

# Corporate Overview

September 2021  
Non-Confidential



ENBIOTIX

# What is EnBiotix?



Rare disease company initially focused on chronic respiratory disorders – a \$15B global market

Built via in-house programs & strategic transactions

Lead asset – ColiFin® – approved & commercialized in EU; U.S. P3-ready, \$300M+ market potential

In active discussions to acquire synergistic assets

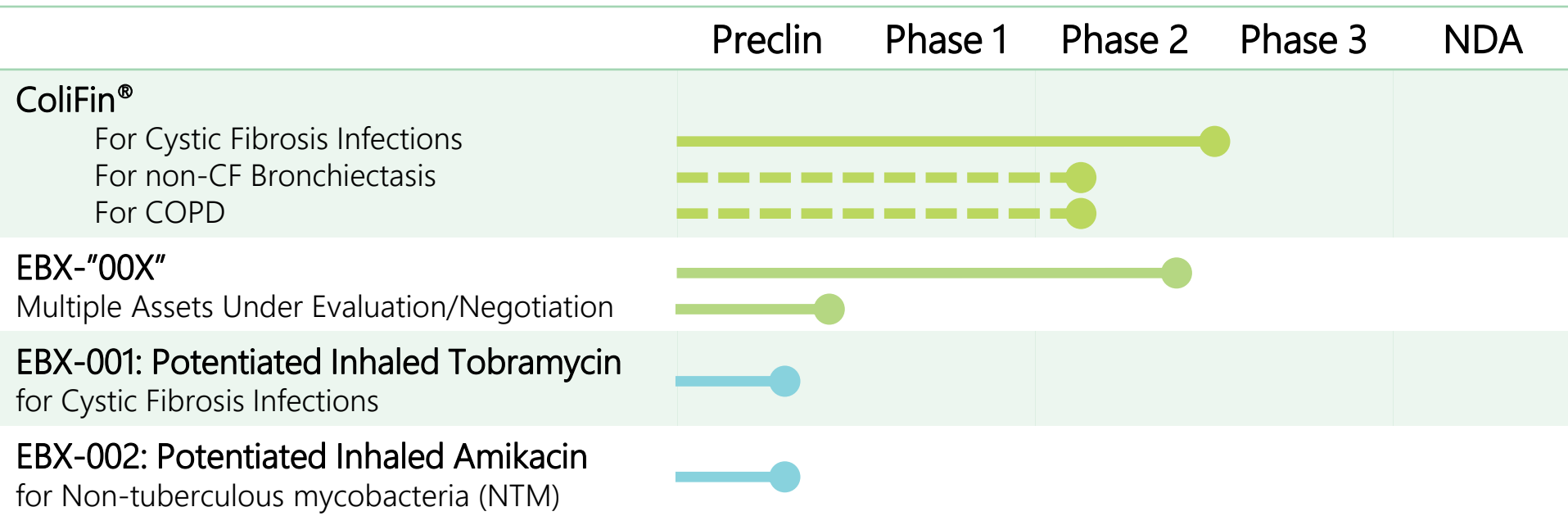
IPO planned for 1Q2022: lead i-banker secured

Raising bridge/crossover round to support IPO

Team and board have done it before



# EnBiotix Pipeline



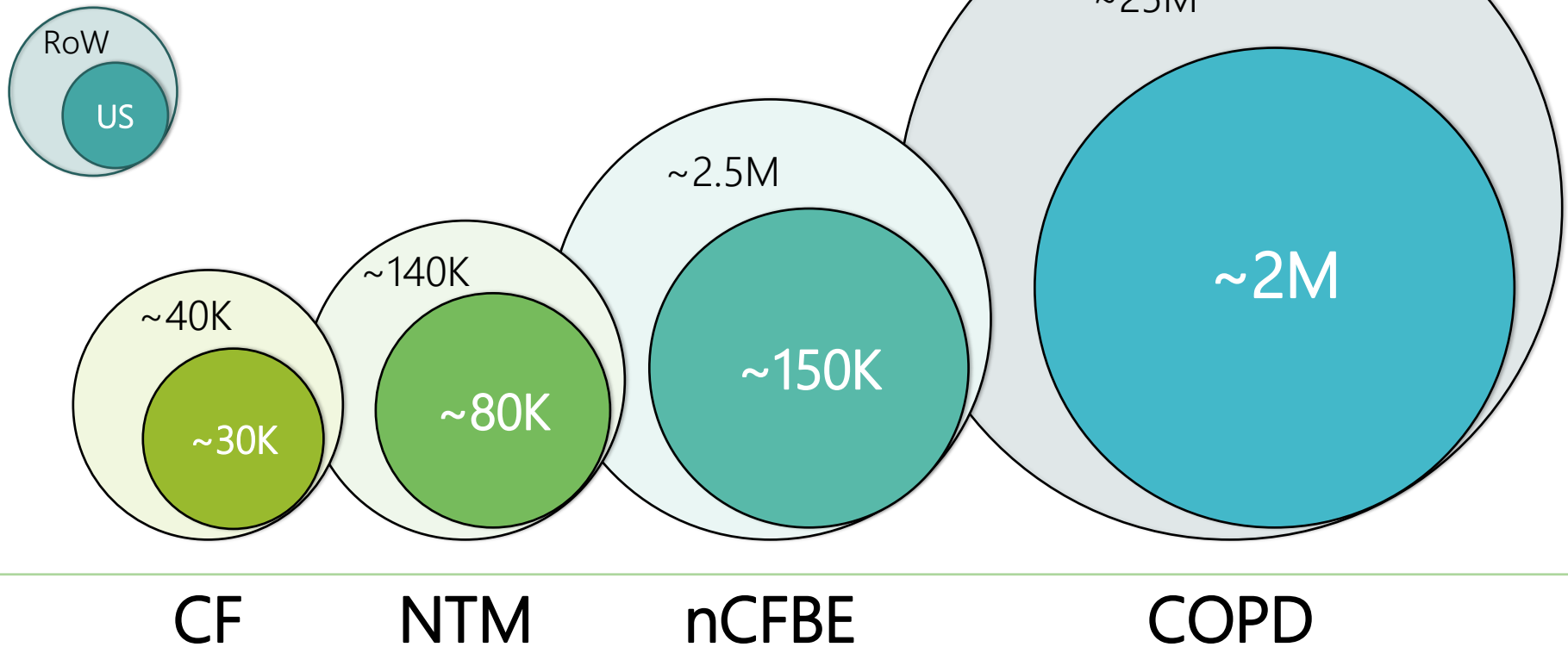
# Treatable Patients With Current & Planned Portfolio

