SOFTOX SOLUTIONS AS

Investor Update

September 2025

TICKER: SOFTX

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Refine SoftOx Solutions AS: Strategic Shift to Chronic Lung Diseases

Chairman of the Board

Ulrik Spork

MSc Eng./ Civ Ing.
(Danish Technical University)

GDBA/Civiløkonom
(Copenhagen Business School)

Spork has extensive experience as Chairman, board member and advisor to emerging Life Science Companies,. Over the last 25+ years he has served on more than 30 boards internationally and deployed venture and PE investments into the global life-science industry Previous Managing Partner in Novo Holdings and head of Corporate Business Development in Novo Nordisk.

CEO/Chief Scientific Officer

Thomas Bjarnsholt

MSc (Danish Technical University)

PhD (Danish Technical University)

DMSc (University of Copenhagen)

In addtion to his work at SoftOx Bjarnsholt is a global expert within the field of biofilms in chronic infections, with over 280 peer reviewed publications. He has investigated chronic and acute lung infections for more than 20 years, both in vitro, in animal models, ex vivo material from chronic infections and directly in patients.

SOFTOX SOLUTIONS

Refine Clinical Focus into Chronic Lung Infections

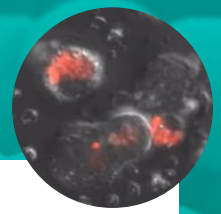
SIS 003 – Proof Of Concept (PoC)

- Clinical Feasibility
- Technology Maximization
- Tangible Market Potential

The Cystic Fibrosis (CF) pathway is a commercially valid, but also strategic, first step; creates a foundation for substantial long-term value creation in the inhaled pan-microbial pharmaceuticals space.

SOFTOX INHALATION SOLUTION

Reinforcing nature's own ability to eradicate unwanted microbes



HOCl (red) in action
produced by immune cells

HYPOCHLOROUS ACID
Documented broad antimicrobial effect

ORGANIC ACID
Antimicrobial stabilizer & biofilm eradicator

- Strong Pan-Spectrum Antimicrobial Effects: Virucidal/Bactericidal properties effectively combat a wide range of pathogens.
- Effective Against Tolerant Bacteria: Targets biofilms, overcoming challenges posed by dormant and tolerant bacteria.
- No Induction of Antimicrobial Resistance: Demonstrates no evidence of contributing to antimicrobial resistance.
- Favorable Safety and Tolerability Profile: No systemic side effects, ensuring patient safety.
- Stabilized Formulation: Maintains effectiveness and reliability throughout the shelf life.
- Completion of Preclinical Studies: All necessary preclinical studies have been successfully completed.
- First In-Human Study Conducted: No Serious Adverse Events (SAEs) reported. Predominantly mild Adverse Events (AEs): 27.9% for volunteers receiving SIS. 21.4% for volunteers receiving placebo. Excellent tolerability profile demonstrated

Synergistic properties give unique ability to eradicate infections

Not a New Antibiotic

- **Stagnant Pharma Pipeline**
  - WHO: Critical shortage of innovative antibiotics
  - Lack of financial incentives for innovation in traditional antibiotic approaches
- **SoftOx Solutions –> The Future of Antimicrobial Therapy**
  - Kills antibiotic-resistant bacteria
  - Eliminates dormant biofilm bacteria
  - No resistance development
  - Pioneering a “resistance-proof” era
- **Novel mode of action**
  - Eradicates bacteria independent of metabolism

More than 39 million deaths from antibiotic-resistant infections between now and 2050

THE LANCET
2024

SoftOx aims to transform the landscape of antimicrobial therapy and combat the critical threat of antibiotic resistance

PROOF OF CONCEPT (POC) INDICATION

Cystic Fibrosis (CF) is a model disease for "all" chronic airway infections...

Traditional antibiotics is NOT the solution

DISEASE OVERVIEW

- Cystic fibrosis (CF) is caused by mutations in the CF transmembrane conductance regulator (CFTR) gene causing viscous mucus which results in persistent bacterial infection. The bacteria are situated in biofilms tolerant to antibiotics, limiting their effect

TREATMENT DYNAMICS

- CF treatment is based on CFTR modulators, mucus thinners, antibiotics, and anti-inflammatories.
- **Despite advances with CFTR modulators, ongoing antimicrobial therapy remains essential** and a cornerstone of CF management.

SIS ADDRESSABLE MARKET

- **68K** — Prevalent Diagnosed Population US & EU4+UK
- **13K** — SIS Addressable Patients US & EU4+UK
- **$75k, €20k** — CF Pricing Benchmark US, EU4+UK
- **$ 600M** — SIS Addressable Market

Adapted from BACK BAY Life Science Advisors

SEE APPENDIX FOR DETAILED INFORMATION

UNMET NEED CF

Despite the emergence of CFTR corrector drugs, bacteria persist in the CF lung

Trikafta impact

- Approved in 2019.
- By 2023, ~89% of eligible patients were prescribed a CFTR modulator.

