

## 1 Q 2024 Earnings Cal May 8, 2024

## **Cautionary Statement**

This presentation includes forward-looking statements relating to, without limitation, our future commercial growth and pipeline advancement, our ability to commercialize pharmaceutical products, statements regarding the commencement of clinical studies of MNKD-101 and MNKD-201, and the data read-outs from clinical studies of Afrezza and MNKD-201. 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. 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.



## Today's Agenda

Operational and Pipeline Highlights

#### Michael Castagna, CEO

**Financial Review** 

Steven B. Binder, EVP & Former CFO

**Additional Comments** 

Michael Castagna, CEO

Analyst Q&A





### Michael Castagna Chief Executive Officer

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Our mission is to give people control of their health and the freedom to live life.

life more humann."

## 1Q 2024 Highlights

Orphan Lung Diseases	<ul> <li>UT: Tyvaso DPI</li> <li>Record royalty revenue of \$22.7M (+94%) and record manufacturing-related revenues of \$24.8M (+118%)</li> <li>MNKD-101 (clofazimine inhalation susp): FDA Fast Track Designation; FDA clearance for IND; expect Phase 3 registrational trial ICoN-1 to start in 2Q</li> <li>MNKD-201 (nintedanib DPI): FDA clearance to proceed to Ph1 trial; expect Phase 1 trial to start in 2Q</li> </ul>
Endocrine Diseases	<ul> <li>IQ Afrezza net revenue of \$14.4M: +16% vs. 2023</li> <li>Afrezza INHALE-1: 26-week top line results expected by EOY</li> <li>Afrezza INHALE-3         <ul> <li>Positive first meal dosing results presented at ATTD in March</li> <li>17-week top-line results at ADA in June</li> <li>India – Subject Expert Comm recommended permission to import &amp; market</li> </ul> </li> </ul>
Financial	<ul> <li>GAAP Net income of \$11M</li> <li>Ended 1Q24 with \$304M in cash, cash equivalents and investments (+\$2M vs. 4Q)</li> <li>Repaid MidCap senior secured debt and Mann convertible debt first week of April</li> </ul>



## **NTM: MNKD-101**

## Clofazimine Inhalation Suspension

#### NTM prevalence is increasing over time and market will likely exceed \$1Billion by end of decade with two players

#### **NTM Epidemiology**





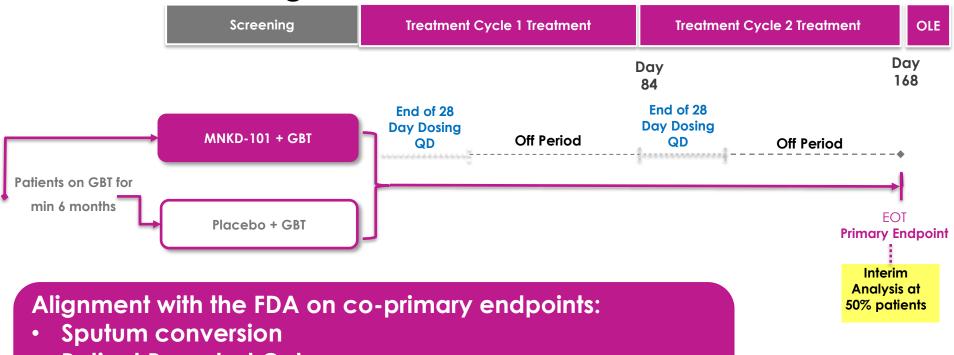
- •2022 NTM disease prevalence of 122K and 159K patients in the U.S. and Japan
- •The prevalence rate of NTM is increasing globally
  - •Within the U.S., claims-based studies suggest an annual NTM prevalence CAGR of 7.5%<sup>1</sup>
- •NTM prevalence and CAGRs suggest a 2032 prevalence of >500K patients in Japan and U.S.

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<sup>1</sup> Winthrop. An Am Thorac Soc.2020.

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### ICoN-1 Ph 3 Study Design – Cleared to Proceed by FDA; FDA Fast-Track Designation Received



ICON-1

Inhaled Clofazimine for NTM

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Patient Reported Outcomes

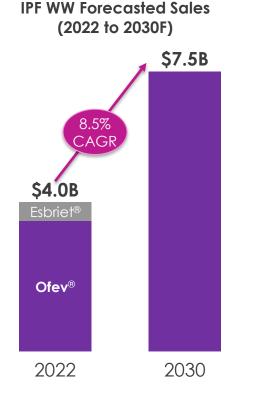
Phase 3 study expected to enroll first patient in June 2024 Orphan + QIDP designation (potential 12 years exclusivity)



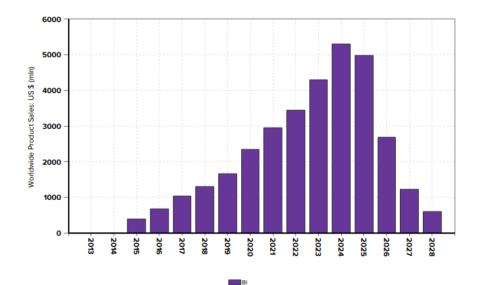
## Pulmonary Fibrotic Diseases: MNKD-201

## Nintedanib DPI

### IPF is a Growing Therapeutic Area, With a Large Unmet Need

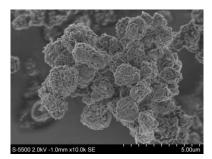


#### Worldwide Ofev Sales Will Exceed ~\$4B



Source: Coherent Market Insights 11 © Copyright 2024. All rights reserved. MannKind Corporation.