Total US Patient Population:

>2M

RoW:

>25M



# Why EnBiotix Will Succeed

1

Proven Ability to Secure Products with High Probability of Clinical & Commercial Success

2

## Front-line Therapy Claim Focus:

- Bridging standard of care ("SoC") from EU to U.S. (ColiFin<sup>®</sup>);
- Next-gen of current SoC (EBX-001, EBX-002)
- Bridging ex-U.S. approval &/or new SoC (add'l assets);

3

## Chronic Indication Focus:

- |  |             |
|--|-------------|
| – Cystic Fibrosis (CF):                            | lifelong Rx |
| – Non-CF Bronchiectasis (nCFBE):                   | lifelong Rx |
| – Non-Tuberculosis Mycobacterial Infections (NTM): | ~18 mos Rx  |
| – COPD:  | lifelong Rx |

4

Pricing and Reimbursement Not Limited by DRG Capitations



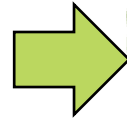
# ColiFin<sup>®</sup> for CF

Already Marketed/Successful in EU; U.S. P3-Ready

# ColiFin<sup>®</sup>: Inhaled Colistin For CF

## ColiFin<sup>®</sup> Validated in EU

- EMA approved 2010
- >15K patients dosed thus far
- Strong efficacy, minimal SAEs
- Front-line Rx for CF in EU
- Licensed to EnBiotix from PARI Pharma GmbH, world leader in nebulized drug delivery



## Leveraging EU Data to US & ROW

- Positive FDA feedback on EU data & clin-reg strategy: only single U.S. P3 trial needed for approval
- P3-start 4-6 mos. post-funding
- U.S. KOLs say ColiFin<sup>®</sup> should become front-line Rx as in EU
- Current CF ABXs priced at premium: \$7k - \$10k per 28d course