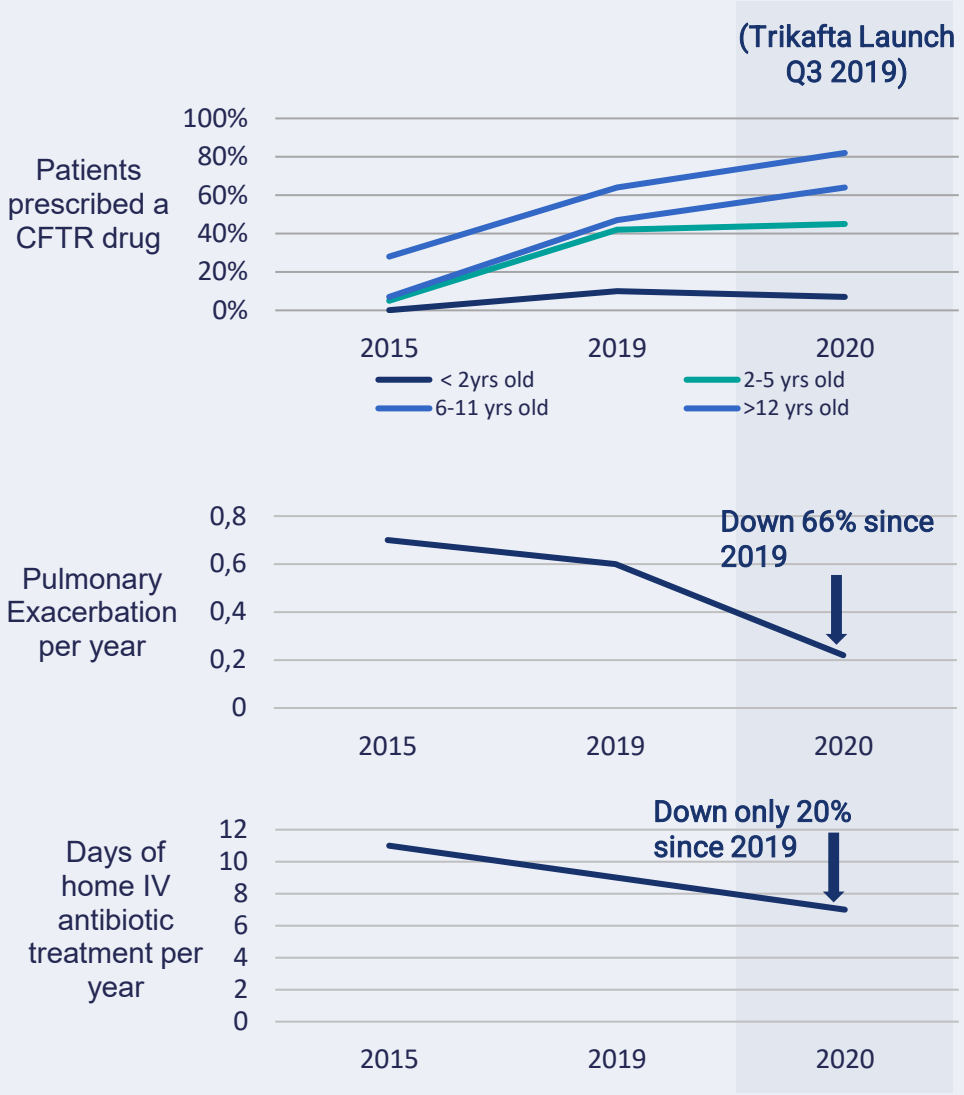
Real-world impact

- 1 fewer antibiotic course per 15 weeks.
- Modeling predicts 16–44% lower IV antibiotic need.
- Tobramycin use fell from 48% (2019) to 20% (2021) in CF patients (n=236).

***P. aeruginosa* lineages persist, despite treatment with corrector drugs**

Adapted from

BACK BAY Life Science Advisors



Antimicrobials are still needed

SOURCES: MILLER ET AL. CLIN INFECT DIS. 2022 FEB 10; 117, KEOGH ET AL. THORAX. 2021 SEP 23; 2020-216265, MIDDLETON ET AL. N ENGL J MED. 2019;381(19):1809:1819, DUEHLMEYER ET AL., J PEDIATR PHARMACOL THER. 2024 APR 8;29(2):135–139; DITTRICH ET AL., INT J INFECT DIS. 2024 FEB:139:124-131; US CYSTIC FIBROSIS FOUNDATION ANNUAL REPORT 2023

PROOF OF CONCEPT (POC) INDICATION IN CF

… opens the door to additional studies across related infections like Non-Cystic Fibrosis Bronchiectasis (NCFB)

Antimicrobial effect in CF will likely be similar in NCFB

DISEASE OVERVIEW

- Non-cystic fibrosis bronchiectasis (NCFB) is characterized by a “vicious cycle” of chronic infection, abnormally dilated airways, excessive sputum production, and recurrent lung infections.
- + Severity and frequency of exacerbations are associated with higher NCFB mortality, infection *with P. aeruginosa*, and comorbidities such as chronic obstructive pulmonary disease

TREATMENT DYNAMICS

- First approval (Aug 2025): Insmed’s Brinsupri (brensocatib) for NCFB patients ≥12 years.
- In addition, treatment focuses on symptomatic management (e.g., oral/IV antibiotics, airway clearance, bronchodilators, corticosteroids) to prevent or reduce infections and exacerbations.

SIS ADDRESSABLE MARKET

- 500k, 640k — Prevalent Diagnosed Population US & EU4+UK
- 445K — SIS Addressable Patients US & EU4+UK
- $75k, €20k — CF Pricing Benchmark US, EU4+UK
- $5B — SIS Addressable Market

Adapted from BACK BAY Life Science Advisors

SEE APPENDIX FOR DETAILED INFORMATION

A REAL EXAMPLE FROM THE CLINIC

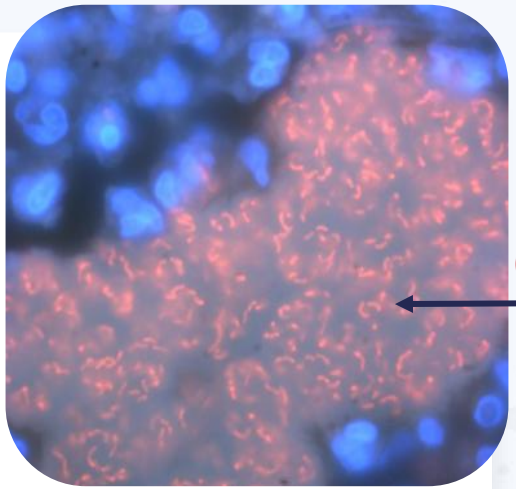
Combat the Biofilm Infections

Treatment regime

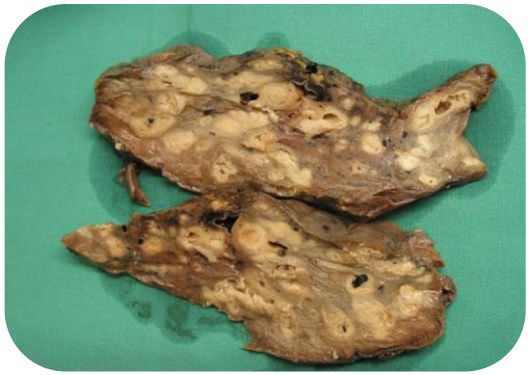
- **2-week** anti-PA treatments
- **20 years of daily colistin/tobramycin inhalations**
- **1 kg** tobramycin,
- **10 kg** beta-lactam anti-pseudomonas antibiotics and **1 kg** of inhaled colistin

