solution company, there will also be an ongoing project for employing the technology for military purposes to counteract biological threats. The timeline of this project is that phase 1B is expected to commence in the middle of 2025 and completed in the middle of 2026. Thus, the project is lagging behind the VAP treatment project.

There are however some interesting findings from the project: 1) Fully covered funding of phase 1: The budget is around NOK90m and is fully financed by the European Defense Fund and Norwegian MoD. All commercial rights still belongs to SoftOx solution. 2) Synergies: With these financial muscles one optimizes the SoftOx Inhalation Solution (SIS), which they have called SIS 2.0. They optimize and increase dosages and thus, the synergies from these expenditures to the VAP part of the business are expected to be large. 3) Large market potential: One expects to be able to defeat any type of biological weapon with the technology, and thus the market potential is large. In NATO and partners, 1m soldiers can be in service within a few months, and SoftOx expects 3-years stockpiling within NATO + partners. Also, they see a possibility of a civilian spin-off for the civilian population (around 1bn people in NATO and partners) if a terror attack or the next pandemic with a potential unknown virus occurs, it might also be relevant to stockpile for the civilian population. If successful, the product is expected to be sold directly to military forces.



### SoftOx Skin and Wound Care

New company seeks separate funding of EUR10m to continue its wound care business

#### **Further development**

- The company has announced that they will seek separate funding of EUR10m to finance wound care development going forward.
- In addition, the board has recommended a smaller issue of up to NOK10m to fund planning of SBE phase 2b/3 and explore the possibility of licensing out the skin and wound care business to industrial players.
- 2024-2025:
  - SoftOx Biofilm Eradicator Phase 2/3.
  - Outsource production first- and next-generation technology.
  - Bring products to market through partners and distributors.
- 2026
  - Distribution of SoftOx wound cleanser in EU and US.
  - Sale or listing as separate unit.

#### **Exit strategy**

- By 2026 aims to exit wound care either through sale of applications, technology platform or seperate listing.
- Primary reasons for not selling wound care now:
  - International advisers: market value is too small
  - Venture Capital: lack of plan for commercialization
  - Industry: too little data



#### Turnover potential in the US<sup>1</sup>



### SoftOx Skin and Wound Care

SoftOx Biofilm Eradicator (SBE) is currently only area of development

#### SBE: treatment for chronic wounds

- Antimicrobial treatment for chronic wounds and is formulated to penetrate and kill microbes including biofilms in the wound bed.
- Phase 1a and phase 1b showed that the solution is safe in humans. In phase 1b, 8 patients with venous leg ulcers wounds showed a 98% reduction in bacterial load after only 5 days of treatment, alongside dose-dependent wound healing.
- With strong phase 1a/1b results, the company aims to advance directly to phase 3 for SBE, combining phase 2b and 3 in one study. The success probability is estimated at ~80%.

#### Wound healing SBE phase 1B



#### SWIS: rinsing product for acute wounds

- Acute wounds are exposed areas on the skin which should heal itself if the area is clean. The current recommended treatment is saline with an 80% market share.
- Due to clinical evidence of significant reduction in bacterial load and better wound healing in acute wounds the company aims to develop SWIS as the preferred wound cleansing product.
- In 2023, FDA approval application for 510(k) clearance of SWIS as a medical device in the US market fell short of requirements, and work with SWIS is paused due to insufficient funding.

#### Wound healing SWIS confirmative study







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### SoftOx is a Norwegian medtech and biotech company

Develops antimicrobial solutions for respiratory infections and wound treatment

#### Areas of development

- SoftOx has struggled with transitioning products from development to market in the past. As the company is currently undergoing a financial restructuring a key focus has been to slim down its business and only focus on products with promising potential.
- Currently, the company's focus is on its inhalation solution (SIS) against Ventilator-Associated Pneumonia and its antimicrobial solution against chronic wounds. SIS has showed pre-clinical efficacy and clinical safety in healthy volunteers, with the goal of demonstrating proof-of-concept in humans during phase 2.
- However, with revenues primarily sourced from government grants and substantial cash outflow due to multiple products previously in research and development, a successful financial restructuring is necessary for further advancement.

#### **Financial restructuring**

- As part of the company's financial restructuring, all debt obligations will be eliminated. Through this process, the company has raised gross proceeds of NOK22.3m, with NOK14m of supplier debt being converted into share capital and NOK8m provided in cash.
- Furthermore, the outstanding debt totaling NOK76m, along with accrued interest, has been converted into equity at the same price per share as in the private placement, at NOK0.2/share.
- In addition, the company is currently in the process of a subsequent offering with a max target of NOK25m.
- The restructuring dilutes existing shareholders as the share count increases from 10.7m shares to 617.7m shares

Segment	Projects	Pre-clinical	Phase 1A	Phase 1B	Phase 2	Phase 3	Regulatory approval
Wound care	Chronic wound treatment				,		
Respiratory care	Inhalation solution				,		



### The new SoftOx

Following the restructuring, SoftOx Solutions will be split into two companies

#### **SoftOx Inhalation Solutions AS**

- **Public company:** Will continue to be listed at Euronext growth.
- **VAP in focus:** Focus on Proof of Concept in Ventilation Associated Pneumonia (VAP).
- **SoftOx Defense Solutions:** SoftOx Inhalation Solutions will control 100% of the company. All commercial rights to EDF project belong to SoftOx Defense Solution AS.
- **Headquarters:** New board and management will be established, with company headquarters in Copenhagen.
- **Funding:** The company will seek funding of NOK50m to finance phase 2 study of VAP. The company has already initiated talks with potential investors who have expressed interest in investing in the company as soon as the company is free of debts and the crawl-out and company-split has taken place.

