

SOFINNOVA

PARTNERS FOR LIFE



Unleashing the True Potential of Inhalation Therapy

*People living with rare lung diseases are
at the center of everything we do*

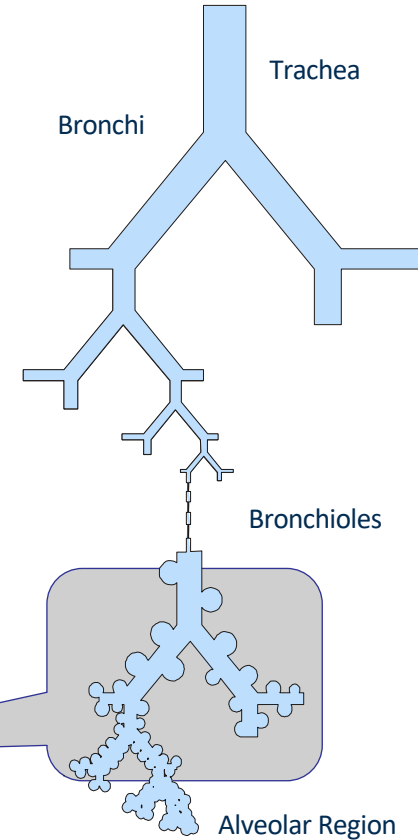
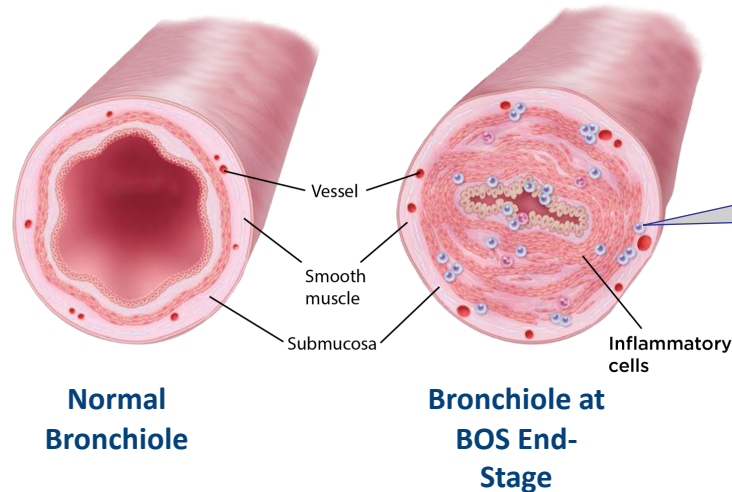
Confidential & Privileged Information



Medical Indication

Bronchiolitis Obliterans Syndrome is a life-threatening disease where the immune system attacks the small airways of the lungs

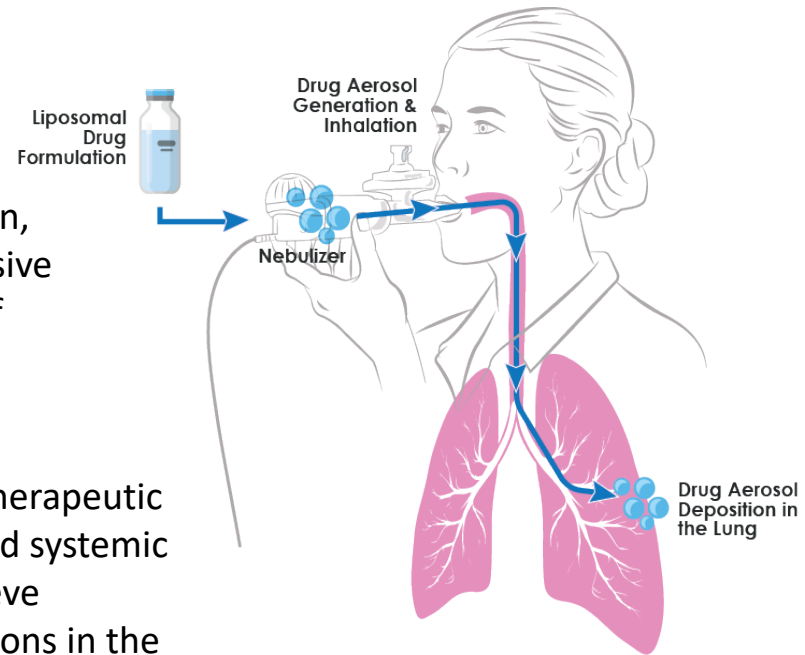
- Bronchiolitis Obliterans Syndrome (BOS) is synonymous for obliteration of the small airways accompanied by persistent decline in lung function
- Histopathology of airways affected by BOS show a T-cell mediated inflammatory process that results in fibrous scarring and obstruction of the respiratory bronchioles