### **MNKD-201 Development Rationale and Progress**





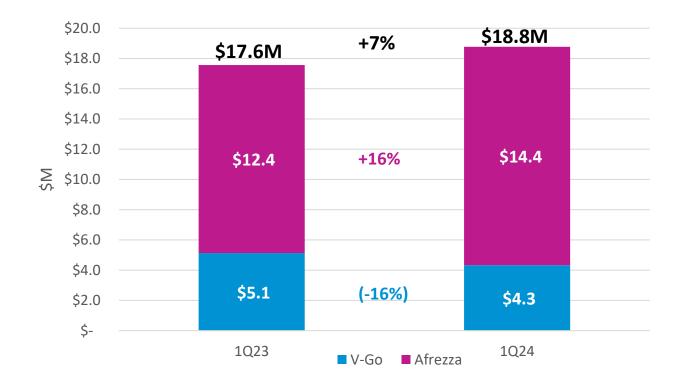
- Potential for better efficacy and improved tolerability relative to Ofev®
  - Orally delivered Ofev efficacy (and lung dose) was not maximized due to GI side effects
- Dosing rationale: Only ~5% of Ofev is bioavailable and we can likely deliver relevant lung concentrations at levels much higher without the GI intolerability.
  - Completed animal studies to triangulate the target lung dose
- Rat PD bleomycin study: MNKD-201 appeared to mitigate inflammation and fibrosis comparable to oral nintedanib at substantially lower doses
- Completed 28-day GLP toxicology & chronic toxicology study in progress
- FDA clearance to proceed to Phase 1 clinical trial





## **Endocrine Business Unit**

### **Endocrine Products Growing +7% on Strength of Afrezza**



## New Afrezza Data Could Impact Growth Trajectory

## INHALE-3

- T1D: Largest switch study from AID pumps
- Utilizes new conversion dose upfront to ensure proper efficacy is maintained or improved
- Meal tolerance test at baseline and week 17

#### • <u>Goal:</u>

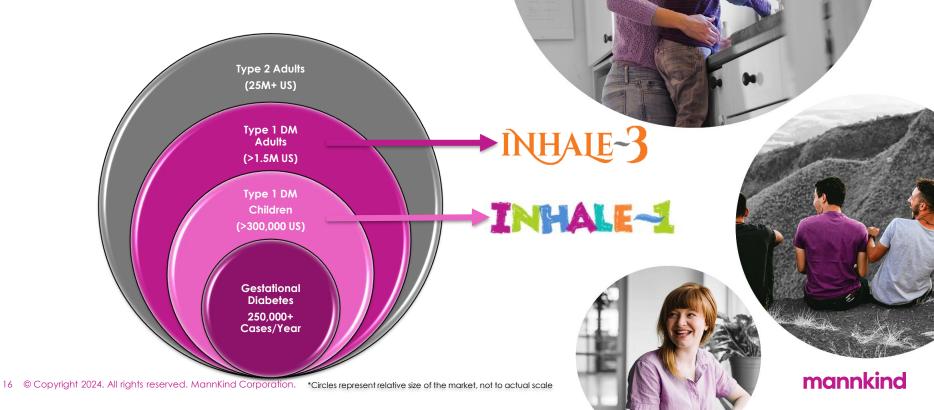
- Equal efficacy to Standard of Care including an AID system
- Update Conversion Figure 1 in the Afrezza label

### INHALE-1

- Pediatric T1D or T2D: Largest study on Afrezza in >10 years
- New conversion dose appears to reduce drop-outs relative to original trials
- Meal tolerance test at baseline with CGM
- **Goal:** Secure pediatric approval in 2025+



### Afrezza Growth Opportunity



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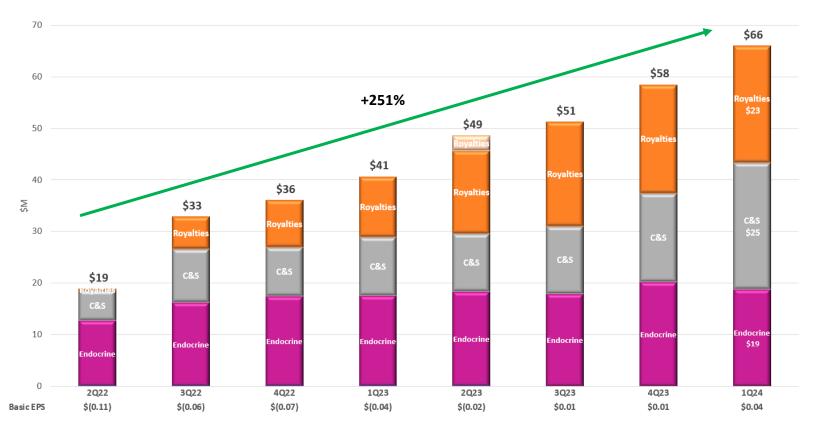
### **Steven B. Binder** EVP & Former Chief Financial Officer