#### SoftOx Skin and Wound Care Solutions AS

- **Private company:** The company will become a non-listed company continuing with the current board and management.
- Wound care: Focus on Wound Care management.
- Extraordinary dividend: Shareholders in SoftOx Solutions AS will receive shares in daughter company SoftOx Skin and Wound Care Solutions AS as extra ordinary dividend.
- **Funding:** Company will seek funding of up to EUR10m to continue development of its wound care business. The board will also recommend a smaller share issue of up to NOK10m to fund the company through the planning of phase 2b/3 and explore the possibility of licensing out the Skin and Wound Care business to industrial players.





### SoftOx's antimicrobial technology

Reinforces the body's own ability to eradicate unwanted microbes



#### HOCI is naturally produced in the body

- The technology is based on a synergistic combination effect between two chemical agents that are naturally produced in the human body, hypochlorous acid (HOCI) and acetic acid.
- HOCI is produced by white blood cells during the body's immune response and acts as a potent oxidizing agent against microbial infections. It kills bacteria by penetrating bacterial cell membranes, causing intracellular damage and death.
- Concentrations and combinations can easily be adjusted to fight different types of infections without inducing new resistance, which de-risk new R&D project's success of accept.

#### SoftOx has solved medical grade stabilized HOCI

- Due to the inherent instability and high reactivity of chlorinebased solutions, most solutions today are unable to maintain a therapeutic level over time.
- SoftOx has managed to achieve medical-grade stabilized HOCI within the therapeutic window, achieving a balance between unacceptable toxicity and insufficient efficacy. The degradation is less than 5% over 2 years and increases reliability and shelf-life.





# **SoftOx Inhalation Solutions (SIS)**

Aims to replace the use of antibiotics in treatment of VAP with Hypochlorous Acid (HOCI)

#### 1. Patients need breathing help



- The function of a ventilator is to help patients breathe by assisting the lungs to provide oxygen and remove CO<sub>2</sub>.
- Many conditions can make mechanical ventilation of ICU patients necessary, including head injury, shock, severe pneumonia, acute respiratory distress syndrome (ARDS) and drug overdose
- Respiratory failure can be lifethreatening, and ventilators are employed to help patients breathe.

#### 2. Some patients develop VAP



- VAP arises from ventilator use, circumventing natural airway defenses and heightening the risk of bacterial infection.
- VAP raises mortality rates in ICUs and, according to SoftOx, intubated patients face a 10-30% risk of developing VAP with mortality rates of up to 50%.
- VAP is difficult to cure as antimicrobial resistance and biofilms limits the effects of antibiotics.

#### 3. HOCI could help cure VAP



- SoftOx hypothesizes that SIS inactivates and kills bacteria, including resistant bacteria and bacteria in biofilms, in the upper and lower respiratory tract, and suggests potential improvements in patient outcomes.
- The hypothesis is proven to be valid in mice. Moreover, results from Phase 1 trial proved that SIS was safe to inhale for humans and showed no signs of resistance developing.


### Why focus on Ventilator-Associated Pneumonia?

A hospital acquired condition with no effective treatment and costs EU&US hospitals USD4bn yearly

#### Pathway to market is short and well-defined

- Treatment: VAP has a high mortality rate and there are currently limited effective treatments on the market.
- Administration: Patient group is well-defined and enrolled into ICU. The targeted delivery of SIS is through already present tubes that will be handled by health personnel without the need for any additional equipment.
- **Pathway to market:** Since VAP is an infection contracted at hospital, the hospital is liable to cover the associated treatment costs without any reimbursement process. VAP comprises a large market with cost reduction potential of USD4bn.
- Cost saving potential:



#### SoftOx Inhalation Solution protected by patent family

- Probability of success: SIS has proven to be highly effective against bacterial biofilms and respiratory pathogens. With proofof-concept studies in animal respiratory infections the clinical success has a favorable probability, and study costs are relatively low.
- **Patents:** Protected by over 90 patents ensuring patent protection for +15 years on vital applications.
- **Competition:** Competitors have not been able to a develop stabilized HOCI within the therapeutic range. Moreover, patent family shields competitors from seeking approval for similar products.





### SIS preclinical efficacy studies supports high probability of success

SIS eradicates all relevant microorganisms and demonstrated proof of concept for treatment in mice

#### Key insights

- **Pulmonary pathogens:** P. aeruginosa and S. aureus are among the most common pathogens in VAP and often present as biofilms. SIS shows strong antibiofilm activity against such pathogens.
- Influenza A in mice: Twice daily SIS-treatment resulted in a 90% reduction of viral titers on post-infections days 1 to 3 and demonstrated proof of concept.
- Sendai virus in mice: SIS treatment prevents infection in mice after exposure and stops virus from spreading further.

#### Effective treatment of Influenza A in mice



#### SIS tested against biofilms grown for 24h with 1h contact



#### Prevents virus from spreading in mice





### **Successful SIS Phase 1 trial**

Showed the solution to be safe and tolerable to inhale for healthy individuals

#### Eligibility

- **Subjects:** Conducted on 56 subjects randomized to receive SIS or placebo in a 3:1 ratio, where 42 received SIS and 14 placebo.
- **Inclusion criteria:** The volunteers were healthy adults between the ages 18 and 55 with a BMI ranging from 18.5 to 30 kg/m<sup>2</sup>.
- **Exclusion criteria:** Recent participation in other trials, blood donation, medical condition or drug sensitivity, user of concomitant medication, positive drugs of abuse test.

#### Outcomes

- Actual study start was October 8, 2021, and primary completion date April 13, 2022.
- Demonstrated safety of up to 4 doses of 5 mL 100µg/mL SIS per day for five days, with no serious adverse effects.
- Still, mild adverse effects were present in 27.9% of SIS recipients and 21.4% for placebo.