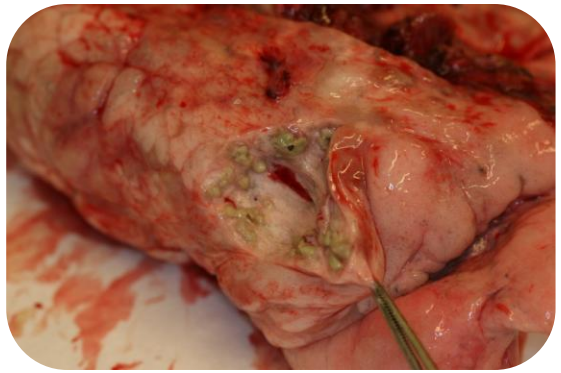
Result

Biofilm persists due to low metabolism of bacteria

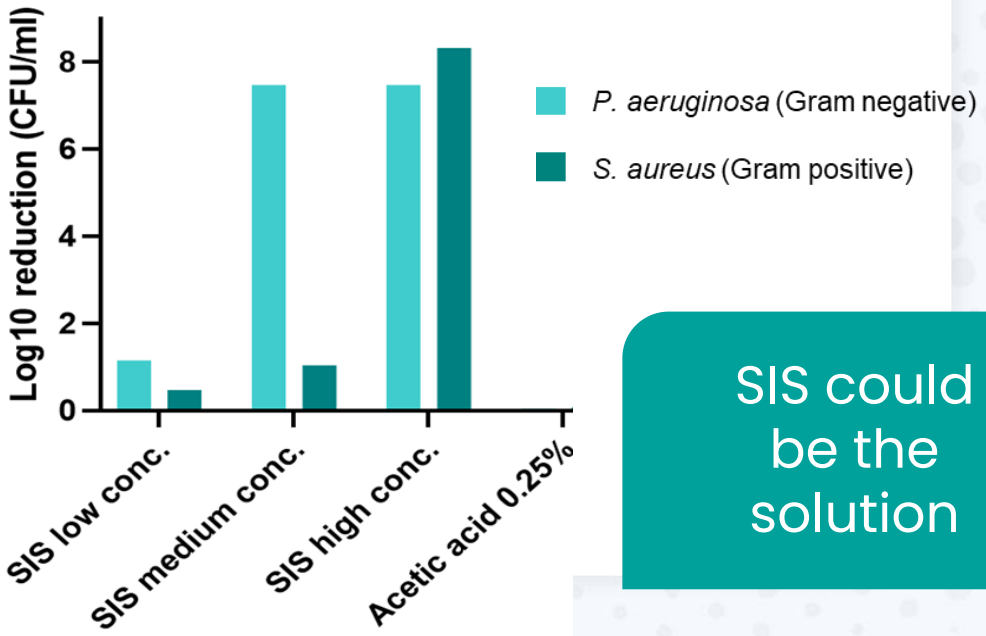


CF male, 28 years of chronic PA infection





How SoftOx can solve this



SIS could be the solution

BJARNSHOLT ET AL; *PSEUDOMONAS AERUGINOSA* BIOFILMS IN THE RESPIRATORY TRACT OF CYSTIC FIBROSIS PATIENTS; PEDIATR PULMONOL. 2009 JUN;44(6):547-58

NEXT DEVELOPMENT STEP

Phase IIa Proof of Concept (PoC) study

Study Objective & Type

- Objective: Dose escalation in healthy volunteers and evaluation of SIS03 efficacy in chronic airway diseases.
- Trial Type: Phase Ib/IIa trial, non-controlled, change from baseline comparison

Study Design

- Participants: Healthy volunteers and patients with chronic lung infections primarily CF.
- Sample Size: 18 for dose escalation and 15-25 for efficacy
- Treatment Regimen: Inhalation of SIS03 via facemask, as a standalone treatment.

Regulatory Compliance

- Designed per EMA/FDA guidance to support progression to later trials and market approval (EU/US).

Strong Study Design & Execution

- Well-defined study population
- Bacterial reduction end point possible
- Conducted with Rigshospitalet's Infection Medicine Department, a specialized CF center.

Endpoints

- Primary: Dose escalation.
- Primary (PoC): Reduction in bacterial load in expectorated sputum, ≥ 2 log10 CFU/g

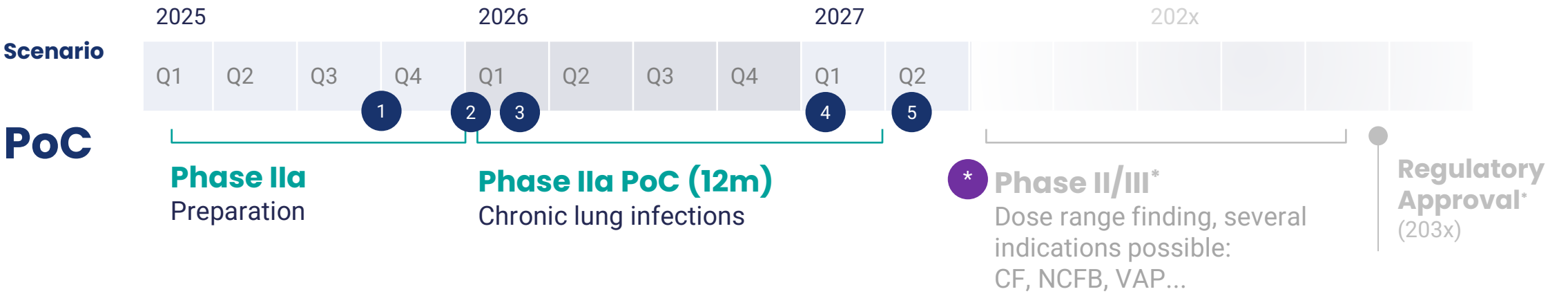
The SIS Phase IIa trial's design, partners and strong regulatory alignment, support its potential for successful PoC

AIRWAY-INFECTED PATIENTS WITH CHRONIC AIRWAY DISEASES

Clinical Development Plan (estimated timelines)

Milestones

1. Submission of CTA
2. Study approval by DKMA
3. First Patient First Visit (FPFV)
4. Last Patient Last Visit (LPLV)
5. End of Study



7-8 M EUR investment to conclude Phase IIa and conduct partnership processes

* Soft-Ox plans to enter partnerships for further clinical development and commercialization

AIRWAY-INFECTED PATIENTS WITH CHRONIC AIRWAY DISEASES

PoC study within timeframe and budget

- CTA (Clinical Trial Application) submission end of September 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

PoC Readout H1 2027

REFINED CLINICAL FOCUS SUMMARY

De-risked clinical pathway, clear proof-of-concept on bacterial load reduction, expanded market opportunities

Tangible market opportunities

- Targeting CF (~$600M) and NCFB (up to ~$5B) provides investors with clear, measurable markets. Several additional indications plausible.
- This expanded potential strengthens the revenue growth outlook and supports growth in shareholder value as data confirm progress.

De-Risked Patient Recruitment & Execution

- CF patients are well-characterized, accessible through established hospital networks, and can reliably report outcomes and provide sputum samples.
- This de-risks recruitment, reduces variability, and improves the credibility of PoC results within viable timelines.
- The use of the same CRO (as in SIS01) ensures operational continuity, with no change to previously communicated timelines or budgets.

Proof-of-Concept on Bacterial Reduction

- The PoC trial is explicitly designed to demonstrate reduction in lung bacterial load in CF patients.
- Achieving this proof validates SoftOx's technology platform and represents a major value inflection point, underpinning confidence in broader applications.

Adressing Unmet Need

- CFTR modulators do not eliminate chronic bacterial infections for CF patients, leaving a viable therapeutic gap.
- SIS directly addresses this by its unique pan-microbial modality, offering differentiated therapy in a high-priced market.

Pathways for Expansion and Partnerships

- Positive PoC results in CF open the door to additional studies in related chronic airway infections such as NCFB.
- The dual-market rationale increases attractiveness for global pharma.