### EU CF Rx: 3 Major Antibiotics



TOBI



Cayston



ColiFin<sup>®</sup>

### US CF Rx: 2 ABX rotation



TOBI

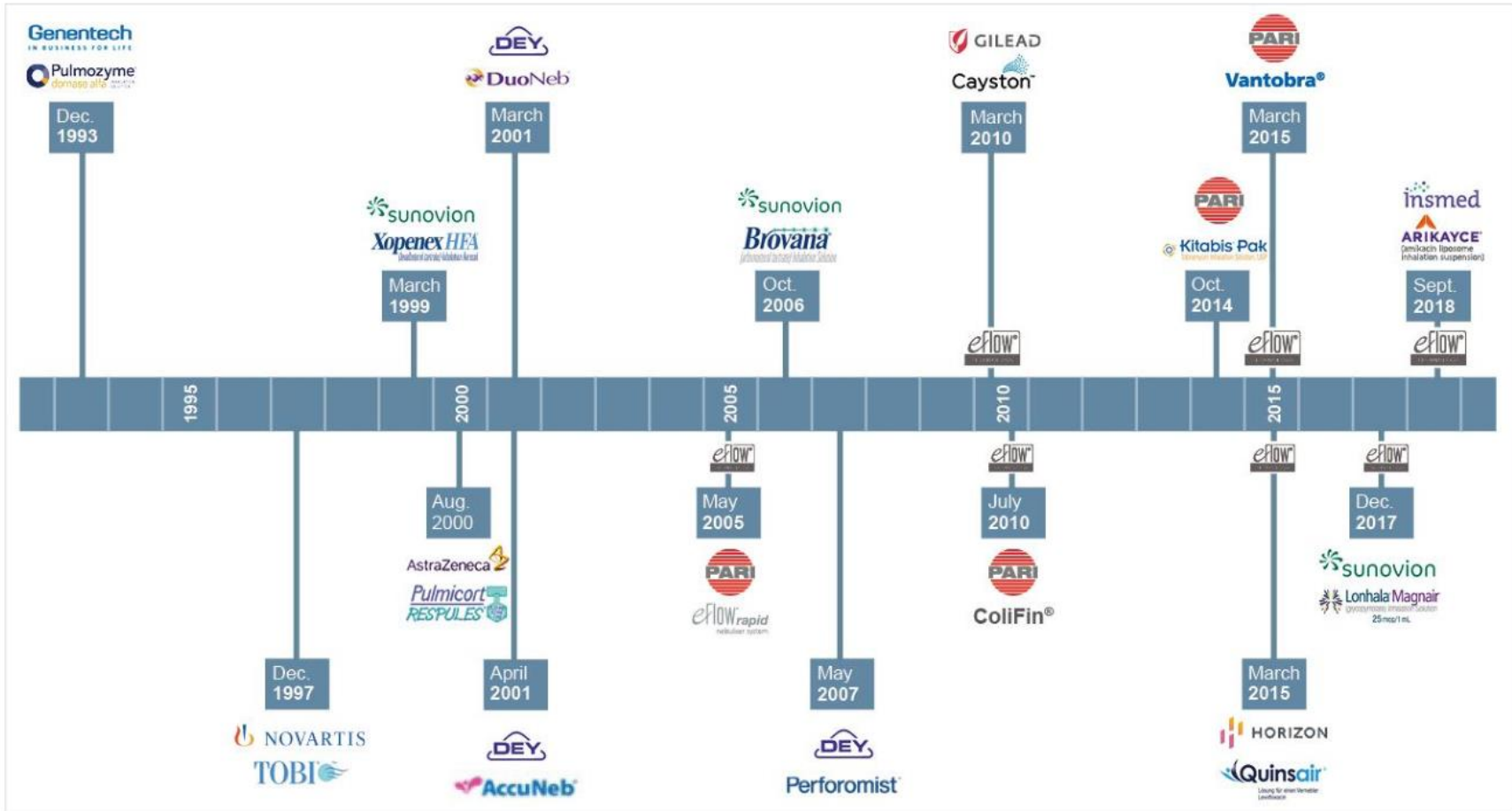


Cayston



ENBIOTIX







# EnBiotix's ColiFin® Partner: PARI Pharma's Proven Track Record



The "Gold Standard" in nebulized drug delivery



# Significant ColiFin<sup>®</sup> Progress Over Last 18 Months

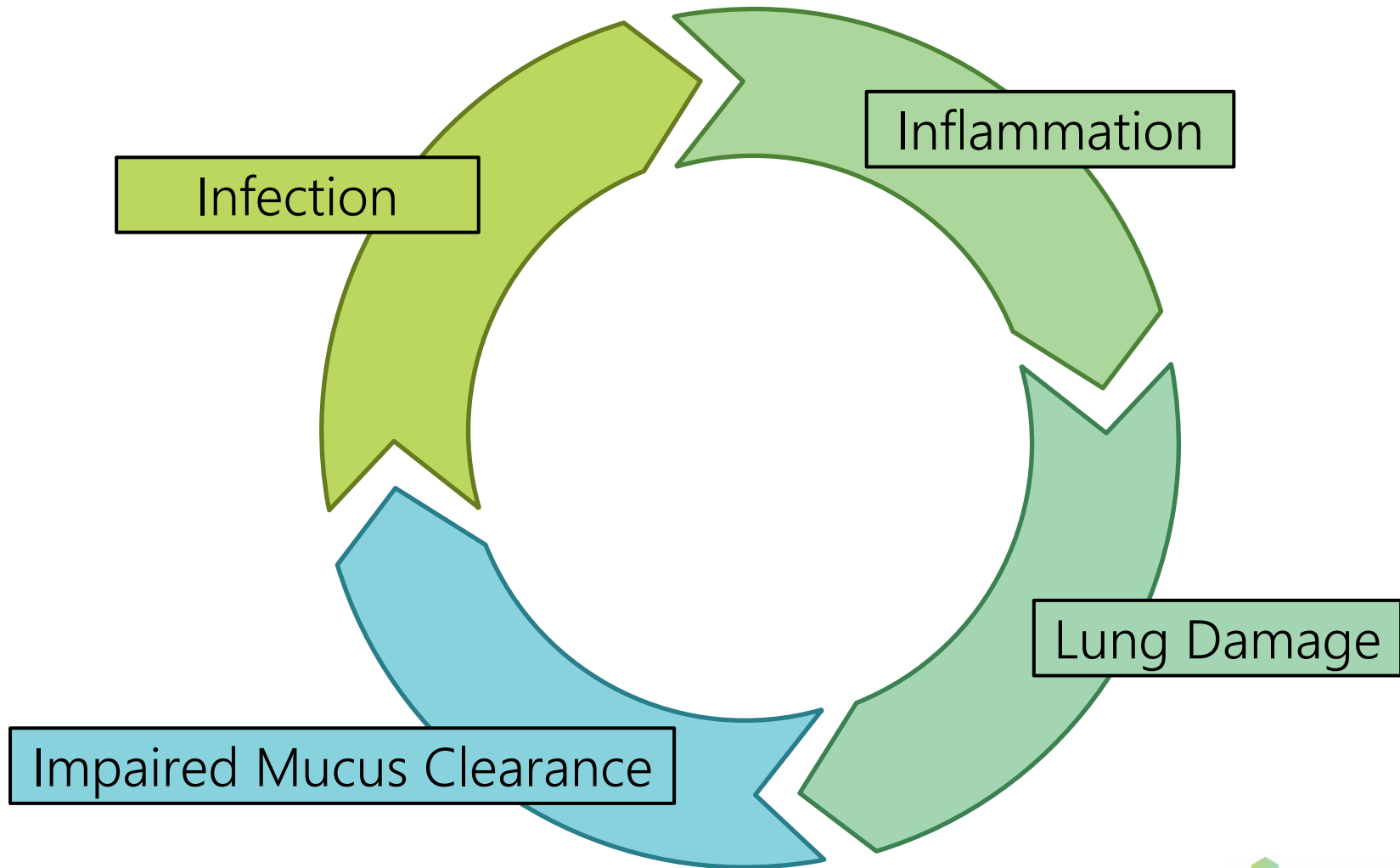
Date	Regulatory Achievement
 Feb 2020	QIDP Designation Granted = 5 Yrs Market Exclusivity
 March 2020	Orphan Drug Designation Granted = Additional 7 Yrs Market Exclusivity ( <b>12 years total</b> )
 April 2020	IND Filed for Phase 3 Program
 May 2020	P3 "Study May Proceed" Letter Received From FDA
 Nov 2020	"Fast Track" Designation Received: Guarantees Expedited (6 mos) Review of Future NDA
 3Q21	CFF's Therapeutic Development Network ("TDN") sanction of P3 trial design/unmet need received