#### Design

- **Design:** Subjects were enrolled into one of three single dose groups or into one of four multiple dose groups.
- **Dosages:** 1<sup>st</sup> two multiple dose groups OD for 5 days. 2<sup>nd</sup> two multiple dose groups BID for 4 days plus day 5 morning dose or QID for 4 days plus morning dose day 5<sup>1</sup>. Max SIS concentration was 100 ug/ml administrated four times daily.
- Administration: SIS administered via a jet nebulizer and inhaled through a mask over a period of up to 15 minutes.

#### Dr Bjarnsholt, Chief Scientific Officer, receiving SIS<sup>2</sup>





### SIS Phase 2 could commence early 2025

But is dependent on funding of NOK50m to sustain operations throughout the phase

#### Lack of funding is a major concern

- Preparations: SoftOx is currently in discussions with hospitals in Denmark to kickstart phase 2 trial, with available slots slated for 2025. All essential documentation has been gathered to facilitate the Clinical Trial Application process, and regulatory approval is anticipated within 2-3 months following submission.
- **Funding:** Phase 2 is not possible before funding is secured. Although discussions with hospital stakeholders suggest a possible early 2025 start, lack of funding will result in delays.
- **Cash:** The company stipulates a requisite funding of NOK50m to sustain operations throughout Phase 2. However, the current quarterly cash burn post-refinancing is NOK10m. Unless cash burn is reduced, this translates to NOK80m in needs the next two years.

#### High probability of Phase 2 success

- The study will comprise 250 ICU patients diagnosed with VAP to assess the efficacy of SIS. 200 patients will receive the solution, while the remaining 50 patients will be administered a placebo.
- Rigorous monitoring protocols will be implemented due to the critical condition of ICU patients, ensuring prompt identification of any serious adverse events.
- Given that SoftOx receives the required funding, Phase 2 should be completed by the end of 2025. According to Chief Scientific Officer the probability of phase 2 success is at least 50%.





### **SoftOx Defense Solution**

Military inhalation solution fully funded by European Defense Fund (EDF), benefiting overall development of SIS

#### SoftOx to be awarded EUR4.1m from EDF

- COUNTERACT: EU research project funded by European Defense Fund and supported by the Norwegian Ministry of Defense. Using SoftOx technology, SoftOx and partners develops medical countermeasures against inhaled biological threats.
- **Financing:** Budget of approximately NOK90m, and product development is outsourced to University of Copenhagen.
- Awards: EUR4.1m will be awarded to SoftOx and EUR4.2m to the consortium of partners to support development. SoftOx has already received NOK9m in prepayment funding. The Norwegian Ministry of Defense will also award SoftOx up to NOK9.6m.



#### Phase 1B to commence in 2025

- **Pre-clinical work:** Scientific advice on SIS 2.0 and phase 1B obtained and optimization of SIS 2.0 performed. Has been tested against a diverse array of pathogens in vitro and vivo, and efficacy testing in animal models is planned for spring 2024.
- **Phase 1B:** Study on healthy individuals to start in 2025. Will increase and optimize dosing possibilities in future trials on both civil and military applications of SIS.
- **Phase 2/3:** Plans to partner up with relevant partners and is scheduled for 2026.

#### Substantial income potential if successful

- Expected value as a preventative preparedness tool for soldiers and the civilian population.
- SoftOx expects the product to be purchased directly by NATOmembers and partners.
- 3-years stockpiling comprising:
  - ~1 million soldiers.
  - ~1 billion civilians.



### SoftOx Skin and Wound Care

SoftOx Biofilm Eradicator (SBE) is currently only area of development

#### SBE: treatment for chronic wounds

- Antimicrobial treatment for chronic wounds and is formulated to penetrate and kill microbes including biofilms in the wound bed.
- Phase 1a and phase 1b showed that the solution is safe in humans. In phase 1b, 8 patients with venous leg ulcers wounds showed a 98% reduction in bacterial load after only 5 days of treatment, alongside dose-dependent wound healing.
- With strong phase 1a/1b results, the company aims to advance directly to phase 3 for SBE, combining phase 2b and 3 in one study. The success probability is estimated at ~80%.

#### Wound healing SBE phase 1B



#### SWIS: rinsing product for acute wounds

- Acute wounds are exposed areas on the skin which should heal itself if the area is clean. The current recommended treatment is saline with an 80% market share.
- Due to clinical evidence of significant reduction in bacterial load and better wound healing in acute wounds the company aims to develop SWIS as the preferred wound cleansing product.
- In 2023, FDA approval application for 510(k) clearance of SWIS as a medical device in the US market fell short of requirements, and work with SWIS is paused due to insufficient funding.

#### Wound healing SWIS confirmative study





### SoftOx Skin and Wound Care

New company seeks separate funding of EUR10m to continue its wound care business

#### **Further development**

- The company has announced that they will seek separate funding of EUR10m to finance wound care development going forward.
- In addition, the board has recommended a smaller issue of up to NOK10m to fund planning of SBE phase 2b/3 and explore the possibility of licensing out the skin and wound care business to industrial players.
- 2024-2025:
  - SoftOx Biofilm Eradicator Phase 2/3.
  - Outsource production first- and next-generation technology.
  - Bring products to market through partners and distributors.
- 2026
  - Distribution of SoftOx wound cleanser in EU and US.
  - Sale or listing as separate unit.