Enhancing SoftOx's partnership potential

CF – Strong Commercial Potential

Key Assumptions

- Prevalence; US+ EU4+UK: ~68k patients diagnosed. 25% with *P. aeruginosa*
- TAM is ~13k patients, assuming ~84% of CF patients who are positive for P.a and >6 years old, receive chronic treatment for at least ~90 days per year with inhaled antibiotics.
- Applying an estimated annual treatment cost of $75k/€20k yields an annual market value of >$600Mio.
- Assuming a feasible market share of 15%, yields annual turnover potential of $90Mio. Additional upside exist in targeting additional bacterial species.

CF addressable market of > $600 M

INVESTMENT CASE

NCFB – Strong Commercial Potential

Key Assumptions

- Prevalence; US+ EU4+UK: ~1.140k patients
- TAM is ~445k patients, assuming ~50% of NCFB diagnosed seek treatment, and 78% experience bacterial colonisation.
- Applying an estimated annual treatment cost equal to CF pricing, would yield annual market value measured in multiple $Bn's. Analysts predict that newly approved Brinsupri™ from Insmed, will be catering for a $5Bn market by 2034.
- Applying market share estimates of 5-12% of a 20-35% TAM, yields annual turnover potential in the range $560-2.400Mio.

NCFB addressable market > $5 billion

INVESTMENT CASE

Key take-aways

- Restructuring concluded. Sole focus on **inhaled pan-antimicrobial** pharmaceuticals.
- Continue cautious **'venture style' approach** to use-of-proceeds and conducting 'mission-critical' activities only, until **value-inflection points** are reached.
- Leveraging strong **synergies with EDF sponsored countermeasure project** towards pulmonary biological warfare threats.
- Pursuing well-defined, promising and **cost-effective clinical development plan**, optimal for generating **robust data within viable timelines**. Funding certainty established, allowing **uninterrupted execution**.
- Near term target is a **PoC study in CF**/chronic airway infections. **Concluded within 18 months** - a pivotal value inflection point for SoftOx!
- CF is a **tangible and commercially attractive** initial indication, which will directly enable the pursuit of the **significantly larger NCFB indication**. Good safety and PoC efficacy data will documen the broad applicability of SIS as an **inhaled pan-antimicrobial pharmaceutical,** for both chronic and acute airway infections

SoftOx well positioned for **partnership** dialogues with **global pharma** companies by 2027.

Q&A Session

Chairman of the Board
Ulrik Spork

CEO/Chief Scientific Officer
Thomas Bjarnsholt

CFO
Ingrid Juven

Clarifications POC study

- Our PoC study will be performed in pwCF since it is a more homogenous group of patients, and we can get a direct efficacy end-point; this makes it superior to a PoC study in VAP
- We will focus on this PoC study, and we do not anticipate to start other trial activities until this study has been finalized
- There is a strong synergy between the PoC study and the EDF program, which granted all partners of the sub-project including SoftOx, a total of approximately 96 million NOK. SoftOx has received less than half of this funding directly. The EDF project is on track, and the PoC study will pave the way for defense-related trials.
- We will obtain scientific advice from EMA regarding orphan drug designation and path. SoftOx has had scientific advice from both FDA and EMA the last years

The PoC trial timeline and budget has not changed

EQUITY PLACEMENT FACILITY

Key Aspects of the Facility

Financing Facility

The financing facility with Long State Investment allows SoftOx to call for funds for a total commitment of NOK 50 million over 24 months, with the option to extend the facility to NOK 80 million over 36 months. This aligns with the cash needs of the Company in the corresponding period.

Key Aspects

Long State

- **Equity Line of Credit:**
  - Full control over timing and terms for fund drawdowns.
- **Pricing at Market Conditions:**
  - New shares will be based on market conditions with a pricing floor set by the Company.
- **Strategic Flexibility:**
  - No obligation to use the facility.
  - Does not prevent pursuing other funding alternatives.
  - The Company will continuously consider other funding sources if they become available.

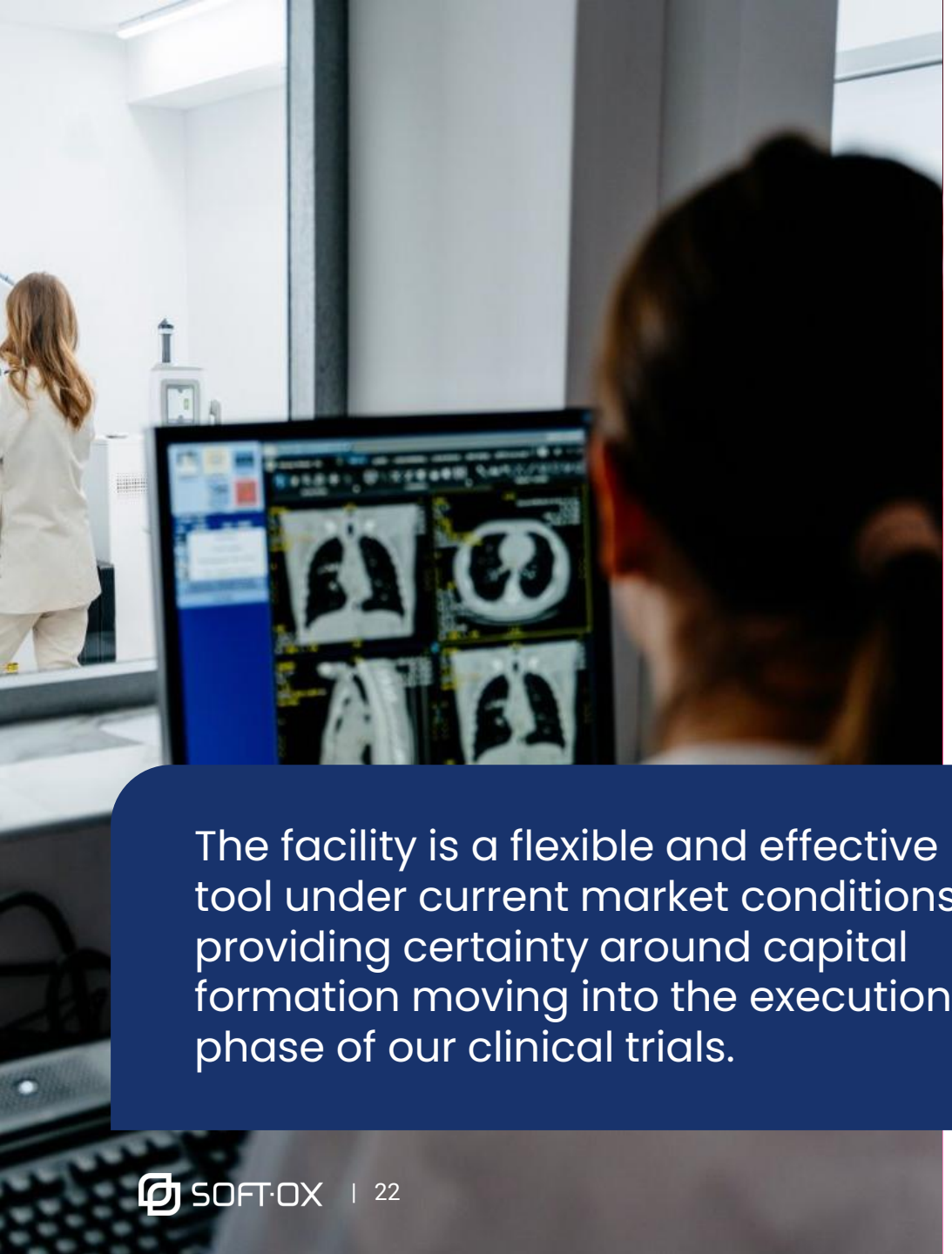
Enhances financial flexibility, supports growth objectives

