

# **Cautionary Statement**

**Statements** in this presentation that are not statements of historical fact are forward-looking statements that involve risks and uncertainties. Words such as "believes", "anticipates", "plans", "expects", "intend", "will", "goal", "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon MannKind's current expectations.

Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of risks and uncertainties, which include, without limitation, risks associated with manufacturing and supply, risks associated with developing product candidates, stock price volatility and other risks detailed in our filings with the Securities and Exchange Commission ("SEC"), including under the "Risk Factors" heading our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 27, 2024, and subsequent periodic report on Form 10-Q and current reports on Form 8-K.

**You are cautioned** not to place undue reliance on these forward-looking statements. which speak only as of the date of this presentation. All forward-looking statements are qualified in their entirety by this cautionary statement, and we undertake no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this presentation.



# Our Strategy

MannKind has a therapeutic focus on two disease areas:



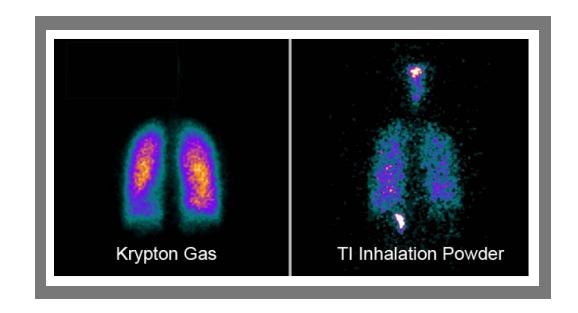


We will leverage our current proprietary technologies, but we will <u>not</u> be limited by them.

# Technosphere® Technology

#### Extremely Versatile Platform With Competitive Advantages

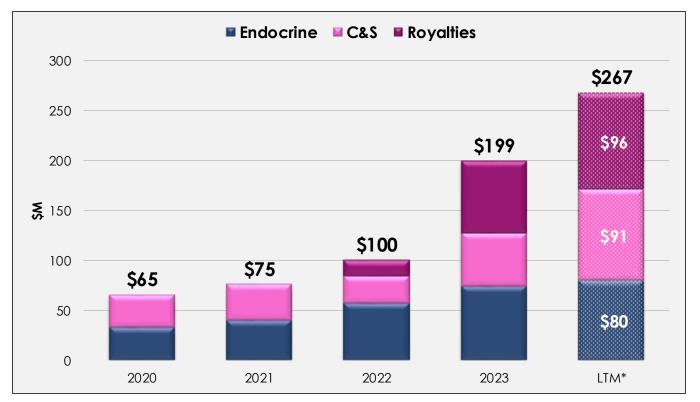
- Two FDA-approved products on the platform
- Extensive distribution of powder throughout lung utilizing FDKP
- Rapid systemic and deep lung delivery





