

Operational restructuring update: "New SoftOx" well equipped to play a central role in the fight against antibiotic resistant infections

OSLO – 8th of January 2024: Through 2023, SoftOx Solutions (SoftOx) has restructured the entire business, as a consequence of a cost base that was too high and an operating model that was not optimal. Following this operational restructuring, SoftOx has now initiated a process of evaluating different financing alternatives.

SoftOx's patent-protected technology has shown an excellent ability to contribute to solving some of the world's biggest health challenges, such as antimicrobial resistance and viral infections in the lungs and in wounds. *"If we succeed developing SoftOx technology for wound and respiratory care, it will be an alternative to today's antibiotic in more than 50% of the cases which lead to death from Antimicrobial Resistance in 2019"*, says Professor Thomas Bjarnsholt, Chief Scientific Officer of SoftOx Solutions AS.

"Despite the fact that last year was a tough year for SoftOx, several positive actions can be highlighted. The strategy for the new SoftOx shall soundly develop the SoftOx technology going forward and enhance shareholder value. With a clear strategy for bringing products to market and continued research & development over the next 2-3 years, our ambition is to deliver results that will confirm a significant value potential within Wound Care, at the same time as secured funding from the European Defence Fund (EDF) will further develop SoftOx Inhalation Solutions (SIS)", says Geir Almaas, executive Chairman of SoftOx Solutions.

The strategy depends on successful financial restructuring of the company, including a solution to the company's convertible debt of about NOK 67 million.

The following progress has been made during 2023:

- Changed Business Model:
 - Established a small and effective organization reducing cost base by 70%:
 - Outsourced product development for SIS and EDF.
 - Prepared a drop down of Wound & Skin care to become a separate company covering its own cost.
 - Achieved a sufficient reduction in the short-term unsecured debt.
- New Research & Development results:
 - *Next Generation SoftOx technology:* The next generation technology will have highly improved stability, even with high concentrations. An abstract of SoftOx Next Generation technology was presented at the US Military Health System Research Symposium in Florida in August.
 - *Biofilm removal:* Research results from use of SoftOx technology in dental health show a unique ability to remove oral biofilm, to prevent and treat periodontitis.

- Customer acceptance and distribution agreement
 - Talks with major international players on distribution of animal health products worldwide, and distribution of human wound rinse in Europe.

“New SoftOx” - Going forward the next two-three years

The new cost-effective business model, promising results from Next Generation technology, and additional research results, create the foundation for the strategy going forward.

Next Generation SoftOx technology – stable solutions at higher concentrations

SoftOx’ clinical studies in wounds have shown that the human body is tolerant of higher doses of the active ingredient hypochlorous acid than was originally anticipated. These findings set the conditions for the development of higher concentrations and more stable solution of hypochlorous acid than what was possible with SoftOx 's First Generation technology.

With the purpose of developing this next generation of SoftOx technology an industrial PhD program was established at the Department of Pharmacy at the University of Oslo. An abstract of Next Generation SoftOx was presented at the US Military Health System Research Symposium in Florida in August 2023. Patent pending, filed Autumn 2022.

Strategically, this technological leap means that SoftOx considers itself to have leading technology for products based on hypochlorous acid. This new technology enables the development of products with higher efficacy and longer shelf-time than what we see in the market today.

Inhalation

The EDF/COUNTERACT project has synergies to the development of SoftOx Next Generation Inhalation solution for the civilian market. The EDF project Phase I aims at regulatory bridging on API (Active Pharmaceutical Ingredient) and finding the maximum tolerated dose in humans. *“The synergies between the military development program and the civilian development are clear, and the market potential is great. Hopefully we will be able to achieve grants from future EDF-programs for phase 2 and 3 when we have successfully finished the program that has already been funded through EDF/COUNTERACT”* says Christian Harstad, Interim CEO SoftOx Solutions.

- *Inhalation Military:* Research and development continue, funded by the EDF/COUNTERACT program until Phase I study (Maximum Tolerated Dose) is completed in 2025.
- *Inhalation Civilian:* Civilian development of the inhalation project will require NOK 30 million in separate funding for a Phase II study (Proof of Concept for hospital acquired pneumonia (HAP)). To avoid double work and to keep required capital at a minimum, the company plans to conduct this Phase II study when we have maximum tolerated dose data from the EDF/COUNTERACT studies. These data will be available late 2025.

In 2023 SoftOx entered into an agreement with the University of Copenhagen for the development of the company's unique technology, where SoftOx outsources its research and product development to the University of Copenhagen.

"University of Copenhagen has some of the best scientists in the world within the field of antimicrobial resistance and infections. Together we will establish new and innovative solutions for fighting infections in the respiratory system", says Harstad.

Wound Care

During 2024, the company intends to continue the work to separate the Wound and Skin care business into a separate company. As a basis for this work, in February 2023, SoftOx obtained an external valuation of the wound technology as a stand-alone technology, which estimated a "fair market value" of the technology to be NOK 2.1 billion (USD 200 million), with significant value upside after successful completion of Phase II study.

It was a severe setback for the company when the American health authorities, FDA in January 2023 rejected the company's application to register SoftOx Wound Rinse as a Medical Device class 2 in the USA. The reason for rejection was insufficient clinical documentation.

"We had large international distributors ready to distribute SoftOx Wound Rinse and we had built up production facilities at Fornebu. With production and distribution in place, together with excellent clinical results, SoftOx Wound and Skin care would have been ready for sale or separate listing. Following this experience, we have decided to cooperate with leading partners instead of trying to do everything ourselves", says Almaas.

Establish a new SoftOx Wound and Skin company

We have considered several solutions for Wound and Skin care, including discussions of merger with a specific NASDAQ NY listed company where SoftOx should keep approximately 85% of the shares in the merged company. After careful considerations, SoftOx concluded that before seeking a listing, SoftOx should receive further clinical data. SoftOx has therefore chosen a model where we first establish Wound and Skin care as a non-listed company and prepare it for either future sale or listing.

The strategy for the new Wound and Skin company will be:

- Finance the new company with separate funding of about EUR 10 million.
- Achieve regulatory approval of Medical Device wound cleanser in Europe and US.
- Perform Phase 2 for SoftOx Biofilm Eradicator (SBE):
 - The estimated probability of success is statistically over 80%.
 - According to the external valuation report the estimated value will double after successful phase 2 (see attachments).
- Establish an outsourced production for both first- and second-generation technology.
- Through partners and distributors, bring products to market within animal health care, human wound health care, oral health care and skin disinfection.

- Within two to three years list/sell the Wound and Skin care company on a relevant international market. If successful, Wound and Skin care can finance further development of SIS or be used to pay dividends to shareholders.

SoftOx Solutions AS

Mail: ir@soft-ox.com

Phone: (+47) 977 50 071 (Chairman of the Board Geir Almås)

About SoftOx Solutions AS

SoftOx Solutions AS (SoftOx, listed on Euronext Growth Oslo) is a Medtech and clinical-stage pharmaceutical company based in Oslo, Norway, with the goal of reducing the spread of infection and emergence of antimicrobial resistance.

For more information on SoftOx, visit www.soft-ox.com