EQUITY PLACEMENT FACILITY

Clarification of Aligned Interests

- Supportive Partnership & Alignment of Interests:
  - Long State focuses on supporting emerging companies through capital provision.
  - Their primary role is to provide financial flexibility.
  - No incentives in the facility to engage in activities that could undermine shareholder value.
- Loan Shares – Technical Settlement
  - 60m shares loaned by key shareholders to enable delivery-vs-payment settlement.
  - No permanent transfer of ownership; shares must be returned.
- Warrants as a Sign of Commitment:
  - The one-time grant of warrants gives Long State the right to purchase shares at a predetermined price, which aligns their interests closely with ours.
  - Their potential gains from these warrants increase with SoftOx's success.
- Market Perception:
  - Engaging in short selling is prohibited and would harm the value of Long State's investment in SoftOx and Long State's reputation.

Compensation structure ensures incentivized partnership for mutual benefit & interest in SoftOx's long-term success



The facility is a flexible and effective tool under current market conditions, providing certainty around capital formation moving into the execution phase of our clinical trials.

EQUITY PLACEMENT FACILITY

Implementation, Terms & Compensation

Implementation & Terms

- Board Authorization:
  - The share placements will be executed by our board under the authorization granted by the general meeting on June 27, 2025.
- The subscription price for the shares will be based on the volume-weighted average price (VWAP) of SoftOx's shares during the pricing period, but **not lower than the Minimum Price** set by SoftOx.

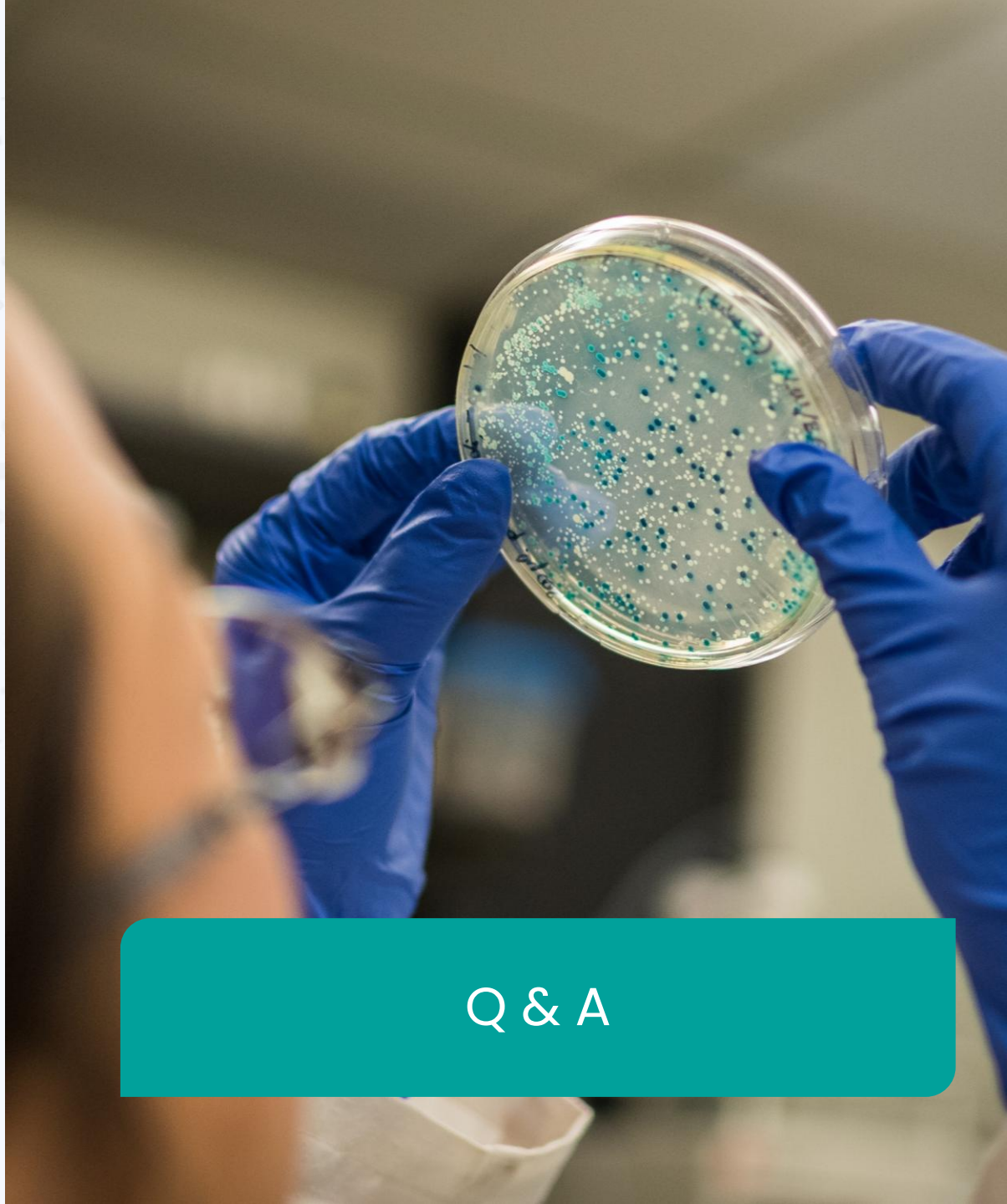
Compensation

- An implementation fee of up to 30 million shares.
- A market-based cash consideration based on a percentage of the actual invested amount.
- A one-time grant of 60 million warrants to subscribe for shares at a predetermined price of NOK 0.1506. The warrant compensation will be resolved by a forthcoming extraordinary general meeting or, if preferred by SoftOx, its cash-value equivalent at the time of grant.

INVESTOR QUESTIONS

Clarification Funding & Business Strategy

- Is VAP abandoned? VAP remains an unmet need where SIS could have an impact. One of several acute indications to explore with partners. Our current activities does not include trial in VAP patients.
- We expect that good PoC data will make SIS an attractive partnering target for Pharma, initially in CF and NCFB. SoftOx does not expect to take products all the way through to commercialization and are flexible re. the form for partnership/risk sharing. We expect that dialogues will evolve subject to data and external interest. We will not comment on such developments until concluded.
- Issue of new equity is inevitable in order to advance clinical trials. The Committed Equity Facility provides funding certainty which enables us to draw cash when needed and execute on plans. It could provide a large majority of funds needed through 2027, but the Company will execute on other available funding modalities in due time, if considered more attractive.
- Raised funds will primarily be dedicated to execution of the Phase IIa study. Currently, we are not disclosing detailed cost budgets.