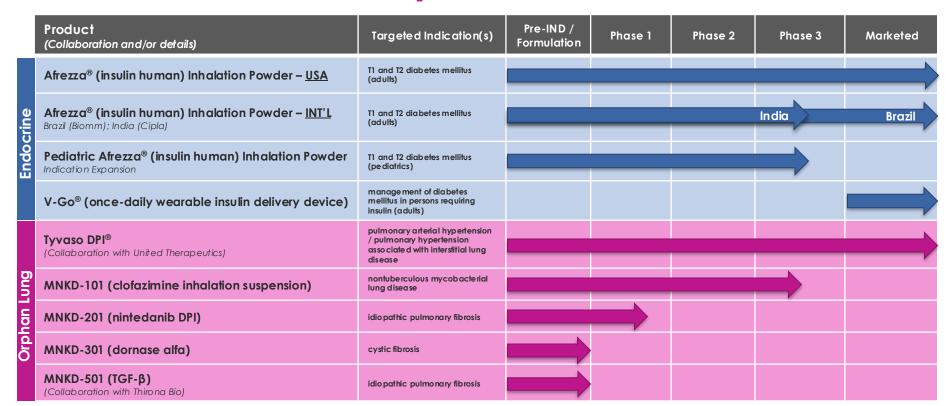
#### Rising Five-Year Revenue Trend

#### Double Digit Revenue Growth YoY





## **MNKD Products & Pipeline**





# Orphan Lung Opportunity

**Products + Trials** 

Tyvaso DPI MNKD-101 MNKD-201



# Our Technology is Differentiated

#### Ease of Use











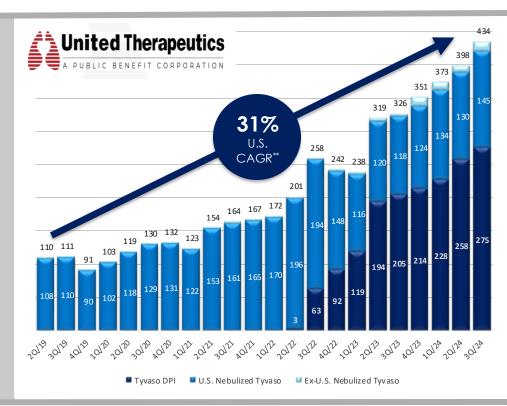
TYVASO DPI is simple-to-use and delivers the trusted safety and benefits of Tyvaso.<sup>1,2</sup>

(1) TYARDO DPI pockage most. Research Thangle Park, NO. Unded Therapoutos Corporation, 2002. (3) Spikes LA, Barger CO, et al. DPE2ZE: open-label clinical study to restaute the safety and translating of respective inhalison powder as Tyarso CPT in patients with pathonary setted hypertension. Pulse Circ. 2002;12:e12003. doi:10.1002/pul2.12003.



# Tyvaso DPI United Therapeutics Collaboration

- Tyvaso DPI annual run rate of >\$1B\*
   MNKD net royalty rate 9%
- Tyvaso DPI lays the foundation for MannKind's orphan lung platform



<sup>\*</sup> Based on 3Q Earnings

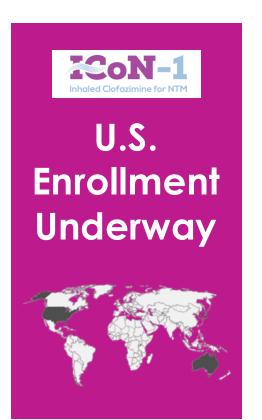


<sup>\*\*</sup> CAGR = compound annual growth rate calculated from 3Q/2019 to 3Q/2024 Quarterly revenue, millions USD (Source: United Therapeutics)

### ICoN-1: Phase 3 Study

#### Clofazimine Inhalation Suspension (MNKD-101)

Targeted Indication	Refractory NTM (nontuberculous mycobacteria) lung disease caused by MAC (mycobacterium avium complex)	
Patient Population (U.S. and Japan)	Estimated as >250,000 Estimated 15-20% are refractory	
Study Size	180 evaluable patients globally	
Locations	100+ sites already selected in U.S., Japan, Australia, South Korea and Taiwan	
Co-Primary Endpoints (U.S.)	Sputum culture conversion by end of Month 6 and change in Quality of Life-Bronchiectasis From baseline to end of Month 6*	



#### **ICoN-1 Development Rationale**

#### Significant Unmet Need in NTM Lung Disease

- Currently available therapies have limitations in both efficacy and safety/tolerability, as well as placing significant treatment burden on patients
- Oral clofazimine is part of the official 2020 ATS/ERS/ESCMID/IDSA clinical practice guidelines for treatment of NTM
- Clofazimine Inhalation Suspension has potential to maximize anti-mycobacterial activity at the site of infection (lungs) while minimizing systemic exposure, possibly leading to an improved safety profile
- Convenient dosing cycle with 28 days on and 56 days off