# Why Another Inhaled ABX For CF?

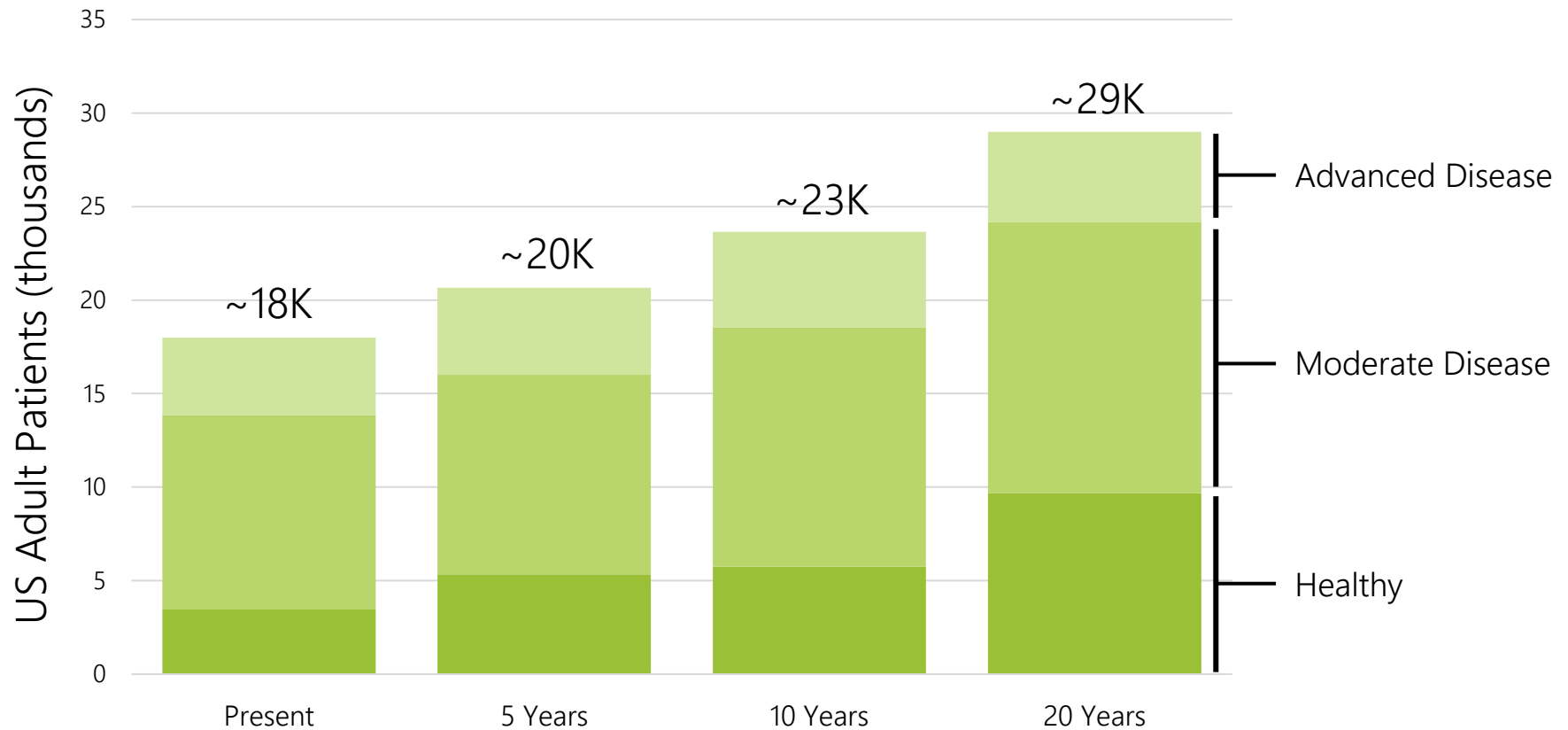
- 1 Because patients and clinicians want it
- 2 CF lung damage requires lifelong inhaled antibiotic Rx
- 3 Current inhaled ABXs inadequate: resistance (up to 40%), tolerability issues, decreased efficacy over time
- 4 Though CFTR correctors available, CFF projects patient population to expand over next 20-30 yrs
- 5 Inadequate *P. aeruginosa* Tx = ↑ hospitalizations = ↑ i.v. ABX use = ↑ toxicities, mortality & costs

KOLs/patients confirm significant & urgent  
need for additional inhaled ABXs!

# Vicious Cycle of Progressive Lung Damage in CF Patients



# CFTR Modulators Will Increase CF Patient Population Targeted by ColiFin®



Reduced mortality / slowed disease progression ->  
More patients at all disease stages

# Why ColiFin<sup>®</sup>?

KOLs/Patients Want It	~12% of U.S. pts already using unapproved inhaled colistin
KOLs/Patients Need It	↑ resistance to TOBI/Cayston <sup>®</sup> (up to 40%) = additional options needed; ColiFin <sup>®</sup> MOA very difficult for <i>P. aeruginosa</i> to mutate around
Safety / Resistance	Comparable-to-superior safety profile to TOBI/Cayston <sup>®</sup>
Already Used & Effective	ColiFin <sup>®</sup> already approved in Europe: safety demonstrated & widely used as front-line Rx for CF infections
Once Daily Dose Possible	Potential for subsequent <i>q.d.</i> dosing = strong patient preference, capture of overwhelming market share