Q&A Session

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20 years of experience in chronic infection research, as a Professor at UCPH.
thomas.bjarnsholt@soft-ox.com

Appendix

Both CF and NCFB are indications characterized by strong commercial potential due to significant addressable markets, high pricing potential, and likely favourable pricing and reimbursement modalities

Indication	Non-Cystic Fibrosis Bronchiectasis	Cystic Fibrosis
Prevalent Cases	US: ~473k patients EU4+UK: ~640k patients	US: ~33k patients EU4+UK: ~35k patients
Unmet Need	No FDA approved inhaled antibiotics; off-label use of CF antibiotics	2 commonly used CF antibiotics (tobramycin and aztreonam)
Competitive Intensity	Limited; 9 assets in the pipeline, 1 antibacterial in Phase 2 of development	Limited; most innovation in CFTR modulators, only 4 antibacterials in Phase 2, none in Phase 3
Treatment Duration	Acute and Chronic use	Acute and Chronic Use
Development Costs	Chronic patients, longer and larger trials but more feasible outpatient	Chronic rare disease requiring specialized centers but smaller sample sizes
Orphan Drug Designation	No	Yes; rare disease
US Reimbursement Dynamics	Medical benefit	Medical benefit
Pricing Benchmark	Current branded therapies (e.g., anti-inflammatory Brinsupri (brensocatib) at $88k/annually)	Current branded antibiotics (e.g., Cayston and TOBI Podhaler at $70-75k/annually)

Sources: Back Bay Analysis

Market opportunities assessed in collaboration with qualified advisors

BACK BAY Life Science Advisors | PREPARED FOR | SOFTOX |

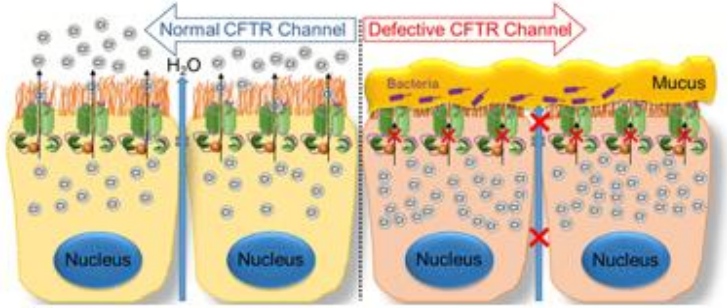
SOURCES: BACK BAY ANALYSIS

Cystic fibrosis (CF) lung disease is characterized by persistent bacterial infection, resulting in accelerated loss of pulmonary function and early mortality

CF Overview

Disease Background

- CF is a multisystem disorder caused by mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, which causes buildup of mucous in the lungs
  - Over 300 mutations of the CFTR gene are known to cause CF
- The mucous clogs the airways and traps bacteria, leading to infections, worsening lung function and eventually causing respiratory failure
  - Lung infections in CF are difficult to treat as bacteria produce a layer of biofilm that block antibiotics from reaching the bacteria



Types of Pathogens

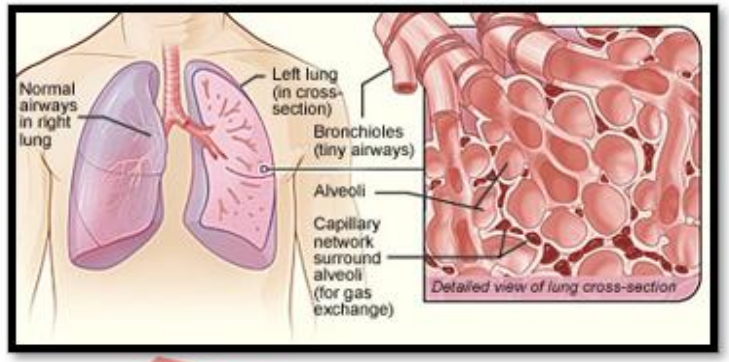
- *Staphylococcus aureus* and *Pseudomonas aeruginosa* are the most prevalent pathogens of persistent CF lung infection
  - Chronic infection with *P. aeruginosa* infection is an independent risk factor for mortality

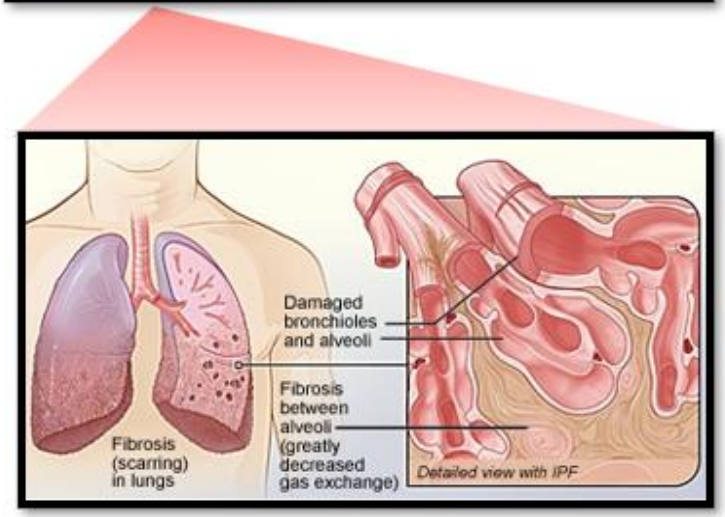
Symptoms of CF Exacerbations

- CF is punctuated by acute episodes of worsening pulmonary status that are referred to as "pulmonary exacerbations", which include increased cough, chest and nasal congestion, and fatigue

Sources: UpToDate, Middleton et al. N Engl J Med. 2019;381(19):1809:1819

Normal Lungs





Lungs with Cystic Fibrosis

SoftOx Implications

CF is a model disease for "all" chronic airway infections

Despite the widespread availability of CFTR modulators in cystic fibrosis (CF), treatment of chronic infection remains an unmet need, leading to an attractive opportunity for SIS in CF

68k	13k	55 pts, 2 yrs	$75k, €20k
Prevalent Diagnosed Population US & EU4+UK	SIS Addressable Patient Population US & EU4+UK	Ph 2b PoC Trial Size, Duration	CF Pricing Potential US, EU4+UK

Disease Overview

- **Cystic fibrosis (CF) lung disease is characterized by persistent bacterial infection**, caused by mutations in the CF transmembrane conductance regulator (CFTR) gene, resulting in accelerated loss of pulmonary function and early mortality
  - + CF is punctuated by acute episodes of worsening pulmonary status that are referred to as "pulmonary exacerbations," which include increased cough, chest/nasal congestion, and fatigue
- *Pseudomonas aeruginosa* is the most commonly treated bacterial species in CF patients, with approximately 50% either intermittently or chronically colonized