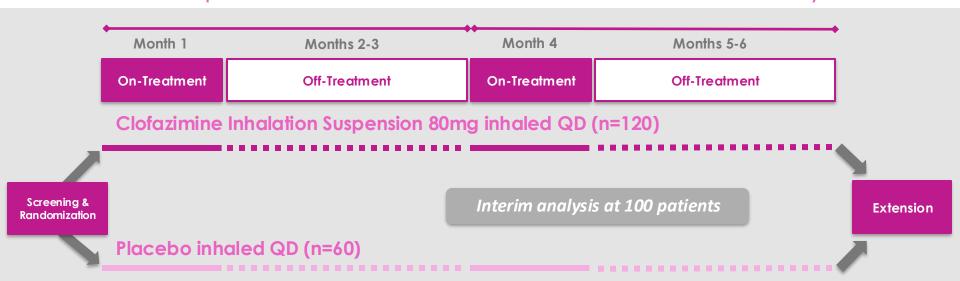
#### NTM On The Rise

- Estimated >250K patients in U.S. and Japan
- Prevalence rising globally >7% a year
- Market likely to exceed \$1B by end of decade with two players



## **ICoN-1 Phase 3 Study**

~25% of Anticipated Sites Activated in Phase 3 Global Study



- **Co-Primary Endpoints:** Sputum culture conversion + Patient Reported Outcomes\*
- Health authority approval in the U.S., Japan, Australia, S. Korea
- FDA Fast Track, QIDP & Orphan (potential 12 years exclusivity)





## **IPF: A Growing Therapeutic Area**

#### Current Treatment Options Not Well Tolerated, High Discontinuation Rates

- Progressing nintedanib DPI as a potential treatment improvement relative to Ofev®:
  - May provide higher pulmonary exposure which may improve efficacy
  - Bypassing the GI system could reduce common adverse effects (GI and neurological) seen with oral nintedanib
- Nintedanib DPI could also potentially be used concomitantly with other current and future IPF therapies





# Nintedanib DPI: Successful Phase 1 Study

No Adverse Events (AEs) as Typically Seen with Oral Nintedanib

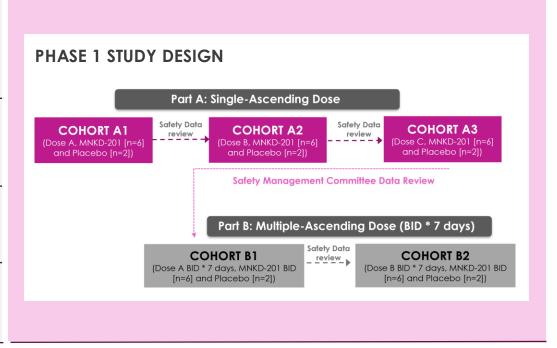
#### **KEY PHASE 1 STUDY HIGHLIGHTS**

Met primary objective demonstrating nintedanib DPI was safe and well tolerated in healthy volunteers

No serious AEs or AEs typically seen with oral nintedanib

Preclinical chronic toxicology study did not show any adverse findings

Expect to meet with FDA in 1H 2025 to discuss advancing to next phase of development



# **Endocrine Business Unit**

Products + Trials

Diabetes



### Rising Five-Year EBU Revenue Trend





#### Afrezza<sup>®</sup>

# Building the next Standard of Care in Mealtime Insulin Therapy

- Indicated for T1DM & T2DM mealtime control
- Taken at the start of a meal
- Demonstrates improved Time-In-Range
- Access at \$35 for Medicare and Commercial

Afrezza is a Unique Mealtime Insulin
That Solves an Unmet Need



Afrezza® Inhaler

# **PLUS**

Afrezza® Insulin Cartridges









4 units 8 units

12 units



mannkind

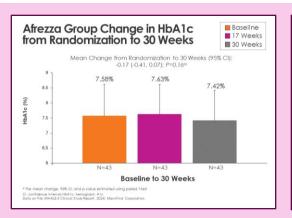
## **INHALE-3: Phase 4 Study**

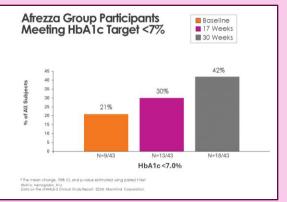
#### Head-to-head Comparison of Afrezza vs. Usual Care\* in T1D