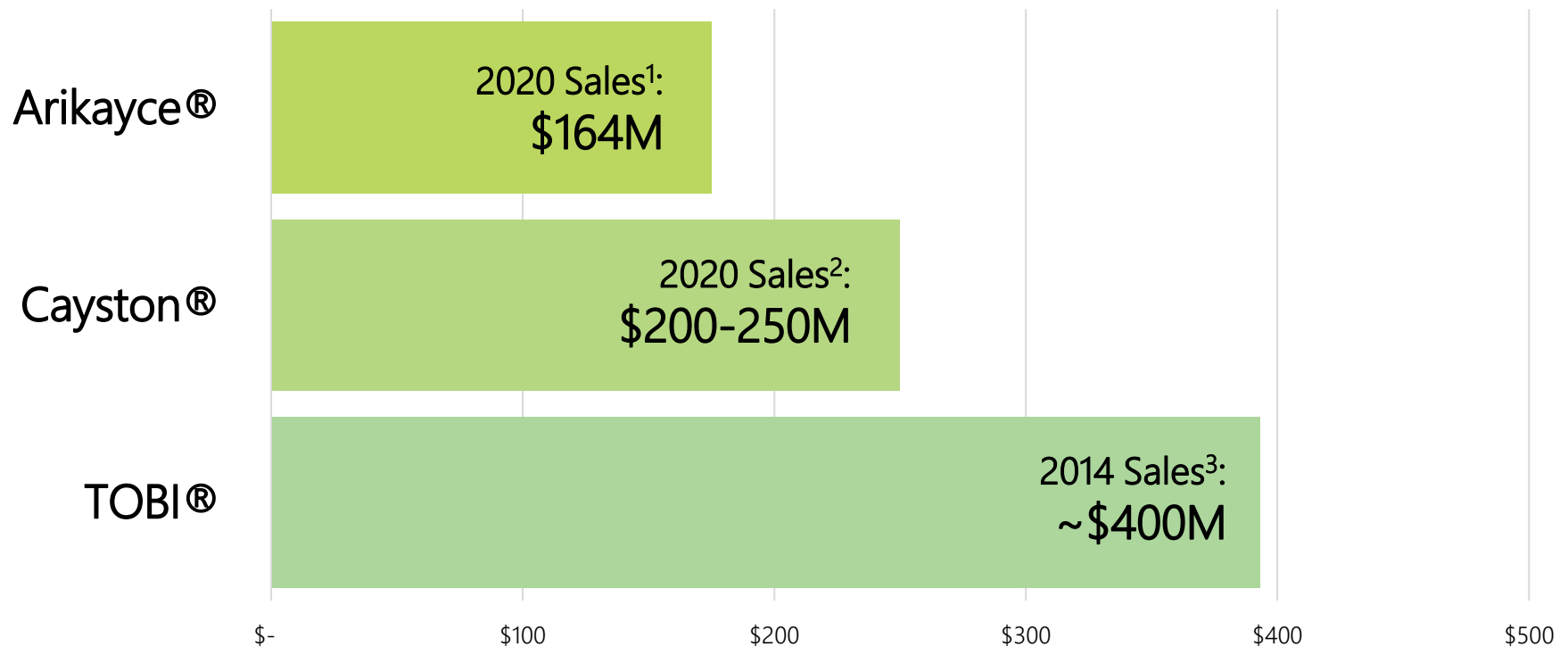


# Comparative Target Product Profiles

Parameter	TOBI®/Cayston®	ColiFin®
Mechanism of Action	Lends to resistance development	Difficult for <i>P.auriginosa</i> to mutate around
Resistance Rates	Increasing, up to 40% in some regions	Rarely exceeding ~5%
Safety	Ototoxicity still a sig problem with TOBI	Latest safety analyses very "clean": no oto/neuro- or nephrotoxicities seen
Efficacy	Decreased efficacy over time	Front-line agent in Europe <u>over</u> TOBI®/Cayston®
Dosing	Continuous alternating therapy ("CAT") (28d Rx on one, then switching to 28d on other) b.i.d.	Continuous (i.e., no CAT) b.i.d. dosing with plans for q.d. dosing
28d Course AWP Pricing	Between ~\$5400 – 11,000 (generics - branded)	Targeting ~\$8,000



# Inhaled Rare Disease Therapeutics Historically Very Attractive



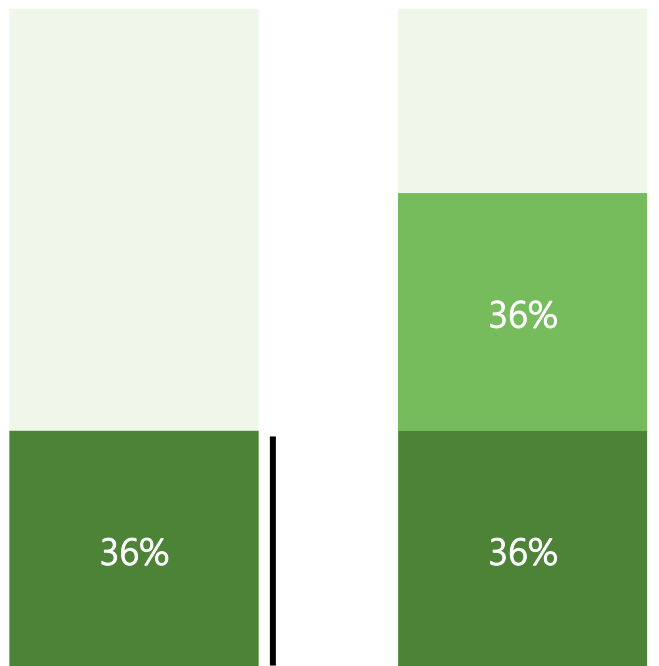
**All three products exceeded \$100M sales by year 2**