#### **Exit strategy**

- By 2026 aims to exit wound care either through sale of applications, technology platform or seperate listing.
- Primary reasons for not selling wound care now:
  - International advisers: market value is too small
  - Venture Capital: lack of plan for commercialization
  - Industry: too little data



#### Turnover potential in the US<sup>1</sup>





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### **Respiratory infection market**

The Global Lower Respiratory Tract Infection Treatment market is estimated to reach USD90bn by 2030





**Global respiratory treatment market** 

### Antimicrobial resistance a major concern

In 2019, there were 1.2 million global deaths directly caused by antimicrobial resistance and >20% of infections in EU were resistant to antibiotic treatment

Projected average proportion of infections caused by bacteria resistant to antimicrobial treatment





### **Antimicrobial resistance R&D Spending**

The US is the leading source of AMR R&D funding



Total funding has seen an overall negative trend after the pandemic



### **Ventilator-Associated Pneumonia**

#### **Frequency and costs**

- Approximately 800,000 hospitalized patients are mechanically ventilated in the US each year.
- In a study from the US National Library of Medicine, an analysis was conducted on 5,155,068 hospitalizations spanning from 2009 to 2017, focusing on patients who underwent mechanical ventilation. Among these cases, 93,432 individuals (1.85%) developed Ventilator-Associated Pneumonia (VAP), with an incidence rate of 2% in 2009 and 1.7% in 2017.
- In the same meta study, it is estimated that Ventilator-Associated Pneumonia (VAP) costs between USD19 325-USD80 013 per case from 5 different studies, with an average of USD47 238. The lowest estimates are from old studies, and in the newest studies the cost is estimated around USD40 000-60 000 per case.

#### Mortality

 From a US Agency for Health Care Research and Quality study\*\*\*, they find that underlying mortality was 0.3 per case of HAC, while estimated excess mortality caused by VAP was around 0.14. Thus, mortality rates increases sharply with VAP





### Likelihood of market approval

SIS product category has high to median probability of success relative to other Biotechnology R&D projects



Infectious and Respiratory related drugs have an average success rate of 18%



### **Probability of phase transition**

SIS product category has high to median probability of transition relative to other Biotechnology R&D projects



Phase I to II

#### Phase III to NDA/BLA



#### Phase II to III



#### NDA/BLA to Approval





# **Duration of phases**

SIS product category on lower end of duration relative to other Biotechnology R&D projects



Total duration is around 10 years for SIS product category



### **Duration of phases**



Phase III to NDA/BLA

Phase I to II







#### NDA/BLA to Approval







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# SoftOx has historically had a high level of cash-burn

And average 2Q23-4Q23 cash burn before WC was ~NOK12m per quarter



#### NOK95m in cash outflow before ▲WC in 2022





#### Average 2Q23-4Q23 cash burn



-14



# Post refinancing, the company will have no outstanding IBD...

...But we estimate the company will burn-rate of ~NOK8m per quarter



Post refinancing, and given 2Q23-4Q23 cash burn, we find a burn rate of NOK9.5m per quarter – however, we estimate a burn rate going forward of NOK8m





#### Post refinancing, company will have no outstanding IBD





### Sources and uses from the debt refinancing

The company will finance phase 2 with a new NOK50m equity offering<sup>1</sup>





# If the company only finance phase 2 with NOK50m at 0.2/share...

... the existing shareholders will still hold 71.5% of the company



#### Ownership existing shareholders after phase 2 financing sensitivity



0.2 share issue price
0.15 share issue price

price 0.1 share issue price



### Investments and cash burn post phase 2

From phase 2 to market approval the company would need an estimated NOK280m

#### Investments and cash burn post phase 2

- Financing needs: The company have done some rough estimates for taking VAP through phase 3 and approval, based on earlier contracts and experience. They estimate the following cost split:
  - Phase 3 NOK60m
  - Production (build up production including produce for phase 3) – NOK30m
  - Administrative costs 2 years including approval NOK40m
  - Total NOK130m
- Exit: The most plausible will be to sell the company post phase 2. However, if the company decides to continue to operate on its own, they will outsource production and distribution which means that there will be limited investments needed post market approval



#### Total estimated investments and cash burn

### The company should have sufficient funding until 2Q26

With a quarterly cash burn of ~NOK8m







# Outstanding shares development after phase 2 refinancing





### **Historical and estimated P&L**

The company do not expect to receive any grants going forward, and will be dependent on sufficient cash

NOKm	2016	2017	2018	2019	2020	2021	2022	2023	2024E	2025E	2026E
Total revenues	0.1	0.0	4.3	4.1	9.8	7.9	7.1	7.0	0.0	0.0	0.0
Operating expenses	-8.7	-12.2	-20.5	-24.3	-58.5	-90.2	-94.3	-32.1	-23.3	-23.3	-23.3
EBITDA	-8.6	-12.2	-16.2	-20.2	-48.7	-82.3	-87.2	-25.2	-23.3	-23.3	-23.3
D&A	-0.3	-0.8	-1.1	-1.7	-2.7	-3.8	-3.9	-7.5	-4.6	-4.6	-4.6
EBIT	-8.9	-13.0	-17.3	-21.9	-51.4	-86.1	-91.1	-32.6	-28.0	-28.0	-28.0
Net financials	0.1	0.0	-0.2	-0.3	1.7	-0.2	-2.6	-9.4	-1.5	-1.0	-2.8
Тах	2.7	3.8	4.5	5.8	12.3	20.9	22.6	9.3	6.5	6.4	6.8
Net income	-6.1	-9.3	-12.9	-16.3	-37.4	-65.4	-71.1	-32.8	-23.0	-22.6	-24.0

NOKm	Q1/23	Q2/23	Q3/23	Q4/23	Q1/24E	Q2/24E	Q3/24E	Q4/24E
Total revenues	9.7	0.5	1.6	-4.8	0.0	0.0	0.0	0.0
Operating expenses	-11.1	-5.1	-6.0	-10.0	-5.8	-5.8	-5.8	-5.8
EBITDA	-1.4	-4.6	-4.4	-14.7	- <mark>5.8</mark>	-5.8	-5.8	-5.8
D&A	-1.0	-1.2	-1.3	-4.0	-1.2	-1.2	-1.2	-1.2
EBIT	-2.4	-5.7	-5.7	-18.8	-7.0	-7.0	-7.0	-7.0
Net financials	0.0	0.3	0.0	-9.7	-0.1	-0.5	-0.5	-0.4
Тах	0.0	0.0	0.0	0.0	1.5	1.7	1.6	1.6
Net income	-2.4	-5.4	-5.8	-28.5	-5.5	-5.9	-5.8	-5.8