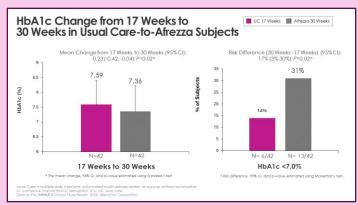
Targeted Indication	Adult Type 1 or Type 2 Diabetes Mellitus	
U.S. Patient Population	More than 26.5 million	
Study Size	123 total randomized adult participants	
Locations	19 certified sites across the U.S	
Primary Endpoints Change in A1c from baseline to		
Timeline	30-week data readout demonstrated that more adults achieve A1c goal with Afrezza	



#### INHALE 3: More Adults Achieve A1c Goal with Afrezza®







#### **KEY 30-WEEK FINDINGS**

- Completer analysis for 2 separate groups: one that utilized Afrezza over 30 weeks and a second who switched to Afrezza at week 17 from usual care\*
- Switching to, or remaining on Afrezza allowed at least 2x as many people to get to goal (<7%) during extension phase



# **INHALE-1: Phase 3 Study**

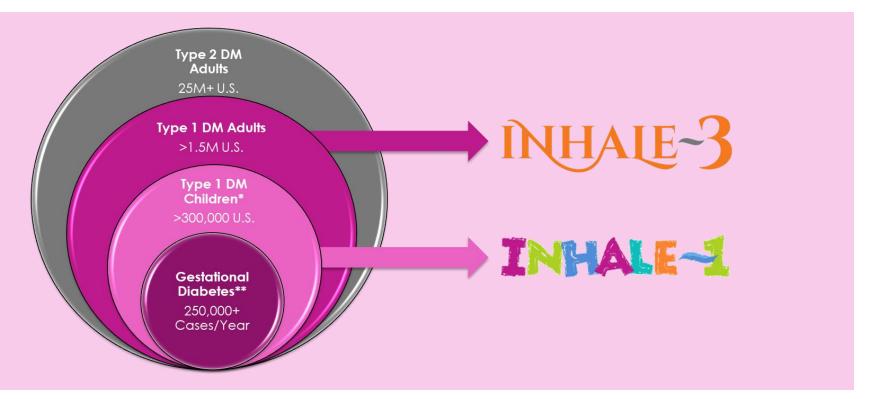
#### Largest U.S. study on Afrezza in More Than a Decade

Targeted Indication	Pediatric Subjects With Type 1 or Type 2 Diabetes Mellitus	
U.S. Patient Population	Estimated as >300,000	
Study Size	230 total randomized Participants (aged 4-17)	
Locations	40 certified sites across the U.S.	
Primary Endpoints	y Endpoints Change in A1c from baseline to week 2	
Timeline	Topline 6 Month data readout 4Q 2024; Expect pre-NDA filing meeting in 1H 2025	



#### Afrezza: Pathway Forward

#### Potential with Pediatrics and Gestational Diabetes



<sup>\*</sup> Source: Diabetes.org

<sup>\*\*</sup> Circles not to actual scale. Gestational diabetes has not been studied or an approved indication at this time.



