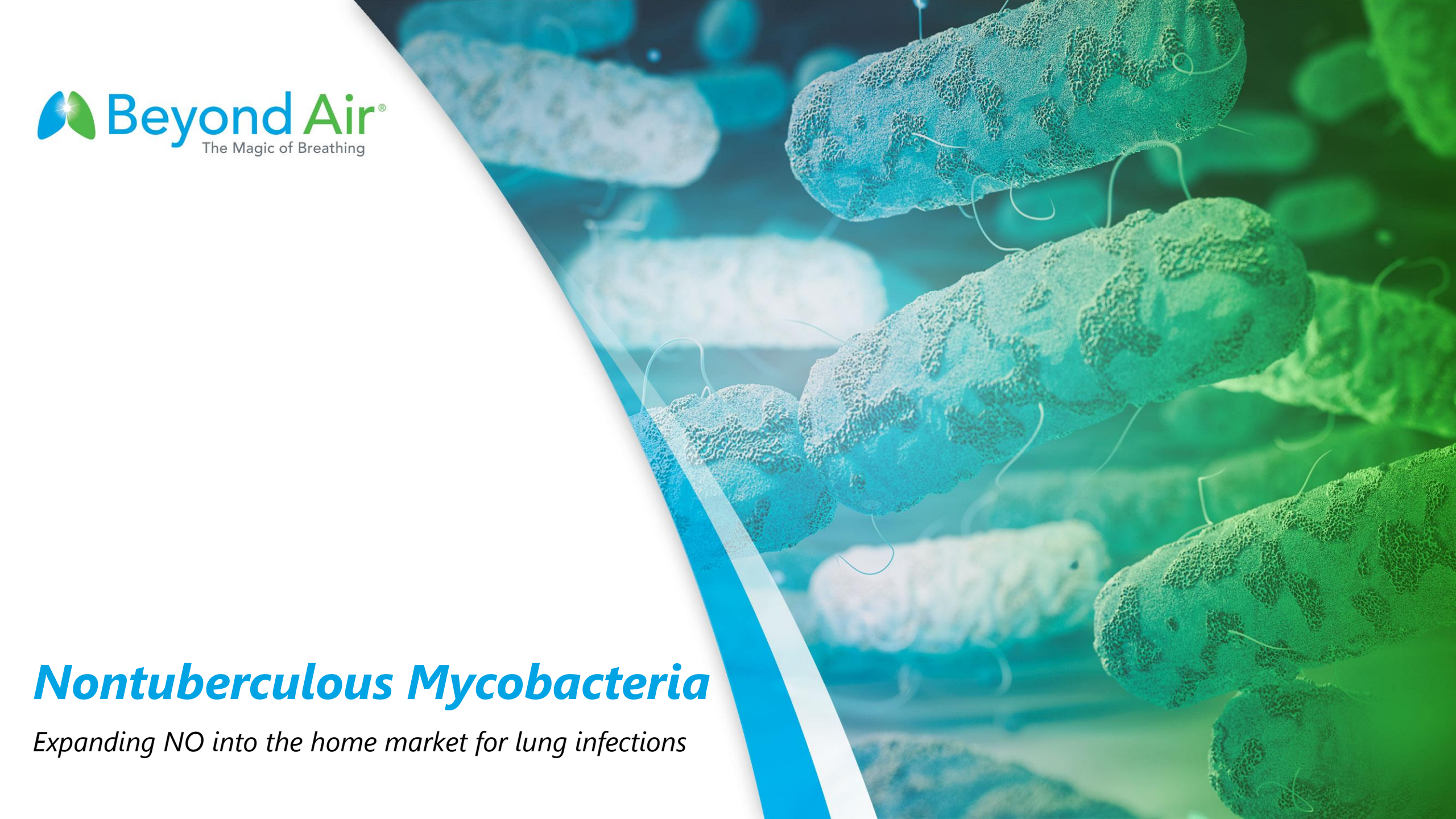
Beyond Air®
The Magic of Breathing



Nontuberculous Mycobacteria

Expanding NO into the home market for lung infections

Home Market: Nontuberculous Mycobacteria (NTM)