### Historical and estimated balance sheet

NOKm	2016	2017	2018	2019	2020	2021	2022	2023	2024E	2025E	2026E
Total intangible assets	6.1	10.7	15.6	23.1	36.7	58.7	82.0	85.4	95.3	105.2	115.5
Production equipment	0.6	0.5	0.3	0.2	3.9	3.5	3.9	0.6	0.6	0.6	0.6
Non-current assets	6.7	11.1	16.0	23.3	40.6	62.2	85.9	86.0	96.0	105.9	116.2
Other current assets	1.8	2.8	6.2	5.7	11.9	8.9	9.4	2.6	2.6	2.6	2.6
Cash	0.3	17.1	1.2	76.0	34.8	57.0	5.3	6.0	51.6	19.2	114.9
Current assets	2.1	19.9	7.4	81.7	46.7	65.9	14.7	8.6	54.2	21.8	117.5
Total assets	8.9	31.0	23.4	105.0	87.3	128.1	100.6	94.6	150.2	127.7	233.7
Share capital	0.0	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Share premium reserve	13.8	47.5	17.8	89.7	76.1	175.0	109.3	59.0	227.5	227.5	357.5
Other equity	-11.3	-20.7	-3.4	-3.4	0.0	-65.5	-70.8	-59.5	-82.5	-105.0	-129.0
Total equity	2.5	26.8	14.4	86.5	76.2	109.7	38.7	-0.3	145.3	122.7	228.7
Non-current liabilities	0.0	0.0	0.0	0.1	0.0	0.4	41.1	45.6	0.0	0.0	0.0
Accounts payable	1.7	3.2	4.4	11.0	5.8	6.0	11.3	20.9	5.0	5.0	5.0
Other current liabilities	4.7	1.0	4.6	7.4	5.3	12.0	9.4	28.3	-0.1	-0.1	-0.1
Current liabilities	6.4	4.2	9.0	18.4	11.1	18.0	20.8	49.3	4.9	4.9	4.9
Total liabilities	6.4	4.2	9.0	18.5	11.1	18.3	61.8	94.9	4.9	4.9	4.9
Total equity and liabilities	8.9	31.0	23.4	105.0	87.3	128.1	100.6	94.6	150.2	127.7	233.7



### Historical and estimated balance sheet

NOKm	Q1/23	Q2/23	Q3/23	Q4/23	Q1/24E	Q2/24E	Q3/24E	Q4/24E
Total intangible assets	81.6	83.3	84.6	85.4	87.8	90.3	92.8	95.3
Production equipment	3.7	3.6	3.4	0.6	0.6	0.6	0.6	0.6
Non-current assets	85.3	86.9	88.0	86.0	88.4	91.0	93.5	96.0
Other current assets	6.5	5.8	2.5	2.6	2.6	2.6	2.6	2.6
Cash	10.2	10.2	10.1	6.0	6.7	68.3	59.9	51.6
Current assets	16.6	<b>16.0</b>	12.6	8.6	9.3	70.8	62.5	54.2
Total assets	102.0	102.9	100.6	94.6	97.7	161.8	156.0	150.2
Share capital	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Share premium reserve	51.3	54.3	54.3	59.0	157.5	227.5	227.5	227.5
Other equity	-15.1	-21.0	-27.4	-59.5	-65.0	-70.9	-76.7	-82.5
Total equity	36.4	33.5	27.2	-0.3	92.8	156.9	151.1	145.3
Non-current liabilities	40.7	40.7	40.7	45.6	0.0	0.0	0.0	0.0
Accounts payable	19.9	17.5	18.3	20.9	5.0	5.0	5.0	5.0
Other current liabilities	5.0	11.2	14.4	28.3	-0.1	-0.1	-0.1	-0.1
Current liabilities	24.9	28.7	32.7	49.3	4.9	4.9	4.9	4.9
Total liabilities	65.6	69.4	73.4	94.9	4.9	4.9	4.9	4.9
Total equity and liabilities	102.0	102.9	100.6	94.6	97.7	161.8	156.0	150.2





### **Historical and estimated cash flows**

NOKm	2016	2017	2018	2019	2020	2021	2022	2023	2024E	2025E	2026E
Profit before tax	-8.9	-13.2	-17.5	-22.2	-49.7	-86.3	-93.7	-42.1	-29.4	-28.9	-30.8
Тах	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
D&A	0.4	1.0	1.1	1.7	2.7	3.8	3.9	7.5	4.6	4.6	4.6
Net financials	-0.1	0.0	0.2	0.3	-1.7	0.2	2.6	9.4	1.5	1.0	2.8
Change in NWC	2.7	-3.1	1.4	9.9	-13.6	9.9	3.9	35.4	-44.4	0.0	0.0
Cash flow from operations	-5.9	-15.3	-14.8	-10.3	-62.2	-72.4	-83.3	10.2	-67.7	-23.3	-23.3
Investments in non-current assets	-3.5	-1.6	-1.4	-3.2	-7.6	-4.6	-4.9	-7.6	-8.1	-8.1	-8.1
Free cash flow	-9.4	-17.0	-16.2	-13.5	-69.8	-77.0	-88.1	2.6	-75.8	-31.5	-31.5
Net financials	0.1	0.0	-0.2	-0.3	1.7	-0.2	-2.6	-9.4	-1.5	-1.0	-2.8
Proceeds from equity issues	4.4	33.7	0.6	88.4	27.1	89.0	0.0	3.1	83.3	0.0	130.0
Other financing activities	0.3	-0.1	-0.1	0.1	-0.3	10.3	40.7	4.5	85.2	0.0	0.0
Paydown debt	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	-45.6	0.0	0.0
Net change in cash	-4.6	16.6	-15.9	74.8	-41.3	22.2	-50.1	0.7	45.6	-32.4	95.7
Starting Balance	0.0	32.8	54.4	35.4	25.4	34.8	57.0	5.3	6.0	51.6	19.2
Ending Balance	25.4	34.8	55.0	31.1	16.6	57.0	5.3	6.0	51.6	19.2	114.9