Therapeutic Concept

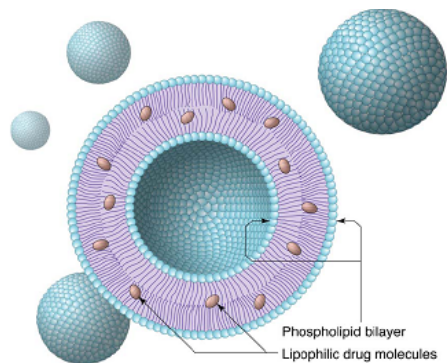
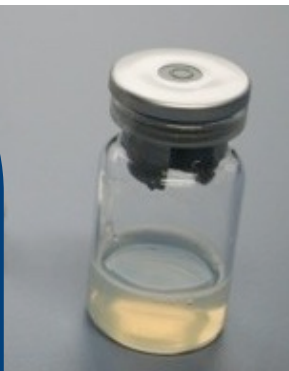
BREATH's core expertise is fast and high dosed pulmonary drug delivery, a concept which can directly target the BOS-related site of action in the lung

- Cyclosporine A (CsA) is a proven, highly potent immunosuppressive drug with appropriate mode of action to treat BOS
- Due to nephrotoxicity the therapeutic window of CsA is narrow and systemic administration cannot achieve sufficiently high concentrations in the lung
- For the first time BREATH's novel CsA-formulation (L-CsA-i) enables the inhalation of an immunosuppressive drug, whereby BOS can be treated directly at the related site of action in the lung with high local drug concentrations and low systemic exposure, minimizing the risk for adverse events.



Drug Candidate

Liposomal
Cyclosporine A
for inhalation
with eFlow[®]
nebulizer
is a fixed
drug-device
combination
product with
multiple layers
of IP protection



L-CsA-i Drug

Novel liposomal drug formulation
of Cyclosporine A with FDA & EMA
Orphan Drug Designation for the
"Treatment of BOS"

eFlow[®] Nebulizer

Drug-specific, high-performance nebulizer system for L-CsA-i
with world-wide exclusive rights



Leadership & Team

BREATH's expert team with ~20 people in the US and Europe is uniquely suited to develop and bring L-CsA-i to market

- Management and team are professionals with proven track record and specialized skills in strategy and execution, drug formulation, manufacturing, aerosol drug delivery, clinical development and commercialization