1. Arikayce® first year sales (~\$110M in 2019) compare favorably to Cayston® first year sales (~\$70M in 2011)
2. Est. sales based on CFF registry data – Gilead does not itemize Cayston® sales in reports
3. TOBI® went off-patent in 2014



# The Colifin<sup>®</sup> Market Opportunity, cont'd

~10,000 US CF Adults w/  
Moderate - Advanced Disease



Immediately  
Capturable:  
3.6K pts;  
~\$100M/yr

After 3-4 Years  
on Market:  
7.2K pts  
\$250-300M/yr

1

CF Foundation estimates ~12% of US CF adults (~36% US CF adults w/ moderate or advanced disease) currently treated w/ unapproved colistin

2

FDA strongly discourages unapproved use

3

@ ~\$25K/yr (very low pricing), ColiFin<sup>®</sup> sales to only these patients ~\$100M/year

TOBI-like penetration grows revenues to \$250-300M/yr

Exact scenario pre-TOBI/Cayston<sup>®</sup> approval  
⇒ rapid sales growth of each post-approval





# Pricing of FDA-Approved CF Inhaled Antibiotics

One Month Supply (estimated AWP)

## Tobramycin Nebulization Solution

TOBI <sup>®</sup>	\$8,800
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Bethkis <sup>®</sup> (generic)	\$7,400
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Kitabis <sup>®</sup> (generic)	\$5,400
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TOBI Podhaler <sup>®</sup>	\$12,000
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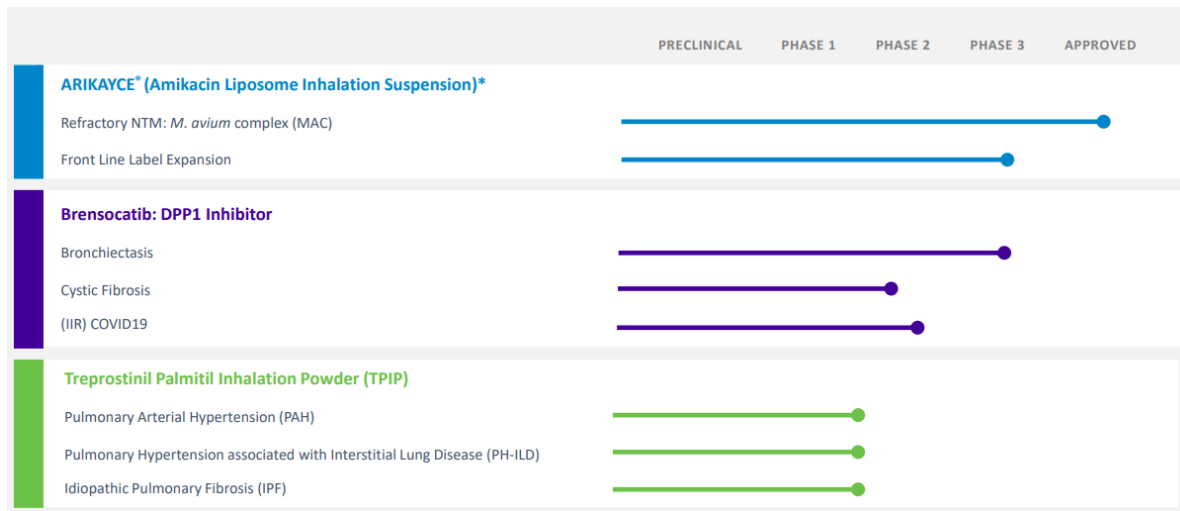
## Aztreonam Nebulization Solution

Cayston <sup>®</sup>	\$11,000
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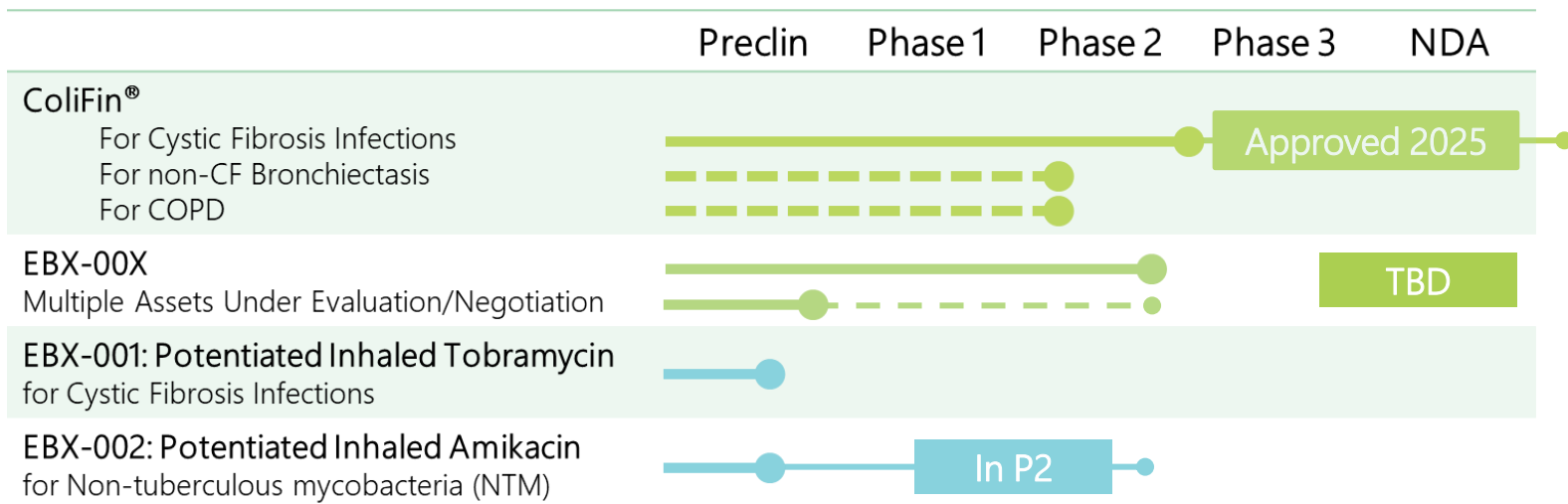


