

Transforming Treatment of Respiratory Infections



SoftOx Inhalation Solutions (SIS): Addressing unmet Medical Needs with Pan-Antimicrobial Solutions

SIS is a broad-spectrum, pan-antimicrobial therapy with potent activity against antibiotic resistant and tolerant bacteria, without inducing resistance. Delivered through a nebulizer, SIS offers a simple and effective approach for treating respiratory infections caused by bacteria, viruses, and fungi. Proof-of-concept efficacy has been demonstrated in animal studies, while a first-in-human trial confirmed its safety and tolerability. Building on these results, the company has recently initiated its first phase 2a proof-of-concept trial in people with cystic fibrosis (CF). Collectively, these data position SIS as a first-in-class therapeutic candidate with potential to fundamentally change how respiratory infections are treated.

The Problem: Chronic infections remain difficult to treat

CF illustrates the core challenge of chronic respiratory infections: persistent bacterial colonization and biofilm formation that render antibiotics ineffective – challenges equally seen in bronchiectasis. Despite advances with CFTR modulators, people with CF still require lifelong antimicrobial therapy, but are not adequately helped by traditional antibiotics which fail to eradicate biofilms, fuel resistance, and fall short of long-term treatment needs.

The Opportunity: Proof-of-concept in CF

SIS represents a new therapeutic principle by targeting tolerant bacteria in biofilms without inducing resistance. In CF, ~13,000 patients in the US and EU4+UK receive chronic inhaled antibiotic therapy, rep-

resenting an annual market of >\$600M, and provides a direct segway to substantially larger indications and market value in other airway diseases such as non-CF bronchiectasis (NCFB). A pivotal Phase IIa CF trial – with topline results expected in Q2 2027 – represents a near-term market validation and a major value inflection point for SoftOx, while confirming the safety, efficacy, and clinical applicability of SIS's patented mode of action.

The Execution: Phase IIa – validating approach and unlocking significant market potential

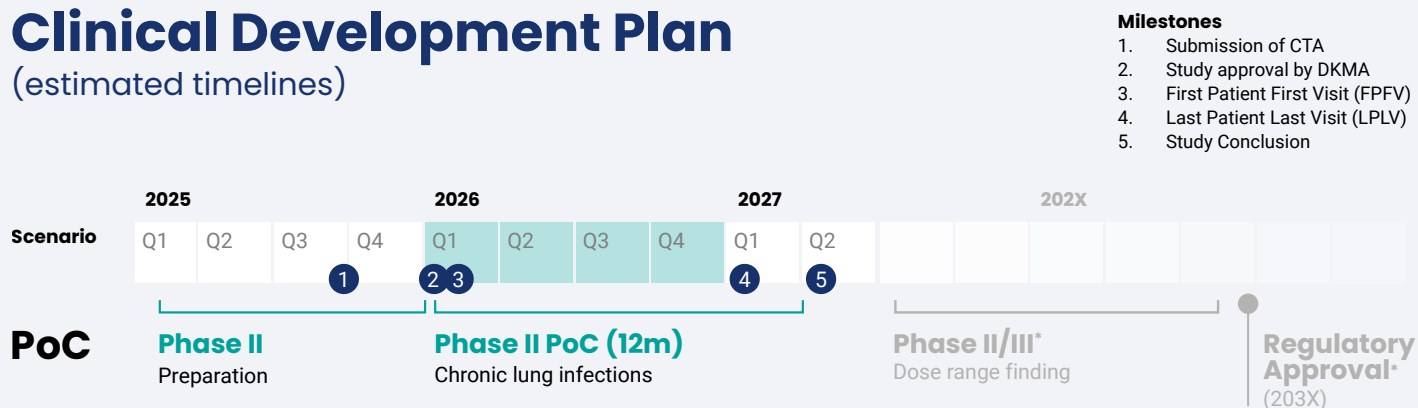
Conducted with Rigshospitalet's world-leading CF center, the trial combines dose escalation in healthy volunteers with an efficacy arm in 15–25 CF patients. The primary endpoint is a $\geq 2 \log_{10}$ reduction in bacterial load in sputum – a clinically meaningful outcome validating SIS's antimicrobial profile. Positive data will drive regulatory progression, and unlock strategic partnering opportunities.

The Potential: Beyond CF

CF serves as the strategic entry point, but the impact of SIS reaches far beyond. By overcoming biofilms, tolerance, and resistance, SIS has the potential to transform respiratory infection treatment globally. The natural next step is expansion into NCFB, affecting ~1.1 million patients across the US, EU4, and UK, of which ~445,000 form the treatable population – a multi-billion USD annual market. Beyond CF and NCFB, SIS holds promise across a wide spectrum of respiratory infections including viral and fungal pneumonias – underscoring SIS' potential as the first truly pan-antimicrobial inhalation therapy.

AIRWAY-INFECTED PATIENTS WITH CHRONIC AIRWAY DISEASES

Clinical Development Plan (estimated timelines)



De-risked path to next value inflection point

- CTA (Clinical Trial Application) submitted Q3/2025
- Using same setup and site (DanTrial) as our FIH study (SIS01) ensures no deviation from timelines
- Well-defined group of patients
- Safe to inhale
- Eradicate or inactivate all relevant microorganisms
- Proof of concept for treatment and prevention in mice
- A single center site with known partners ensures no deviation from communicated budget & timeline

(*) 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 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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