Jens Stegemann, PhD
Chief Executive Officer



Anne Burger
Chief Financial Officer



Noreen Henig, MD
Chief Medical Officer



Peter Shadday
Chief Commercial Officer



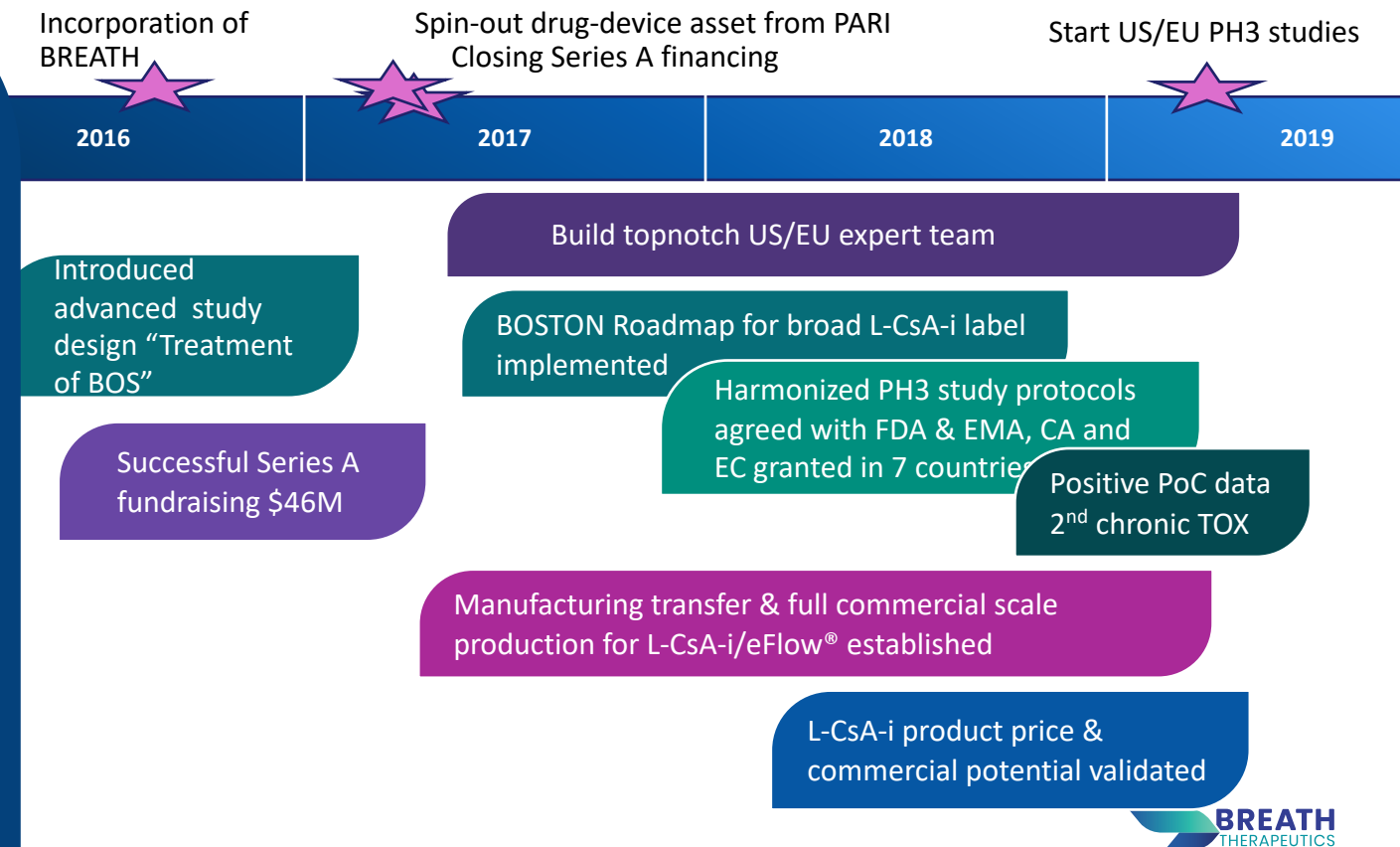
Oliver Denk, PhD
Chief Operating Officer

- BREATH has established EU/US offices in Munich and SF Bay Area



Proven Track Record

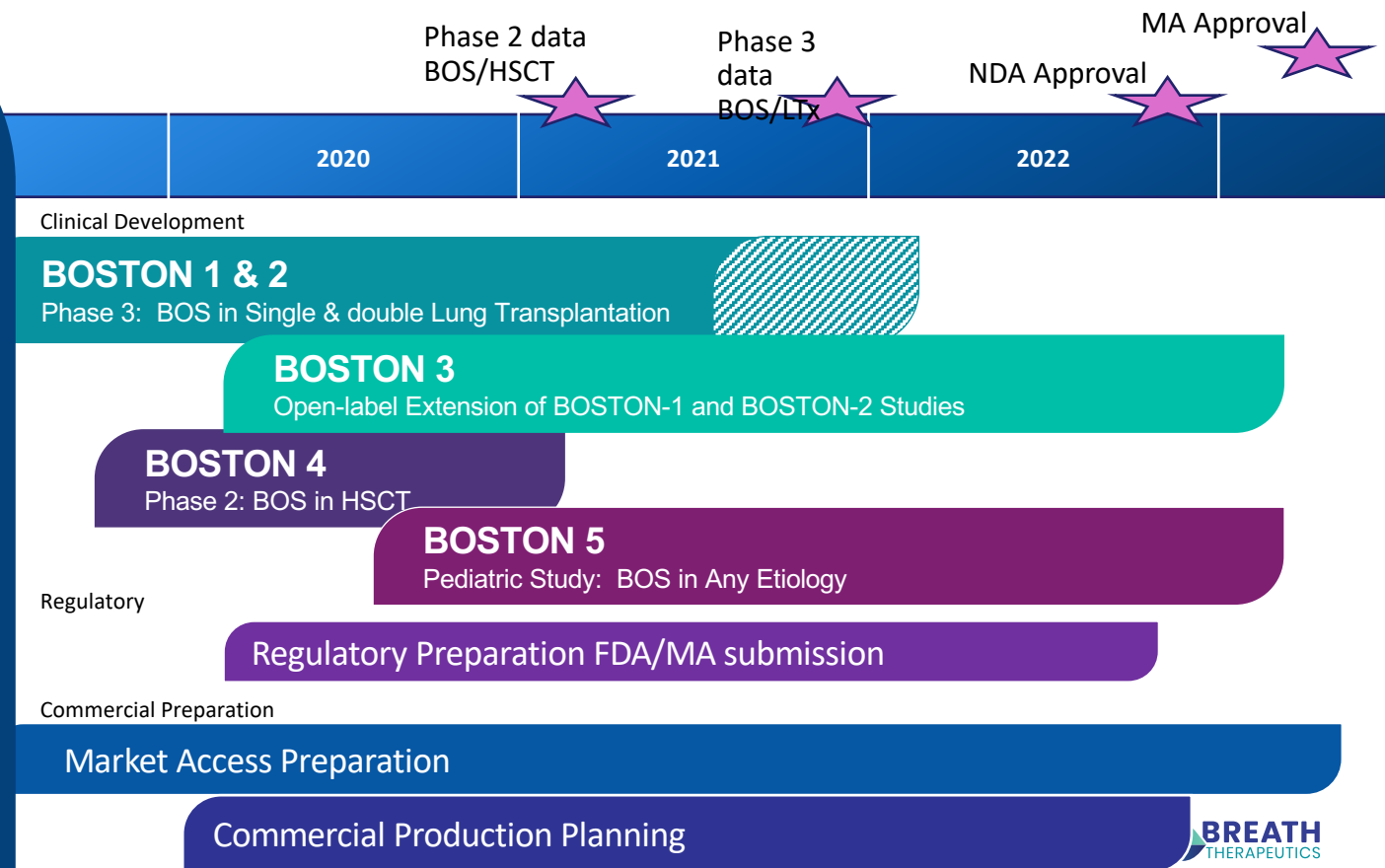
BREATH has established itself as the “BOS Company” with a lead drug in Phase 3 and validated commercial opportunity and no competition in clinical stage