# Financial Update

3Q 2024 Milestones Key Value Drivers



# **Strong Financial Position**



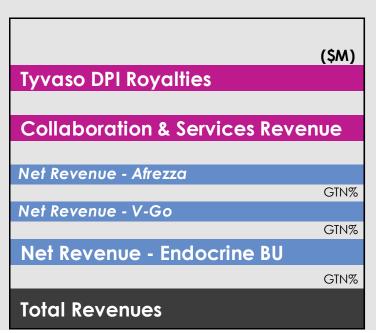
Funding Development





#### **3Q 2024 Total Revenues +37%**

#### Driven by Tyvaso DPI



QTD vs. Prior Year			
3Q24	3Q23	% Chg	
27	20	34%	
23	13	78%	
		, 0,0	
15	13	12%	
36%	38%		
5	4	<b>5</b> %	
47%	58%		
20	18	10%	
39%	44%		
70	51	37%	

YTD vs. Prior Year			
YTD 2024	YTD 2023	% Chg	
75	51	48%	
74	36	108%	
46	39	16%	
35%	38%		
14	14	(6%)	
51%	55%		
59	54	10%	
39%	44%		
209	140	49%	

#### Continued Net Income Increase

#### GAAP to Non-GAAP Reconciliation

	(\$M)
GAAP net income (loss)	
Non-GAAP adjustments:	
Sold portion of royalty revenue	
Interest expense on liability for sale of future roya	Ities
Stock compensation	
(Gain) loss on foreign currency transaction	
Gain on bargain purchase	
Loss on extinguishment of debt	
Gain (loss) on available-for-sale securities	
Non-GAAP adjusted net income (loss)	

QTD vs. Prior Year		
3Q24	3Q23	
12	2	
(3)		
4	-	
5	5	
2	(2)	
(5)	-	
-	-	
-		
15	4	

YTD vs. Prior Year			
YTD 2024 YTD 2023			
20	(13)		
(8)	-		
13	-		
16	14		
1	(1)		
(5)	-		
7	-		
2	(1)		
45	(1)		

#### **Milestones**

		1H 2024	2H 2024	1H 2025
ng	MNKD-101 Clofazimine Inhalation Suspension	<ul> <li>✓ IND Submission U.S.</li> <li>✓ Fast Track Designation</li> <li>✓ ICoN-1 Phase 3 Global Trial Initiated</li> </ul>	✓ ICoN-1 Trial Expansion into Japan, Australia and So. Korea, Taiwan Imminent	Continued Global Site Initiation and Study Enrollment
Orphan Lu	MNKD-201 Nintedanib DPI	<ul><li>✓ IND Submission U.S.</li><li>✓ Phase 1 Trial Initiated</li></ul>	<ul><li>✓ Phase 1 Study Results</li><li>✓ Preclinical Chronic Tox Findings</li></ul>	Outcome of Phase 1 Meeting with FDA on Study Design
ō	TYVASO DPI (Collaboration with United Therapeutics)	<ul><li>✓ High-Speed Fill/Finish Line</li><li>✓ New High Speed Fill Pack Line Operational</li></ul>	✓ UT: TETON 2 Completed Enrollment / TETON 1 & TETON PPF Enrollment Ongoing	Spray Dry Expansion Capacity Coming Online
Endocrine	INHALE-1 Afrezza Pediatric (Indication Expansion)	<ul><li>✓ 100% Enrollment</li><li>✓ All Participants are Completed</li></ul>	Top-line RCT Data Readout	Presentation/Publication of data Pre-NDA filing meeting
	INHALE-3	<ul> <li>✓ 1st Meal Dosing Released @ATTD</li> <li>✓ 17-Week Data Released @ADA</li> </ul>	✓ 30-Week Readout Filing FDA label update	Continued Data Dissemination at Scientific Conferences



# **Anticipated Key Value Drivers**



- MNKD-101 Phase 3 Trial Initiated
  - Every 1,000 patients is ~\$100M in Revenue
- MNKD-201 Phase 1 Trial Completed
  - 2023 Ofev net revenues of ~\$3.8B

**ORPHAN LUNG** 



- Growth and Conversion to Tyvaso DPI
  - Every 10k covered patients is ~\$300-350M in Revenue

UT TETON 1&2 Studies (IPF), TETON PPF





- INHALE-1 (Pediatrics)
  - Each 10% share ~\$150M in Revenue
- INHALE-3 (Pump Sparing)
- International Expansion

**ENDOCRINE** 



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