### Historical and estimated cash flows

NOKm	Q1/23	Q2/23	Q3/23	Q4/23	Q1/24E	Q2/24E	Q3/24E	Q4/24E
Profit before tax	-2.4	-5.4	-5.8	-28.5	-7.0	-7.5	-7.5	-7.4
Тах	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
D&A	1.0	1.2	1.3	4.0	1.2	1.2	1.2	1.2
Net financials	0.0	-0.3	0.0	9.7	0.1	0.5	0.5	0.4
Change in NWC	5.5	4.5	8.9	16.5	-44.4	0.0	0.0	0.0
Cash flow from operations	4.0	-0.1	4.5	1.7	-50.2	- <b>5.8</b>	-5 <mark>.</mark> 8	-5.8
Investments in non-current assets	-0.5	-2.7	-2.4	-2.0	-2.0	-2.0	-2.0	-2.0
Free cash flow	<b>3.6</b>	-2.8	2.1	-0.3	-52.2	-7.9	-7.9	-7.9
Net financials	0.0	0.3	0.0	-9.7	-0.1	-0.5	-0.5	-0.4
Proceeds from equity issues	0.0	3.1	0.0	0.0	8.3	75.0	0.0	0.0
Other financing activities	-0.3	-0.5	-0.6	5.9	90.2	-5.0	0.0	0.0
Paydown debt	0.0	0.0	0.0	0.0	-45.6	0.0	0.0	0.0
Net change in cash	3.3	0.1	1.5	-4.1	0.7	61.6	-8.3	-8.3
Starting Balance	5.3	10.2	10.2	10.1	6.0	6.7	68.3	59.9
Ending Balance	10.2	10.2	10.1	6.0	6.7	68.3	59.9	51.6





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### In Europe and the US, total VAP market amounts to NOK18bn

Based on a cost savings potential of NOK54bn where 1/3 is allocated to supplier

#### 130k yearly VAP cases and NOK54bn in extra costs

- Hospital costs: Studies report 70,000 and 60,000 yearly cases of VAP in Europe and the US, respectively. Estimates show that it leads to extra costs of USD47k per patient in the US and USD30k per patient in the EU<sup>1</sup>.
- **Revenue potential:** Common practice during the patent period for companies is to charge hospitals based on the cost reduction provided by the product. Typically, the industry standard ranges from 20-40%. Hence, revenue potential is based on assumption of charging 1/3 of the cost savings.

#### If SIS is approved, we assume a 10% market share by 2030

- **Patent protection:** SIS is protected by its patent family from competitors getting approval of similar products.
- **20/80 rule:** Generally, 20% of the largest companies account for 80% of the market. Assuming the 20% largest hospitals are similar in size, SIS would only need to penetrate a fraction of these hospitals to achieve substantial market presence.
- **Growth potential:** The company expects continued growth beyond 2030, driven by both high mortality rates and significant cost savings potential. However, we believe a 10% market share is fair.





#### SIS revenue potential



### SIS income margin 40% as sole focus is providing hospitals

We use peers' EBITDA post-tax as benchmark given anticipated focus on expanding market shares and product use once approved, rather than further investments



#### Potential cash earnings



#### SIS margins should be higher than that of peers

- Peers allocate significant R&D expenditure to new products in early stages, with low probability of success, leading to the recognition of these costs as opex.
- Furthermore, SoftOx will sell their product directly to hospitals, which means that marketing costs will be low. The net income margin should thus align with the product margin.



# Fair P/E of 12.5x on 2030 earnings with a 15% discount rate

Given that the project is successful

#### Median P/E 2010-20231



#### Fair P/E 12.5x as low capex reduces growth potential

- **Capex:** If SIS enters the market, there is room from growth without further capex based on market share potential of 10% and the use of product as both treatment and preventive.
- Growth: Given the assumption of no maintenance/growth capex needed, growth should align with inflation, and thus 14-15x seems like a fair multiple. However, growth variations affect multiples, and a reasonable range is [10,20], and as lower investments reduces the growth potential we argue for a more conservative valuation between P/E 10-15x.

#### Peers rNPV discount rates



#### 15% discount rate after risk adjusting

- **Methodology:** Utilizing the risk-adjusted NPV method involves the adjustment of NPV by incorporating corresponding probabilities. This method is widely used in valuing binary cases and is generally seen as a more precise estimate than adjusting for the risk of failure solely in the discount rate.
- **Discount rate:** According to studies the rates for products in mid-stage development is 10-22%. Given the high probability of SIS not being unsuccessful, we argue that 15% is fitting.



### **Shares outstanding development**

If Phase 2 is successful, we assume SoftOx will be able to issue new shares far above current share price



#### Based on an issuance price of NOK1/share, the company would have a total of 1.108m shares outstanding



### Fair value range of NOK0.53-0.69/share...

... when we assume different equity issuance prices between NOK0.5-1.5/share post-phase 2 study

Calculations 2024	NOKm	Assumptions	
		Market size (NOKm)	18,040
Revenues	1,804	Market share	10 %
Net income	722	Net income margin	40 %
Equity value	9,020	Fair P/E multiple	12.5x
Risk adjusted	1,637	Probability of Phase 2 to approval	18.2 %
Discounted	708	Discount rate	15 %
Implied share price	0.64	Shares outstanding	1,108

#### Implied value given future equity issuances at NOK1/share

### Comments

- Under the assumption of a NOK130m issuance at NOK1/share following a successful phase 2 study and NOK100m issuance at NOK1/share after market approval (these equity issuances should differ in price due to differences in risk – but we employ the same price for simplicity), there would be 1,108m shares in the company.
- With an equity value of NOK708m, this gives us a price of NOK0.64/share, or 3.2x the last private placement at NOK0.2/share.