Treatment Dynamics

- CF treatment focuses on managing symptoms, improving lung function, and addressing the underlying cause of the disease with CFTR modulators, mucus thinners, antibiotics, and anti-inflammatory agents
  - + Chronic airway infection is a major contributor to disease progression in CF and an independent risk factor for reduced survival; therefore, **despite advances with CFTR modulators, ongoing treatment of infection remains recommended and will likely continue to be a cornerstone of CF management**
- The CF development pipeline is limited, with no therapies in 3 and only four antibacterials in 2

Trial Considerations

- Based on benchmark trials of CF therapies (i.e., BiomX's BX004, Clarametyx's CMTX-101, Gilead's Cayston), a proof-of-concept and pivotal trial would likely entail:
  - + Phase 2b trial: ~55 patients, ~2 years, primary endpoint of Δ in sputum bacterial burden from baseline
  - + Phase 3 trial: ~200-300 patients, ~3 years, primary endpoint of Δ in CFQ-R Respiratory Symptoms Scale (RSS) Score

SIS Opportunity

- **The total addressable market for SIS in CF is ~13k patients across the US and EU4+UK**
  - + The main opportunity for SIS is in patients with chronic *P. aeruginosa* infections, as ~84% of these patients are currently treated with chronic inhaled antibiotics
- Using CF cost analogs such as inhaled antibiotics (e.g., Cayston, TOBI Podhaler) and CFTR modulators (e.g., Vertex's Alyftrek, Trikafta), SIS can likely be priced from $70-80k/year in the US and €20k/year in the EU

Sources: Back Bay analysis

SoftOx Implicatons

Unmet Need
- 13k addressable patient population
- $75k, €20k pricing benchmark

Addressable market:
- $600 million

Non-Cystic Fibrosis Bronchiectasis (NCFB) is a debilitating and progressive chronic respiratory disease, characterized by abnormally dilated airways, excessive sputum production and recurrent lung infections

NCFB Overview

Disease Overview – NCFB is a chronic lung condition caused by permanent bronchial dilatation and inflammation, and is characterized by daily cough, sputum, and recurrent exacerbations

- Bronchiectasis is characterized by a "vicious cycle" of chronic infection, structural lung changes, inflammation, and deterioration in mucociliary clearance (i.e., the way that the body clears the lung of mucus)
- Bronchiectasis may be triggered by various diseases and external insults, resulting in a heterogeneous population that is difficult to treat
- NCFB patients colonized with *Pseudomonas aeruginosa* are at a higher risk of declining lung function, impaired quality of life, higher rates of hospital admissions (~6-7x) and worse mortality (~3x)

Diagnosis - Diagnosis is established using CT scans, and is also useful in determining the severity of the disease and detecting an underlying cause

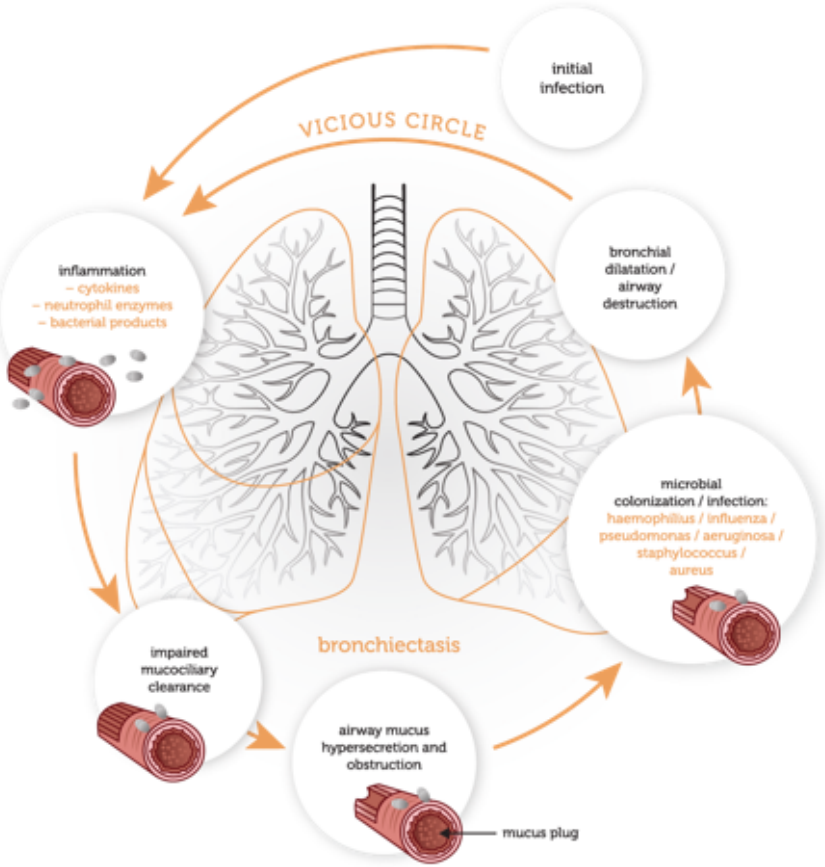
Treatment – Insmed's Brinsupri (brensocatib) was the first FDA-approved NCFB therapy in August 2025, following a demonstrated reduction in bronchiectasis exacerbations in the Phase 3 pivotal trial

+ Prior to Brinsupri's approval, disease management mainly included symptomatic treatments to prevent or reduce respiratory infections and exacerbations (*for details see slide 40*)

Prognosis and Survival: Mortality is higher for NCFB patients with frequent and severe exacerbations, infection with *P. aeruginosa*, and comorbidities, such as chronic obstructive pulmonary disease

Unmet need - Lack of approved therapies to improve respiratory function, decrease exacerbations and eradicate *P. aeruginosa* remain key unmet needs

"Vicious Cycle" of Bronchiectasis



Bronchiectasis Toolbox (bronchiectasis.com.au)

Sources: UpToDate, Baker & Karamooz, JAMA. 2025;334(3):253–264

SoftOx Implicatons

POC in CF could make SIS technology Phase 2b) ready in NCFB

There is a strong rationale for SIS in non-cystic fibrosis bronchiectasis (NCFB), due to the high rate of bacterial infection within the patient population

500k, 640k	445k	145 pts, 2 yrs	$75k, €20k
Prevalent Diagnosed Population US & EU4+UK	SIS Addressable Patient Population US & EU4+UK	Ph 2b PoC Trial Size, Duration	CF Pricing Potential US, EU4+UK

Disease Overview

- Non-cystic fibrosis bronchiectasis (NCFB) is characterized by a "vicious cycle" of chronic infection with abnormally dilated airways, excessive sputum production, and recurrent lung infection
  - **Severity and frequency of exacerbations is associated with higher NCFB mortality**, infection *with P. aeruginosa*, and comorbidities such as chronic obstructive pulmonary disease