NTM is an FDA disease area of focus with limited treatment options

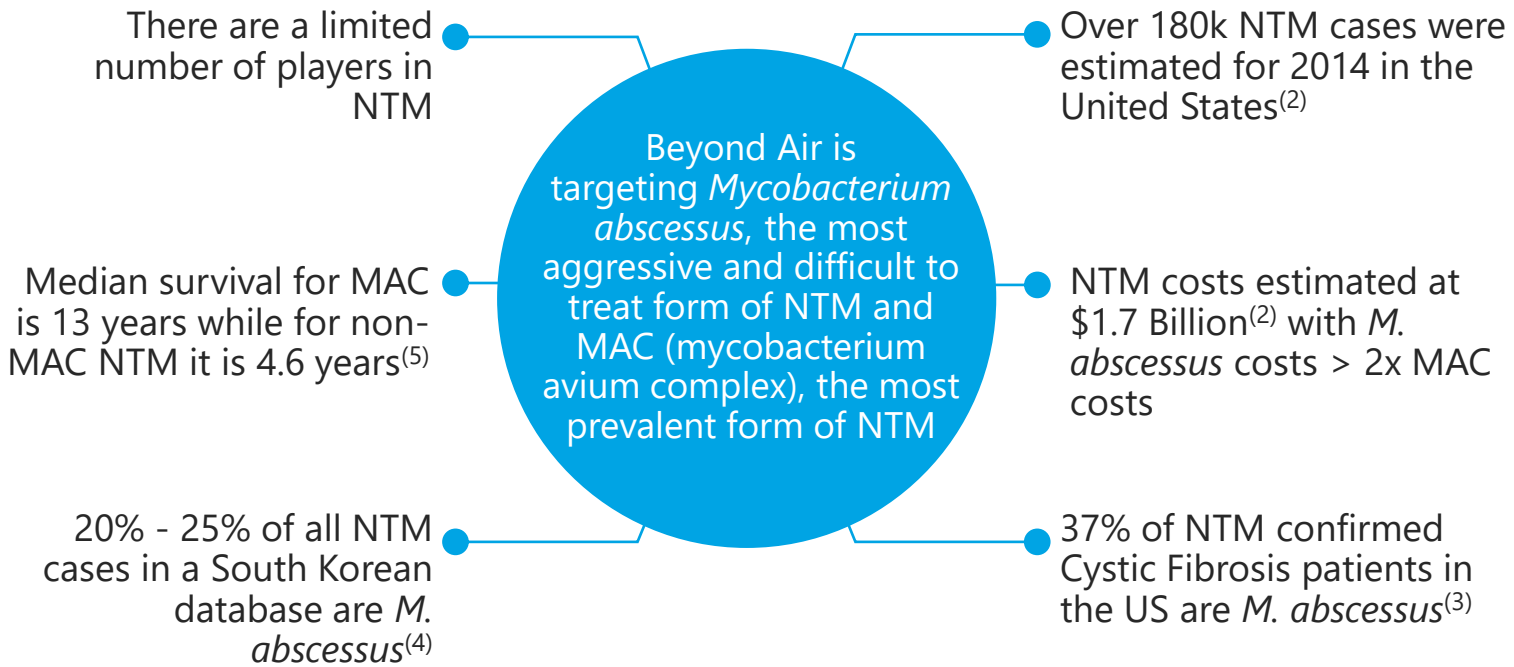
How is NTM acquired?(1)

- Acquired by inhalation from the environment
- Water thought to be the main source
- Warmer climates have higher infection rates
- Patient to patient transmission possible

Who is at risk?(1)

- Underlying lung disease and/or genetic predisposition
- Cystic Fibrosis (CF)
- COPD (chronic obstructive pulmonary disease)
- Bronchiectasis
- Receiving immunosuppressive therapy

NTM Market Dynamics



1) Data: www.ntmfacts.com, FDA
2) Strolloet al. The Burden of Pulmonary Nontuberculous Mycobacterial. Pub 27-July-2015
3) Data presented at ATS 2017 (Derek Low et al, Medical University of South Carolina)
4) Data presented at ATS 2017 (Keun Burn Chung et al, Seoul National University College of Medicine)
5) Kotilainen, H. et al. "Clinical Findings in Relation to Mortality in Non-Tuberculous Mycobacterial Infections: Patients with Mycobacterium Avium Complex Have Better Survival than Patients with Other My cobacteria." European Journal of Clinical Microbiology & Infectious Diseases 34.9 (2015)