# Over Next 3-4 Yrs, We Will Track Insmed's Strongest Market Cap Growth Phase

**insmed**  
Today  
Mkt Cap:  
~\$3B

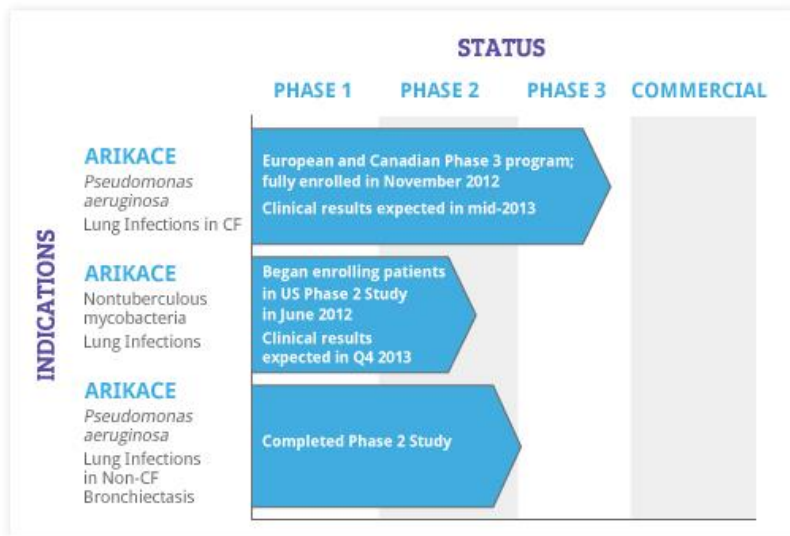


**ENBIOTIX**  
By  
2025

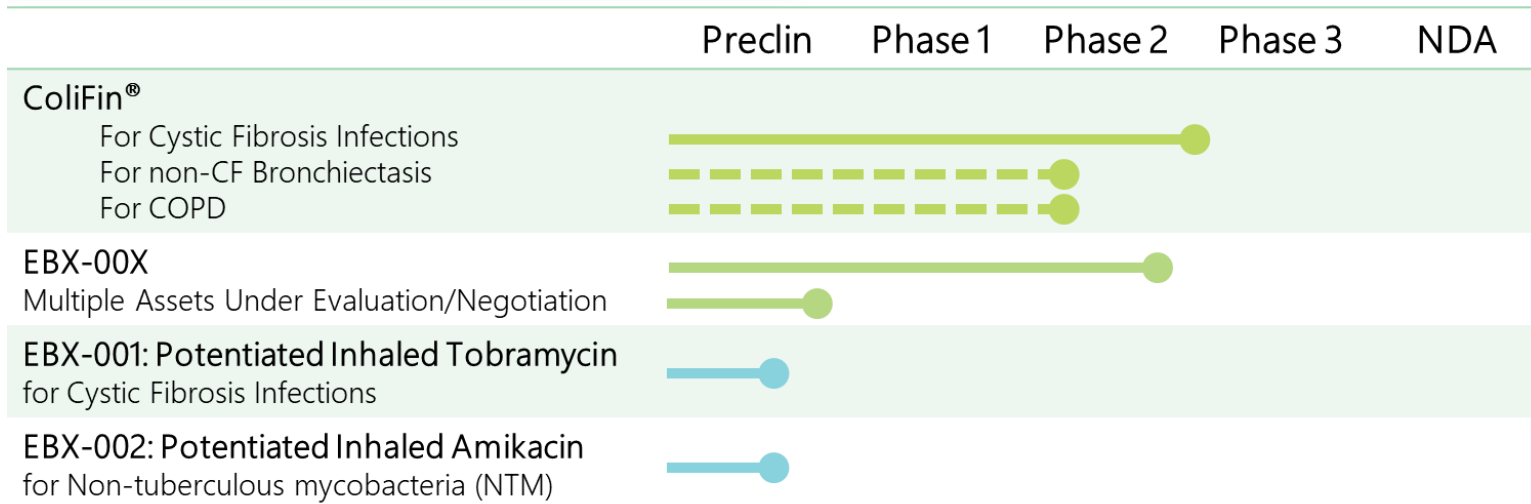


# Over Next 3-4 Yrs, Pipeline Will Track Insmed's Strongest Market Cap Growth Phase (2)

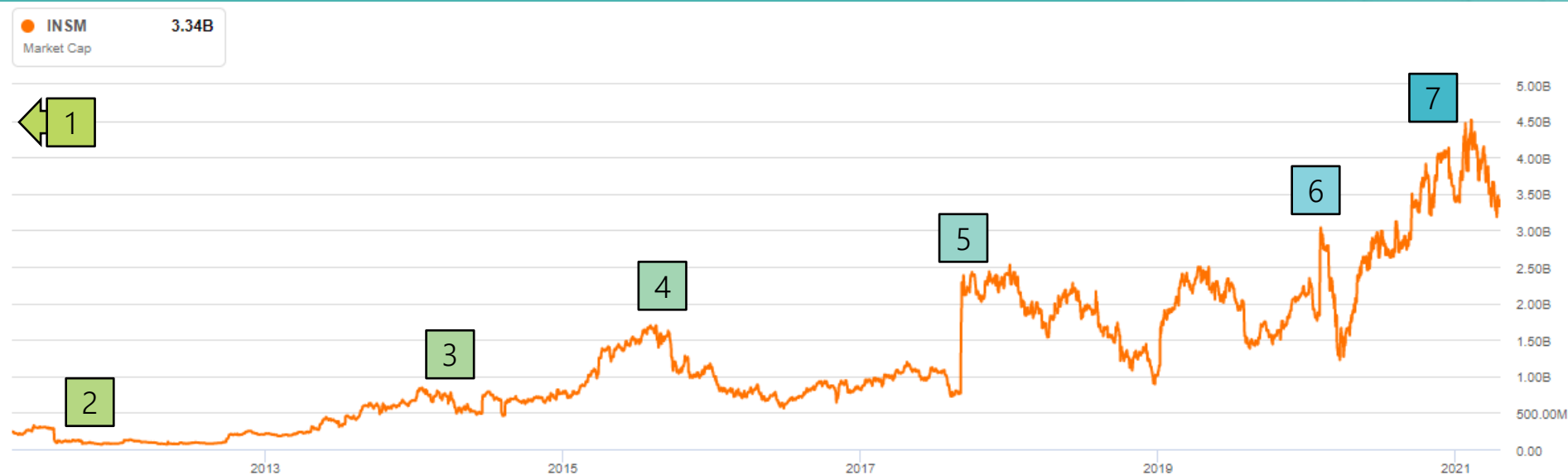
**insmed**  
 In 2013  
 Mkt Cap:  
 ~\$100M



**ENBIOTIX**  
 Today



# Over Next 3-4 Yrs, Pipeline Will Track Insmed's Strongest Market Cap Growth Phase (3)



#	Year	Mkt Cap	Value-Inflecting Milestones	EnBiotix/ColiFin <sup>®</sup> Achieving In:
1	2010	\$77M	Merger with Transave (owner of ARIKYACE <sup>®</sup> , CF P2 complete)	2019
2	2012	\$90M	ARIKAYCE <sup>®</sup> P3 started in CF, P2 started in NTM	2021
3	7/2013	\$430M	Follow-on financing raises \$67M (\$10.40/share, Leerink underwriter) Post-Offering Pipeline: Only ARIKAYCE <sup>®</sup> (P3 CF, P2 NTM, P2 nCFBE)	2022
4	2015	\$1.35B	Positive readout of NTM P2 – P3-ready in late 2015	
5	2017	\$2.33B	Positive results announced from two ARIKAYCE <sup>®</sup> P3s in NTM	2023
6	2020	\$2.95B	ARIKAYCE <sup>®</sup> full year 2019 sales announced: \$136M.	2025
7	2021	\$4.51B	ARIKAYCE <sup>®</sup> full year 2020 sales announced: \$164M	2026
	Present	\$2.5-3.5B	Current Market Cap	

# Leadership Has Done it Before

**Jeffrey Wager, MD**  
Chairman & CEO

30 yrs VC & CEO leadership;  
>\$335M VC & \$2.5B in public  
& M & A capital raised



**Juergen Froehlich, MD**  
CMO

30+ yrs CMO/Sen. Reg Affairs experience



**Stephan Wehselau**  
CFO

20+ years CEO & CFO experience,  
~\$400M raised in career



**Dennis Ausiello, MD**  
Director

17yrs Physician-in-Chief, MGH  
8 yrs lead director, Pfizer board



**William Gerhart**  
Director

20+ yrs inhaled drug  
CEO experience



