

# Helping the world fighting infections



## ADDRESSING UNMET MEDICAL NEEDS WITH PAN-ANTIMICROBIAL SOLUTIONS

### The Solution: A pan-antimicrobial technology

SoftOx Inhalation Solution (SIS) has a broad-spectrum pan-anti-microbial effect, including against biofilms, and does not induce resistance. SIS is effective against various airway infections caused by bacteria, virus and fungi, including SARS-CoV-2, influenza, COPD exacerbations, cystic fibrosis, disease X, etc., making it a panacea of respiratory infections. Proof-of-concept data exists from animal experiments, and SIS has been proven safe and tolerable in a first-in-human trial. It is now ready for testing as treatment in Ventilator Associated Pneumonia (VAP) patients in a large Phase II trial. Significant investments have already been made in 2023/2024 to secure Drug Substance and Drug Product for the VAP project. SIS is easily administered using a CE-marked nebuliser.

### The Problem: Ineffective treatments

VAP affects 10-30% of intubated patients in intensive care units (ICUs), with a mortality rate of up to 50% despite intense antibiotic treatment. This is due to factors such as antibiotic resistance and biofilm formation.

### The Opportunity: Realizing Phase II Trials

Establishing proof-of-concept in humans through Phase II trial significantly strengthens the business case and paves the way for Phase III trial and subsequent market approval. A strategic exit upon completion of Phase II with good data is a tangible option. With over 130,000 VAP patients annually in the EU and US, the market potential for SIS as a live-saving treatment is substantial.

### The Execution: Phase II Trial Platform

VAP patients are ideal candidates for our SIS trial. SIS has the potential to save lives while demonstrating efficacy in this challenged cohort. Since VAP patients are hospitalized in ICU's, recruitment, efficient drug administration and data collection is facilitated. The trial will be conducted using an adaptive platform-based setup, in collaboration with a highly motivated incept.dk organisation.

### The Investment: A Paradigm Shift

Investment of €7M during 2025-2027 in the proof-of-concept Phase II trial in VAP patients is a pivotal step towards a paradigm shift in the treatment of respiratory infection diseases. SIS is protected by several patent families, with patents issued or pending in all relevant jurisdictions.

### Investment thesis: Transformation fuels growth

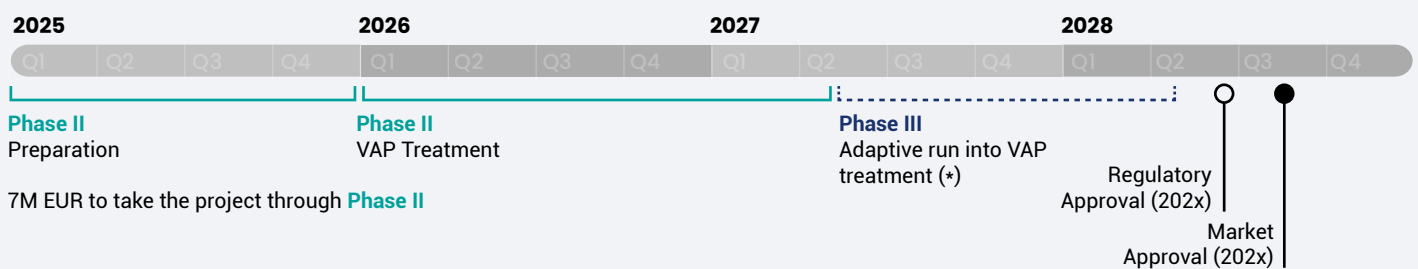
Upon a transformational restructuring of the SoftOx group, new leadership is now executing a 'venture style' ultra focused development of the key clinical asset emerged from the broad-based previous efforts within the corporation. A relatively modest investment yielding near term pivotal data, can unlock very substantial shareholder value. Current conditions allow for attractive entry value for new investors.

### The Potential: The VAP market – and beyond:

It is estimated that VAP draws costs of more than \$4 billion annually, affecting >130,000 patients in EU and US alone. Effective treatment with SIS will save both lives and costs and holds promise to fundamentally impact the way we combat any respiratory infection in the future.

## VENTILATOR ASSOCIATED PNEUMONIA (VAP)

# Clinical Development Plan (estimated timelines)



### High probability of success

- Collected all documentation to prepare CTA (Clinical Trial Application)
- Well defined group of patients
- Reaches both upper and lower respiratory parts of the lungs
- Eradicate or inactivate all relevant microorganisms
- Safe to inhale
- Proof of concept for treatment and prevention in mice
- The study will be conducted with Incept.dk at the ICUs in the Capital Region of Denmark

(\*) Soft-Ox plans to team up with relevant partner(s)

SoftOx Solutions AS, a clinical-stage pharmaceutical company listed on Euronext Growth Oslo, has been collaborating with leading research institutions since 2012 to develop groundbreaking, non-toxic antiseptic/pan-antimicrobial technology. This highly effective technology is fully bactericidal, virucidal, and fungicidal, uniquely capable of both eradicating and preventing acute and chronic infections, including biofilms, setting a new standard for infection control.

## KEY CONTACTS



### Investment

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### Science

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