### 1Q 2024 Total Revenues +63%; TDPI-related revenues continue to drive exceptional growth

(\$M)	1Q 2024	1Q 2023	% Chg
Tyvaso DPI Royalties	23	12	94%
Collaboration & Services Revenue	25	11	118%
Endocrine BU:			
Net Revenue - Afrezza	14	12	16%
Net Revenue - V-Go	4	5	-16%
Total Revenues	66	<u> </u>	63%



### Rolling 8 Quarter Revenue & EPS Growth



Note: 2Q 2023 includes ~\$3M royalties associated with TDPI inventory build at specialty pharmacies

#### 1Q 2024 Net Income: \$11M GAAP/Non-GAAP Reconciliation

	Three Months Ended	
(\$M)	<u>2024</u>	<u>2023</u>
GAAP net income (loss)	11	(10)
Select non-cash adjustments:		
Sold portion of royalty revenue	(2)	-
Interest expense on liability for sale of future royalties	4	-
Stock compensation	4	4
(Gain) Loss on foreign currency transaction	(1)	1
Non-GAAP net income (loss)	15	(5)



### **Capital Allocation – Executing Near-Term Priorities**

#### Development Pipeline

- MNKD-101: Fund Phase 3 global registrational trial
  - FDA clearance to proceed to Phase 3 trial
- MNKD-201: Fund Phase 1 trial; expect to fund Phase 2/3 in 2025
  - FDA clearance to proceed to Phase 1 trial
- Afrezza
  - INHALE-3: If positive data/label change
  - INHALE-1: If positive data/label change
- Debt
  - MidCap (senior secured): Balance of \$28M @ 03/31/24
    - Paid in full April 2024
  - Mann Convertible Note: Balance of \$9M @ 03/31/24
    - Converted/Paid in full April 2024; reduced potential dilution by 2M shares
  - Senior Convertible Notes: Balance of \$230M @ 03/31/24
    - Expect to reduce future dilution



#### Michael Castagna Chief Executive Officer

### Looking Forward & Closing Comments

## **CFO Transition**

#### Steve Binder, MNKD CFO 2017-2024

Retiring Dec 31, 2024 Transitioning to EVP Special Projects

#### Chris Prentiss, MNKD CFO Effective Apr 22, 2024 Prior: CFO ADARx, Adamas Pharmaceuticals MNKD employee 2005-2012 (Corp Controller)





### Expected/Accomplished 2024 Milestones

	Q1 2024	Q2 2024	Q3 2024	Q4 2024
Afrezza	<ul> <li>✓ INHALE-3</li> <li>First meal dosing</li> <li>released at ATTD</li> </ul>	INHALE-3 17-week top-line data released @ ADA	INHALE-1 Primary endpoint data completion	INHALE-1: Primary endpoint analysis. Approval to market Afrezza in India (Cipla)
MNKD-101 (clofazimine susp)	✓ IND filed	ICoN-1 Phase 3 Global Trial Initiated		
MNKD-201 (nintedanib DPI)	✓ IND filed	Phase 1 Study Initiated	Phase 1 Data Read Out	Chronic Tox Completed
Tyvaso DPI	<ul> <li>✓ High-speed fill/finish line</li> </ul>	New spray drying capacity		UT expected to complete Teton 1 & 2 enrollment mennkine

## **Anticipated Key Value Drivers**



- MNKD-101 Phase 3 trial underway in 2Q 2024
   Event 1 000 patients is ~\$100M in Povenue
  - Every 1,000 patients is ~\$100M in Revenue
- MNKD-201 Phase 1 trial cleared to proceed in 2Q 2024
   2023 Ofev net revenues of ~\$3.9B



- Growth and Conversion to Tyvaso DPI
   Every 10k covered patients is ~\$300M-\$350M in Revenue
- UT Teton Studies (IPF & PPF)



Endocrine

- INHALE-1 (Pediatrics)
  - Each 10% share ~\$150M in Revenue
- INHALE-3 (Pump Sparing)
- Afrezza Int'l

### **Annual Shareholders Meeting**

- May 15 10:00 ET (held via internet)
- Ability to submit questions

### **Scientific Conferences**

Endocrine:

ADA in Orlando June 21-24, Inhale-3 17-week topline results (90 min symposium) ADCES in New Orleans Aug 9-12, Inhale-3 presentation (pending acceptance)

Lung:

•NTM and Bronchiectasis Patient Conf in San Diego May 16-17 •American Thoracic Society Conf in San Diego May 17-22

### **Investor Conferences**

• RBC in New York May 14 •Leerink in Boston July 9-10



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# Thank you

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