SOFTOX SOLUTIONS AS:

Refines Clinical Focus and Advances into Chronic Lung Disease Treatments

OSLO/COPENHAGEN, SEPTEMBER 2ND, 2025 – SoftOx Solutions AS ("SoftOx" or "the Company" – TICKER: SOFTX) today announced a shift in its initial clinical focus towards chronic lung diseases in the upcoming proof-of-concept (POC) trial. It will evaluate the safety of SoftOx Inhalation Solution (SIS) across escalating doses and its effects on pulmonary bacterial load, thereby establishing a foundation for additional clinical advancements. The change will not negatively impact previously announced budgets and timelines. Expected readouts from dose escalation in H1 2026, and PoC study concluded in Q1 2027.

Rationale for clinical refocusing

Over the recent quarters, the board and leadership, assisted by external experts, have carefully evaluated the strategic options for advancing SoftOx's inhaled pharmaceutical platform. Following this review, the Company has decided to refine the initial clinical focus by initiating its first PoC study in chronic lung disease, focusing on people with cystic fibrosis (pwCF), rather than ventilator-associated pneumonia (VAP). The chronic lung disease indication offers a tangible and feasible development path, and positive outcomes will demonstrate the ability of SoftOx's technology to broadly eradicate bacteria in lung infections. Such results will represent a major value inflection point and be a solid foundation for broader clinical development, either by SoftOx or in partnership, including additional chronic indications such as non-cystic fibrosis bronchiectasis (NCFB), as well as acute indications such as VAP.

Despite the availability of recent advances in the treatment of pwCF restoring the gene defect, treatment of chronic infection remains an unmet need, leading to an attractive opportunity for SIS in CF. Similarly, there is a strong clinical rationale for SIS in NCFB, given the high rate of bacterial infection within the patient population. Both of these indications are characterized by strong commercial potential due to significant addressable markets and likely favorable pricing and reimbursement modalities. The addressable market for SIS in CF is estimated to be above $600 million, and for NCFB, it could be as much as ~$5 billion, subject to market developments in this emerging therapeutic indication. SoftOx believes that SIS in these indications will be attractive partnering candidates for global pharmaceutical companies, once positive data from the forthcoming clinical trial becomes available.

Patient Population and Study Design

"The patients we are targeting for the PoC study live with infections and attend hospitals frequently for treatment. While there are differences amongst them, they form a relatively homogeneous group accessible through established networks. They are familiar with hospitalization, can reliably convey potential adverse events, treatment effects, and provide test samples, directly linked to trial endpoints. These traits are pivotal for generating convincing PoC results within viable timelines, and the revised setup of this initial patient trial allows us to document a larger dosing headroom than would have been possible in VAP," says CEO Thomas Bjarnsholt.

About the POC trial

The trial is designed in two stages: first to evaluate the safety of SIS in healthy volunteers at higher dose levels than previously tested, and then to demonstrate proof-of-concept by measuring reductions in lung bacterial load among patients with chronic airway infections. The study will be set up at the same site as SoftOx's Phase I study, ensuring that the previously communicated timelines and budgets will not be affected. The clinical trial application will be submitted at the end of September 2025, and study initiation is planned for Q1 2026 with a 12-month duration, which will require a €7-8 million investment.

Focus on value creation

"Due to the unique mode of action of SIS, SoftOx believes it may be applied effectively in several pulmonary indications. Therefore, the stronger and broader applicable PoC foundation we can generate, the better. Consequently, proving the platform in CF and expanding the therapeutic window makes compelling sense both scientifically and commercially. Although orphan, CF is a highly relevant, tangible, and commercially attractive opportunity, but equally important, results here will directly enable us to pursue NCFB, and the PoC safety and efficacy data will document the broader applicability of SIS as an inhaled pan-microbial pharmaceutical in both chronic and acute settings. We truly believe this new approach to reducing pulmonary infections has potential to positively impact the lives of thousands of patients and their families", stated COB Ulrik Spork.

Applications

SoftOx is initiating a proof-of-concept trial of its inhaled pan-antimicrobial pharmaceutical candidate (SIS) in patients with chronic lung diseases. In parallel, the Company is advancing early-stage development of the same technology as a countermeasure against biological warfare threats, under a European Defence Fund (EDF) contract in collaboration with the Norwegian Defence Research Establishment (FFI) and other European partners.

About Cystic Fibrosis (CF):

Cystic fibrosis (CF) is a genetic disorder caused by mutations in the CFTR gene, that primarily affects the lungs and digestive system. It is characterized by the production of thick, sticky mucus, which leads to chronic respiratory infections, impaired lung function, and difficulties with nutrient absorption. Advances in treatment, such as CFTR corrector drugs, have increased life expectancy, but their effects are variable, and they do not eliminate the need for anti-infective therapy. Chronic bacterial infections and inflammation remain the main drivers of disease progression and premature mortality, underscoring the continued unmet need for effective supplementary treatments. Globally, tens of thousands of individuals are affected by CF, with the highest prevalence in North America and Europe.

Beyond its direct unmet needs, CF is also considered a model disease for studying chronic airway infections in general. The pathogens, host–response mechanisms, and treatment challenges seen in CF overlap with those in other respiratory conditions, including non-CF bronchiectasis and even acute viral infections such as COVID-19, where secondary bacterial infections are a major complication. Demonstrating efficacy in CF could therefore provide proof-of-concept (PoC) for broader application of SoftOx's technology across a spectrum of airway infections.

About Non-Cystic Fibrosis Bronchiectasis (NCFB):

Non-Cystic Fibrosis Bronchiectasis (NCFB) is a debilitating, progressive respiratory disease characterized by permanent bronchial dilatation, chronic infection, excessive sputum production, and recurrent lung infections.

The disease follows a "vicious cycle" in which infection, structural lung changes, inflammation, and deterioration in mucociliary clearance (i.e., the way that the body clears the lung of mucus) perpetuate one another. NCFB can be triggered by various underlying conditions and external insults, resulting in a heterogeneous population that is difficult to treat. Like pwCF, those with NCFB (pwNCFB) are frequently infected with pathogens such as Pseudomonas aeruginosa. These chronic lung infections drive lung function decline, repeated hospitalizations, and impaired quality of life, underscoring the urgent need for new intervention strategies.

FOR MORE INFORMATION, PLEASE CONTACT:

Ulrik Spork,
Chairman of the Board,
SoftOx Solutions AS,
+45 31 38 83 87

Thomas Bjarnsholt,
CEO, SoftOx Solutions AS,
+45 20 65 98 88

Mail: ir@soft-ox.com

About SoftOx Solutions AS

SoftOx Solutions AS (ticker: SOFTX) is a clinical-stage pharmaceutical company listed on Euronext Growth Oslo. The company is developing highly effective pan-antimicrobial pharmaceuticals targeting bacteria, viruses, and fungi. The Technology is based on extensive research and development in partnership with leading Nordic research institutes.