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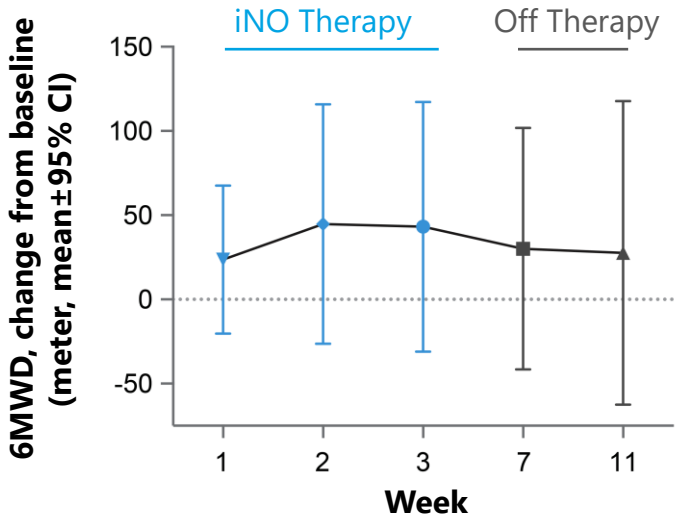
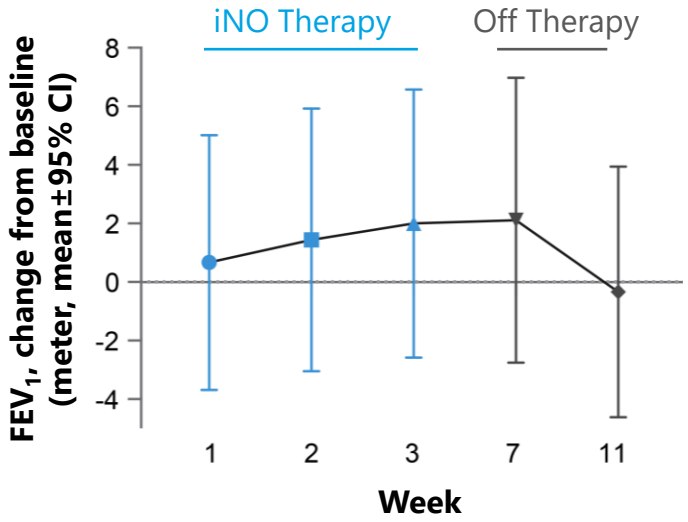
Pilot Study in NTM infected CF Patients Demonstrates Safety and Efficacy

Single arm study with 160 ppm NO showed a reduction in bacterial load and improvements in quality of life
Data Published in the Journal of Cystic Fibrosis (Bentur et al., 2019)

Mean change in
6MW Distance (meters) from Baseline



Mean change in
FEV1 from Baseline



- 9 CF patients with refractory MABSC were treated at 3 centers in Israel with NO added to background antibiotic therapy
  - 160 ppm NO was given via mask for 30 min 5x/day for 14 days and 3x/day for 7 days
  - Primary endpoint of safety was met, with no NO-related serious adverse events (SAEs) observed
  - Bacterial load, as measured by qPCR showed a 65% reduction at day 81 versus baseline
    - One patient was culture negative at Day 51 and Day 81, two others had one negative culture
  - Quality-of-Life data showed positive trends on relevant questions
- 4 patients treated under compassionate use experienced similar results
  - 1 treated at NIH with LungFit™, 1 treated safely with 250 ppm NO, 1 culture conversion

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Pilot LungFit™ NTM Study Protocol Summary

- Open label pilot study with 12 weeks of treatment and 12 weeks of observation
- Approximately 20 subjects >18 years of age with NTM lung infection refractory to antibiotic therapy
  - Both MAC (Mycobacterium avium complex) and *Mycobacterium abscessus* will be included in CF and non-CF patients
- Study start fourth quarter 2020 with interim results expected late 2Q21 and final results in 2H21
- Four doses of NO per day for 14 days followed by two doses of NO per day for 70 days (all patients will remain on background antibiotic therapy)
  - Each dose lasts 40 minutes and are 4-5 hours/at least 9 hours apart
  - Subjects will be titrated from 150 ppm up to 250 ppm in hospital with all subsequent administrations at home
- Primary endpoint is safety
- Key Secondary endpoints
  - Culture conversion/bacterial load
  - Quality of Life
  - Respiratory function
  - Physical function (activity tracker, 6MWT, etc.)