**Robert Clarke, PhD**  
Director

20+ yrs inhaled R & D,  
CEO experience



**Dan Hartman, MD**  
Director

25+yrs R & D leadership;  
Head of \$2B Gates malaria portfolio



**Roberto Guttman**  
Director

30+ years serial entrepreneur/CEO/investor experience



**Dave Knudson**  
Observer

Lead lawyer for billionaire investor T. Denny Sanford;  
S.D. Senate Majority Leader & 4-term State Senator



# Key Scientific & Clinical Advisors

## Scientific Advisory Board



Jim Collins, Ph.D.,  
Co-Founder & Chair

- MIT Termeer Prof. of Bioeng, Vice Chair, Broad; academic co-founder, Wyss Institute



Donald VanDevanter, PhD

- Noted inhaled ABX developer for CF/NCFBE/NTM
- Key CF Foundation advisor



Mark Murcko, Ph.D.

- CSO Dewpoint
- CSO Relay
- CTO Vertex
- Multiple SABs and Boards



Jared Silverman, Ph.D.

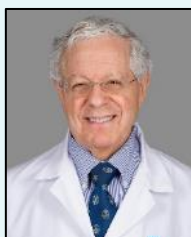
- Head of Translational Discovery at Gates Medical Res. Inst.
- Kaleido, SVP Research
- Cubist, VP Disc. Biol.



Dao Nguyen, M.D.

- Leading CF clinician-scientist & *Pae* microbiologist
- Assoc. Prof. Medicine at McGill University

## Clinical Advisors



Jeff Gelfand, MD

- Infectious Disease physician MGH
- Clinical Prof. Medicine at Harvard Med
- CSO Boston BioCom



Henry Dorkin, MD

- Co-Director of the CF Clinical Center Boston Children's Hospital
- Assoc. Prof. Pediatrics at Harvard Med



Patrick Flume, MD

- Dir. CF Center & Prof. Pulmonary & Critical Care Medicine at Medical U of South Carolina



Mike Konstan, MD

- Vice Dean for Trans. Res. & Tucker Prof. of Pediatrics, Case Western; leading inhaled colistin KOL



David Nichols, MD

- CFF TDN Medical Dir.
- Assoc. Prof. Pediatrics at University of Washington & Seattle Children's Hospital

# Thank You!

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