Future Development Plan

BREATH has a clear development plan straight forward to FDA & EMA drug approval and own product commercialization

Next financing round is aimed to close Q4/2019



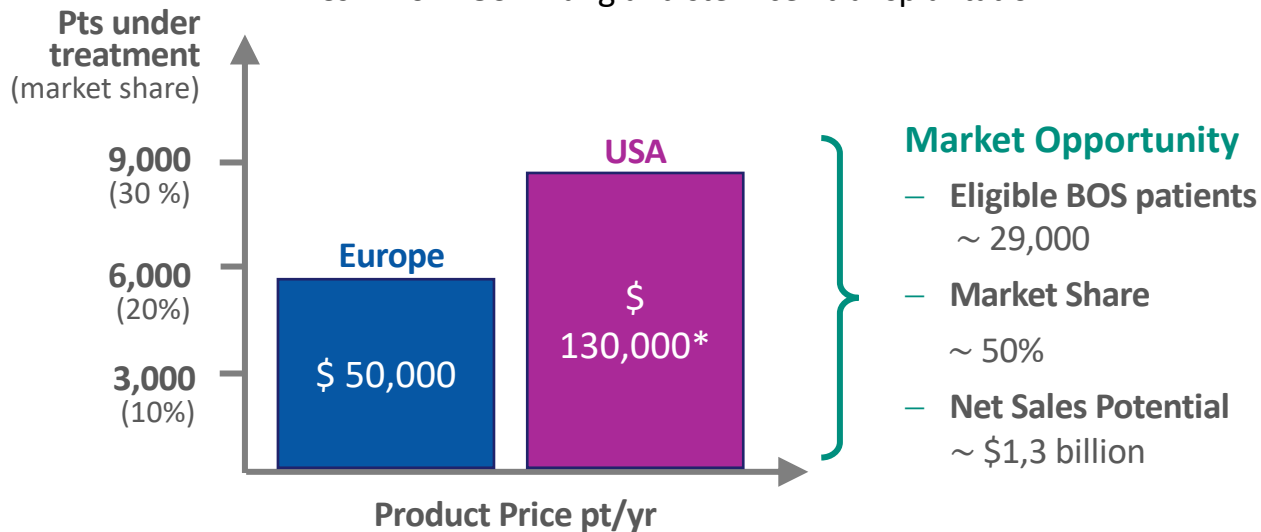
Market Opportunity

L-CsA-i in BOS is a first in class orphan drug for a very high unmet medical need

Peak global sales potential of over \$1 billion are driven by a concentrated and high price US market