Treatment Dynamics

- **In August 2025, the first NCFB therapy was approved** (Insmed's Brinsupri (brensocatib) in patients ≥12 years of age)
  - Prior to this recent approval, treatment primarily consisted of symptomatic disease management (e.g., oral/IV antibiotics, airway clearance techniques, bronchodilators, corticosteroids) to prevent or reduce respiratory infections and exacerbations
- **The NCFB pipeline is very limited, with a total of 9 assets in development**; with 1 antibacterial in Phase 2 (AstraZeneca's AZD-0292 *P. aeruginosa*-targeting bispecific)

Trial Considerations

- Based on precedent trials (i.e., Insmed's Brinsupri, Armata's AP-PA02, AstraZeneca's AZD-0292) a proof-of-concept and pivotal trial would likely entail:
  - Phase 2b trial: ~145 patients, ~2.5 yrs, primary endpoint of Δ in sputum bacterial burden from baseline, # of adverse events
  - Phase 3 trial: ~984 patients, ~4 yrs, primary endpoint of Reduction in pulmonary exacerbations over ~52 weeks

SIS Opportunity

- **The total addressable market for SIS in NCFB is ~195,000 patients in the US and ~250,000 patients in the EU4+UK**
  - Based on a prevalent population of 500k patients in the US and 640k patients in the EU, assuming ~50% of NCFB patients seek treatment and ~78% of patients experience bacterial colonization
- Cost analogs such as CF inhaled antibiotics (e.g., Cayston, TOBI Podhaler) and recently-approved Brinsupri lead to potential pricing assumptions of ~$75k in the US and ~€20k in the EU

Sources: Back Bay analysis

SoftOx Implicatons

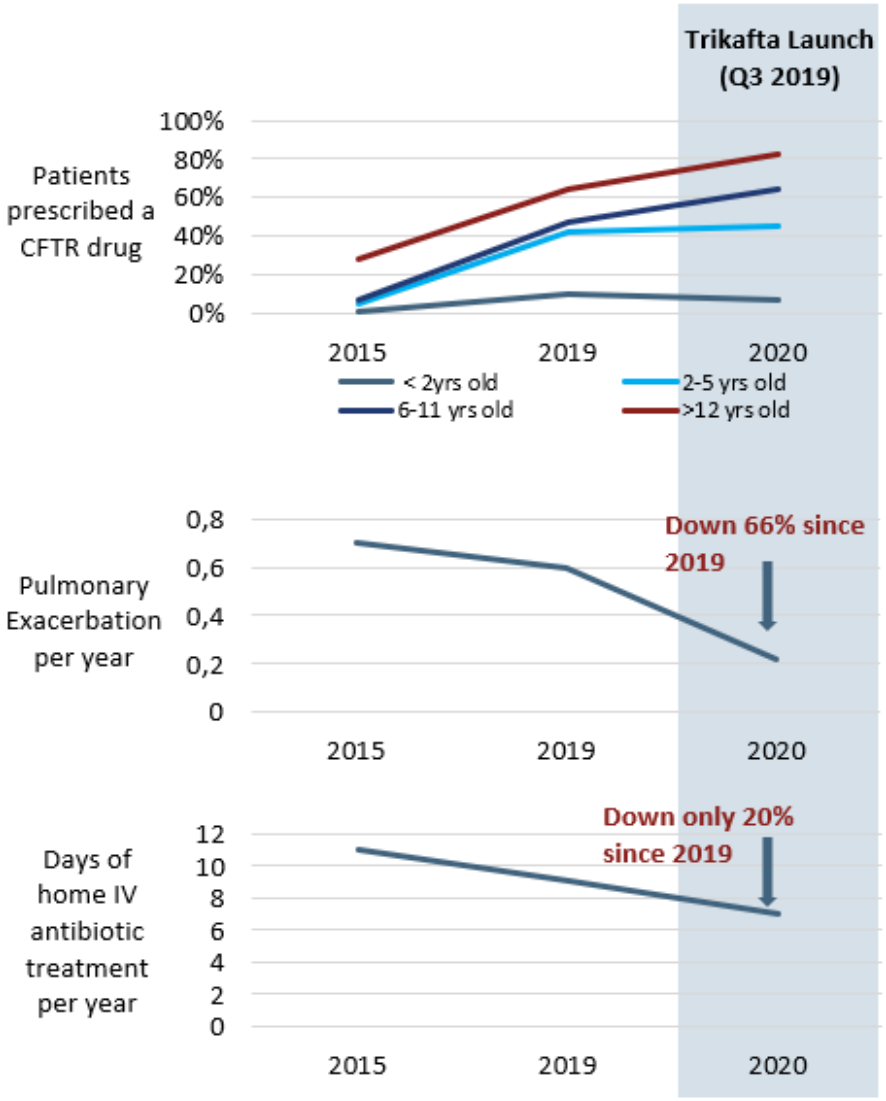
Unmet Need

- 445k addressable patient population
- $75k, €20k pricing benchmark

Addressable market:

- $ 5 Billion

The antibiotic treatment of respiratory infections will remain the mainstay of CF therapy for the foreseeable future despite the emergence of CFTR drugs as patients continue to experience infections



Unmet Need

- With the launch of the triple combination CFTR therapy Trikafta in 2019, ~92% of CF patients are now eligible for CFTR therapies based on genotype but not currently approved for patients < 6 years old
- In 2023, ~89% of CF patients who were eligible for a CFTR modulator was prescribed one, with Trikafta being the most frequently prescribed CFTR therapy in ~83% of those patients
- In pivotal studies, Trikafta led to a 63% decrease in pulmonary exacerbation (PEX) compared to placebo
  - Events leading to IV antibiotic use also decreased by ~80%
  - **CF patients (44%) continued to experience infective pulmonary exacerbation of CF while on Trikafta**
- Trikafta decreases lung infection-related visits with 1 fewer antibiotic prescription regimen over a 15-week period
  - Modeling studies predict the drug will decrease the Pharmacal need of IV antibiotics in the CF population by ~16-44%
- A retrospective study of inhaled tobramycin prescriptions for chronic infections in CF patients (n=236) observed a reduction in prescriptions from 48% in 2019 (Trikafta launch year) to 20% in 2021
- Nonetheless, *P. aeruginosa* clonal lineages have been found to persist after treatment with Trikafta
  - In a study evaluating changes in the detection frequencies of *P. aeruginosa* and *S. aureus* for 21 months before and after initiation of Trikafta (n=1,092) reported a decrease in detection from 39.9% to 22.6% and from 54.3% to 40.2%, respectively

SoftOx Implicatons

Antimicrobial treatment is still needed

Sources: Miller et al. Clin Infect Dis. 2022 Feb 10; 117, Keogh et al. Thorax. 2021 Sep 23; 2020-216265, Middleton et al. N Engl J Med. 2019;381(19):1809:1819, Duehlmeyer et al., J Pediatr Pharmacol Ther. 2024 Apr 8;29(2):135–139; Dittrich et al., Int J Infect Dis. 2024 Feb:139:124-131; US Cystic Fibrosis Foundation annual report 2023