#### Share price sensitivity





### **Sensitivities**

The company is highly sensitive to market share and probability of success in phase 2

#### Assumptions

Assumptions	
Market size (NOKm)	18,040
Market share	10 %
Net income margin	40 %
Fair P/E multiple	12.5
Discount rate	15 %
Phase 2 equity funding need	50m
Equity funding neeed ex phase 2 funding	230m
Equity issuance price post phase 2 success	NOK1/share
Probaility of phase 2 transition	30 %
Probaility of phase 2 transition, SoftOx estimate	50 %
Probaility of phase 3 transition	65 %
Probability of phase NDA/BLA to approval	95 %
Probability of phase 2 to market approval	18 %

#### Highly sensitive to market share assumption of 10%



### Compared to last private placement, the stock seems attractive despite a scenario of additional funding need for completion of phase 2 at NOK0.2/share



### Given SoftOx estimate of +50% probability of phase 2 success, and no additional funding need above the estimated NOK50m, we find a 5.3x candidate




## **Sensitivities**

## Assumptions

Assumptions	
Market size (NOKm)	18,040
Market share	10 %
Net income margin	40 %
Fair P/E multiple	12.5
Discount rate	15 %
Phase 2 equity funding need	50m
Equity funding neeed ex phase 2 funding	230m
Equity issuance price post phase 2 success	NOK1/share
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Probaility of phase 3 transition	65 %
Probability of phase NDA/BLA to approval	95 %
Probability of phase 2 to market approval	18 %

## **Discount rate sensitivity**



## Post phase 2 success, we assume NOK130m in funding to come to market approval, and NOK100m in buffer funding post market approval



## P/E Multiple sensitivity





# Scenario: SIS is owned by a sole proprietor post-phase 2...

... Using NOK230m of own funds to finance development, the expected value of SIS could be NOK3bn in 2026



compared to a market cap of NOK176m (at 0.2/share post

NOK50m equity issuance from external investor).

•

## 2026 value of company given phase 2 study success

## Present value phase 2 risk sensitivity



## Current market cap implies 10% success rate in phase 2

- If SIS was owned by a sole proprietor post-phase 2 and invested NOK130m in 2026 plus a buffer of NOK100m in 2030, expected fair 2026 value after risk adjustments would be NOK3,019m,
  - However, given SCO's belief in >50% probability, fair market value of the company can be above NOK1,091m. Current market cap at NOK176m implies a 10% probability of phase 2 success.

Studies indicate a phase 2 study success rate of 30% (average





# Scenario: SIS is owned by a sole proprietor post-phase 2...

... Using NOK230m of own funds to finance development, the expected value of SIS could be NOK3bn in 2026

## **Calculations & Assumptions**

Calculations	NOKm	Assumptions 2030	
		Market size (NOKm)	18,040
Revenues	1,804	Market share	10 %
Net income	722	Net income margin	40 %
Equity value	9,020	Fair P/E multiple	12.5x
Less buffer capital	<i>8,920</i>	Buffer capital	100
Discounted back to 2026	5,100	Discount rate	15 %
Less investment phase 3	4,970	Investment Phase 3	130
Fair value, risk adjusted	3,069	Market approval post phase 2	61.75 %
Expected value loss of Phase 3 investment	-50	Failure to meet approval	38.25 %
Fair value 2026	3,019		
Discounted back to 2024	2,283		
Risk adjusted	685	Probability of Phase 2 transition	30.0 %
Fair value 2024	685		



# When adding the 4 different outcomes...

... the expected value yields a fair value of NOK635m, based on our assumptions





# **European Defense Fund project**

Large market potential with a counteracting product to biological threats



EDF project phase 1 expected to be finalized in mid2026

The company technology of stabilized hypochlorous acid has many use cases. Within SoftOx Inhalation Solution company, there will also be an ongoing project for employing the technology for military purposes to counteract biological threats. The timeline of this project is that phase 1B is expected to commence in the middle of 2025 and completed in the middle of 2026. Thus, the project is lagging behind the VAP treatment project.

There are however some interesting findings from the project: 1) Fully covered funding of phase 1: The budget is around NOK90m and is fully financed by the European Defense Fund and Norwegian MoD. All commercial rights still belongs to SoftOx solution. 2) Synergies: With these financial muscles one optimizes the SoftOx Inhalation Solution (SIS), which they have called SIS 2.0. They optimize and increase dosages and thus, the synergies from these expenditures to the VAP part of the business are expected to be large. 3) Large market potential: One expects to be able to defeat any type of biological weapon with the technology, and thus the market potential is large. In NATO and partners, 1m soldiers can be in service within a few months, and SoftOx expects 3-years stockpiling within NATO + partners. Also, they see a possibility of a civilian spin-off for the civilian population (around 1bn people in NATO and partners) if a terror attack or the next pandemic with a potential unknown virus occurs, it might also be relevant to stockpile for the civilian population. If successful, the product is expected to be sold directly to military forces.