Sales estimate for combined US/EU market

L-CsA-i for BOS in lung and stem cell transplantation



- Market opportunity has been validated and confirmed, also by potential strategic partners
- US price of L-CsA-i will be strongly supported by recently FDA approved reference product from Insmed*
- A lean commercial sales model and attractive sales margins are supporting the business case

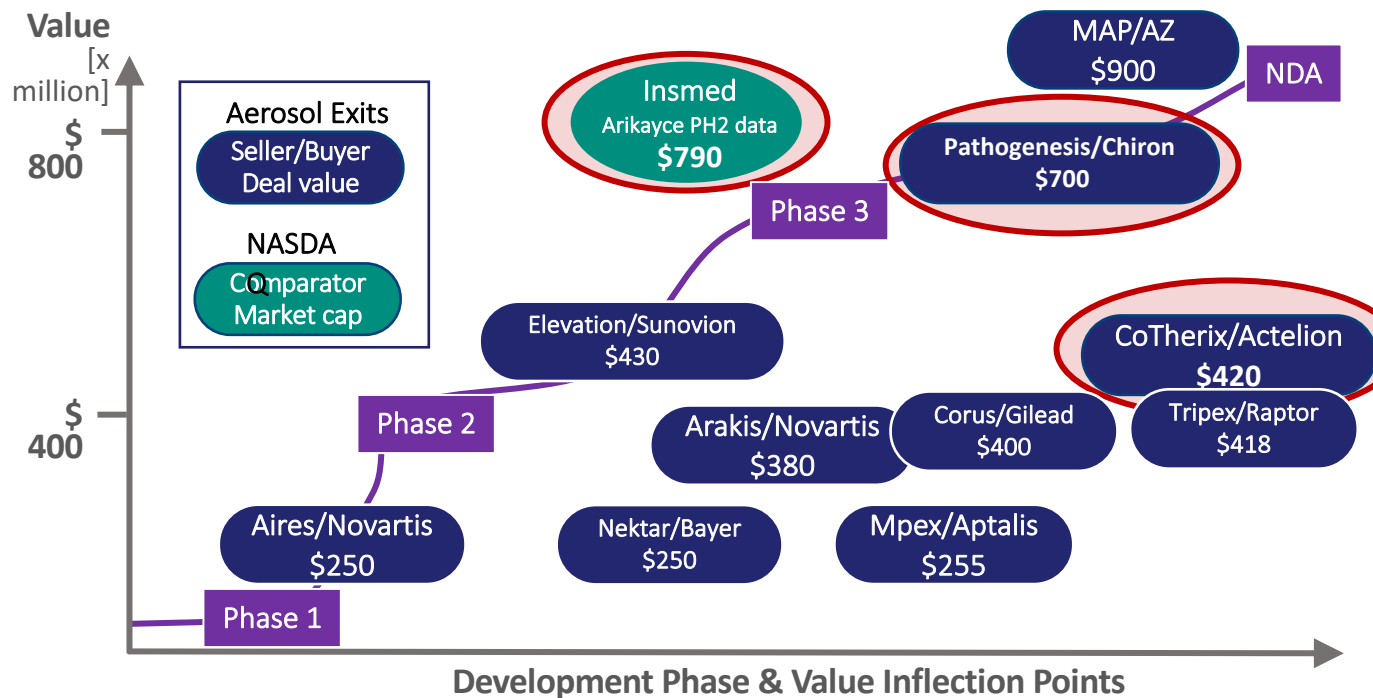
*Arikayce®, amikacin liposome inhalation suspension for inhalation with PARI eFlow technology for the treatment of Mycobacterium avium complex (MAC) lung disease. FDA

Reference Values

BREATH has generated a significant increase in value and an early on M&A potential

Well-known companies and deals in respiratory can serve as reference for BREATH

Deal Values & Market Cap in Respiratory



- Best reference values for Breath Therapeutics are **Pathogenesis** (First-in-class inhaled antibiotic in CF), **CoTherix** (First-in-class inhaled vasodilator in PAH) and **Insmed** (First-in-class treatment MAC infections)



LEVERAGE OUR EXPERIENCE IN **SPIN-OFF** TO NEGOCIATE THE
DEAL WITH PARI 



RAISED **\$46m SERIES A SYNDICATE** WITH 3 INVESTORS
– 31% FOR SOFINNOVA CAPITAL VIII



WORKED ON **BUILDING MANAGEMENT TEAM**



PLAYED A KEY ROLE IN THE **SALE TO ZAMBON** FOR A TOTAL
COMPANY VALUE OF UP TO \$476m



2.5 Y from SERIES A to EXIT