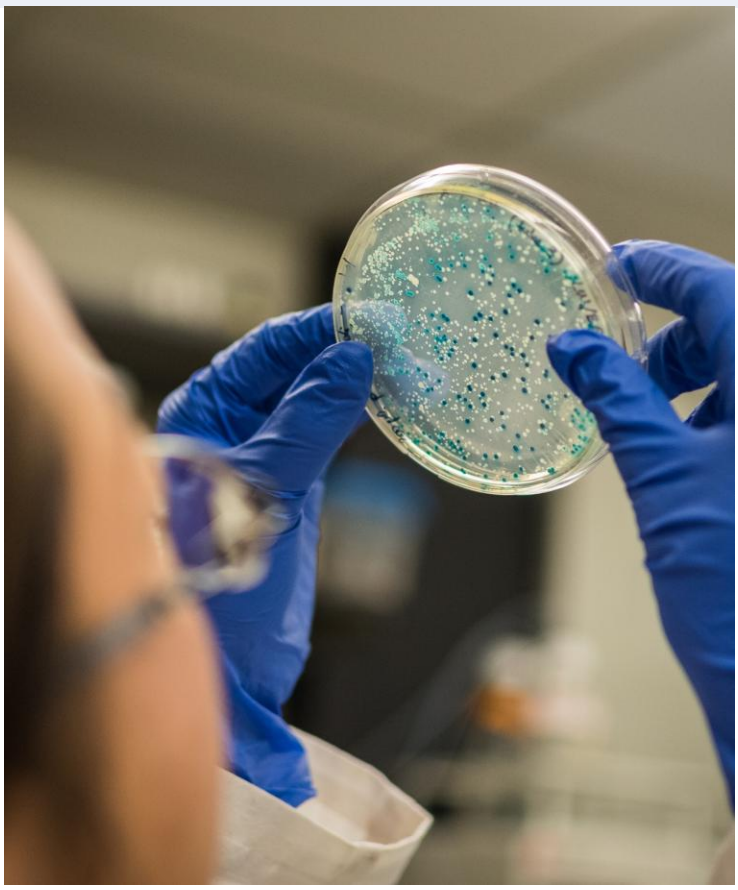
INVESTOR UPDATE

Danish Medicines Agency Approves Phase 2a Trial for SoftOx Inhalation Solution



Oslo / Copenhagen – SoftOx Solutions AS ("SoftOx") today announces that the Danish Medicines Agency has approved the Company's clinical trial application for a combined Phase 2a dose-escalation and proof-of-concept (PoC) study of the SoftOx Inhalation Solution (SIS).

This regulatory clearance marks a significant de-risking milestone for the program and materially increases the visibility and value of the SIS development pathway.

The approved Phase 2a trial includes:

- A dose-escalation study in healthy volunteers, designed to confirm safety and tolerability at increasing dose levels.
- A proof-of-concept (PoC) study in people with cystic fibrosis (CF), aimed at assessing safety at higher doses and generating key data on bacterial load reduction in the CF airway environment.

This combined study structure marks a critical advancement in SoftOx's clinical program and represents the Company's first human efficacy-oriented assessment of SIS in a target patient population.

Material de-risking and value creation

Regulatory approval removes the key uncertainty heading into Phase 2a and transitions SIS into a stage where execution is now the primary remaining risk ahead of clinical readouts. This milestone meaningfully increases the program's probability of technical and regulatory success, aligning SoftOx's clinical roadmap with industry-standard development trajectories. For investors, this represents a clear value inflection point, as SIS can now advance to human testing on a well-defined development plan and timeline.

Large commercial opportunity

SIS targets biofilm-associated infections through a patented, non-antibiotic mechanism designed to avoid resistance. In CF alone, an estimated 13,000 patients across the US and EU4+UK receive chronic inhaled antibiotic therapy, representing a market of >USD 600 million annually.

The same mechanism is relevant to non-CF bronchiectasis, a significantly larger indication affecting ~445,000 patients with a potential market opportunity exceeding USD 5 billion.

CEO Thomas Bjarnsholt comments:
"Regulatory approval of our Phase 2a trial is a transformative step for SoftOx. This milestone substantially de-risks the program and gives us a clear, predictable path into human testing. The upcoming dose-escalation readout in 1H 2026 and the PoC results expected in Q1 2027 are major catalysts for the Company as we advance SIS toward later-stage development."

Upcoming value-driving milestones

- 1H 2026: Dose-escalation topline data – a key validation point and gating event for initiating PoC testing
- Q1 2027: Final Phase 2a PoC readout – expected to be the next major value inflection point for the SIS platform

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.

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