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## Management



## Johan Christian Harstad Chief Executive Officer

Former submarine commander and deputy leader in the Norwegian Special Operation Forces with rank of Commodore

- Experience with US Special Operations Command, Norwegian Armed Forces central staff, and Ministry of Defence
- Security policy and foreign relations studies at the US Naval War College



#### Ingrid Juven Chief Operating Officer

- 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)



#### Elin Jørgensen, DVM, PhD International Senior Project Manager

- DVM with broad clinical experience and profound research experience with infection models, especially wound models, including biofilm infected wounds
- Lead on SoftOx' commitment in the EDF project COUNTERACT (9 WPs) with development of SoftOx inhalation solution
- · SoftOx R&D expert and veterinary advisor



#### Klaus Kirketerp Møller, MD, PhD Co-inventor/ Scientific Advisory Board Member

- Medical Doctor, PhD at Copenhagen Wound Healing Center,
- Bispebjerg Hospital Denmark
- · Co-inventor of the SoftOx technology
- 15+ years' research focus on chronic wounds and bacterial biofilms



### Dr Thomas Bjarnsholt Chief Scientific Officer

- Expert in the role of bacterial and fungal biofilms in chronic infections with over 245 peer-reviewed publications
- Co-inventor of the technology with financial rights
- Professor at the Costerton Biofilm Center, Department of Immunology and Microbiology (University of Copenhagen)
- Member of the Global Wound Biofilm Expert
  Panel



## **Board of Directors**



## Geir H. Almås Executive Chairman

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



## Olav Jarlsby Non-Executive Director

- Former Counsel & Attorneyat-law, Elopak AS
- · LL.M. law (UiO)



## Henrik Nielsen Non-Executive Director

- · Founder & CEO at CAP Partner
- Director of the European Wound Management Association
- Advisory Council Member for EXCITE International
- Expertise in association management, advocacy, fundraising and organization as well as many years of experience in the medical device industry



#### Jørgen Berggrav Non-Executive Director

- Many diverse roles in Armed Forces as submarine commanding officer, Defence attaché, Director General in the Ministry of Defence, representative to the Supreme Allied Commander Transformation and "NATO's operational command, SHAPE.
- Royal Norwegian Naval Academy; German Command and General Staff Academy; Norwegian Defence University College



## Adrian Bignami Non-Executive Director

- · Early co-inventor of the SoftOx technology
- Vice President of Finance, Business Planning and Analysis at C4 Therapeutics, Inc
- Over 20 years of experience in management consulting, investment banking, entrepreneurship, business development and corporate finance across pharmaceutical and biotechnology sectors
- SM, Biomedical Enterprise Program, Harvard-MIT Health Sciences and Technology & MBA, (MIT Sloan School of Management)



## **Risks**

## Specific to the market in which SoftOx operates

- The Company relies on various partnerships for development, production, and distribution, and any failure to maintain these could hinder product development, increase costs, or prevent product commercialization.
- The Company's success relies on retaining and attracting skilled personnel, and competition for such individuals is high. Failure to maintain or protect against competitive actions from former employees could adversely affect operations.
- There is a risk that the Company's obtained patents is insufficient to prevent other competitors to commercialize competing products incorporating the Company's methods.
- The Company faces intense competition from established and new entities, and any inability to compete effectively could necessitate changes in clinical programs, increase costs, or impede product commercialization
- The biopharmaceutical market's rapid evolution requires the Company to innovate and adapt continuously; failure to do so could materially affect its business and financial success.
- The Company's competitive position and revenue depend on protecting its intellectual property, and failure to do so could allow competitors to erode its market share or lead to costly legal disputes.

## Specific to the industries in which SoftOx operates

- Pharmaceutical investments are speculative, with substantial risks due to high initial costs and the possibility that product candidates may not be effective, obtain regulatory approval, or become commercially viable.
- Completing clinical trials is critical for the Company and is subject to various internal and external factors that could cause delays or failures, impacting the ability to obtain regulatory approval and commercialize products.
- Clinical programs may need changes due to technological advances, shifts in medical science, or regulatory demands, potentially affecting the Company's capital requirements and revenue flow.
- Early positive results in product development may not predict later success, and most product candidates may never receive approval or reach the market, which could significantly impact the Company's finances and operations.
- Side effects in product candidates can hinder clinical development, prevent regulatory approval, and limit commercial potential, leading to significant negative consequences including legal disputes.
- Late-emerging side effects of approved products could lead to withdrawal of approvals, additional warnings, or reduced acceptance, potentially resulting in legal disputes and reputational damage.



## **Risks**

## Key risks specific to financial risks

- The Company's success hinges on its ability to commercialize product candidates, which involves numerous challenges including funding, clinical trials, regulatory approval, and acceptance within the medical community.
- Existing or future debt arrangements could limit the Group's liquidity and flexibility in obtaining additional financing and/or pursuing other business opportunities.
- Dependence on third-party manufacturers and suppliers exposes the Company to risks that could increase costs and delay or limit product supply, affecting the development process and time to market.
- The Company may require more funds to cover operational and development costs, and there is no guarantee that additional financing will be available on acceptable terms, if at all.
- Public grants and reimbursements play a significant role in funding the Company's projects, and the inability to secure such funding could have a material adverse effect on its operations.
- The Company cannot make any assurances that the Company will be able to continue to obtain public grants or reimbursements or to have grant applications approved in the future, on the same terms or at all.

Key risks related to laws and regulations etc.

- The Company may become subject to new or increased burdensome government regulations affecting the industry
- Legal disputes and liability claims related to clinical trials or product use could result in significant costs, distract management, damage reputation, and adversely affect the Company's finances and operations.
- The Company may not be able to obtain the required approvals or marketing authorization from health authorities(domestic or multi-national (EU, etc.) for its products, which is required in order to enter the commercial phase.
- Compliance with extensive regulations is crucial for the Company, and failure to comply or adapt to new regulations could lead to increased costs, fines, or operational shutdowns.
- Expansion into international markets involves regulatory challenges and compliance with various laws, which could lead to litigations, penalties, and other sanctions, adversely affecting the Company's business and reputation.
- The Group may be subject to legal disputes in the future.





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Recommendation	Percentage of companies under coverage with this recommendation	Percentage of companies under coverage for which SB1 Markets has provided investment banking services in the past 12 months		
Buy	57.7%	18.9%		
Neutral	31.7%	10.0%		
Sell Total	10.6% 100%	6.7%		



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