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# MannKind Corporation: Paving the Future of Orphan Lung

J.P. Morgan 41st Annual Healthcare Conference

Michael Castagna, PharmD Chief Executive Officer

## **Cautionary Statement**

This presentation includes forward-looking statements relating to, without limitation, our future commercial growth and pipeline advancement, and our ability to commercialize pharmaceutical products. 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 our 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 product commercialization, risks associated with developing product candidates, risks associated with our ability to manage existing cash resources or raise additional cash resources, the impact of the COVID-19 pandemic, 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, 2021, filed with the SEC on February 24, 2022. 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 Mission**

# To give people control of their health and the freedom to live life.

life more humann.



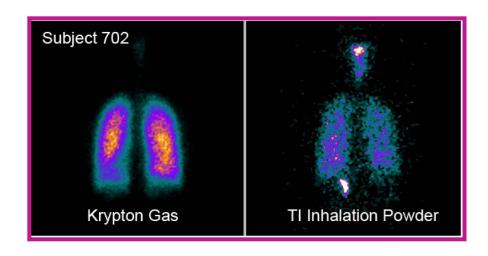
## Our Strategy

- We have a therapeutic focus on two disease areas:
  - Orphan lung diseases
  - Endocrine diseases
- We will exploit our current proprietary technologies, but we will not 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
- Rapid systemic and deep lung delivery



### **MannKind Evolution**



## Expanding our Growth Levers



- Royalties and manufacturing revenue
- Expansion potential for IPF
- Scale Afrezza Growth:
  - Stronger uptake in the US
  - Indication expansion into pediatrics
  - International market expansion
- Business Development:
  - MNKD-101 (inhaled clofazimine)
  - V-GO® Insulin Delivery Device
  - New collaborations

2015 **→** 2020

Pipeline Deals with UTHR,

Establish our

**Commercial Base** 

Afrezza® approved in US

Over 125,000 prescriptions

written for Afrezza

RLS, and Fosun

and Brazil

2020 → 2025



#### **Pipeline Launches**

Goal is 1 new indication or product per year



2025  $\rightarrow$  2030



Endocrine

Orphan Lung

Third-Party Programs mannkind

## Orphan Lung Diseases

## United Therapeutics Collaboration & Tyvaso DPI

- Worldwide exclusive licensing and collaboration agreement for Technosphere Treprostinil (Tyvaso DPI)
  - Low double-digit royalties
  - Established high-potency commercial manufacturing
- TYVASO/DPI
  (I/C)/CSI(III) Property of the control o

- 10-year Commercial Supply Agreement to manufacture Tyvaso DPI
  - Manufacturing expansion is underway at Danbury facility

Option to license platform for 2<sup>nd</sup> PAH product



## Tyvaso DPI® is Differentiated

#### Ease of Use







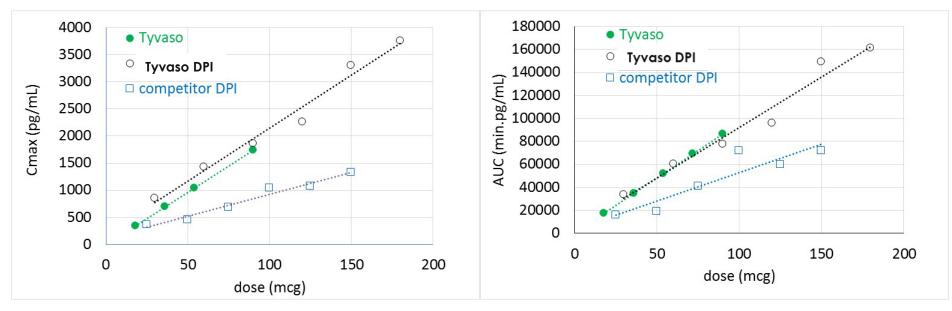




TYVASO DPI is simple-to-use and delivers the trusted safety and benefits of Tyvaso.<sup>1,2</sup>



## Comparison of DPI Delivery of Treprostinil\*



Dose: amount emitted from inhaler (Tyvaso), cartridge content (Tyvaso DPI and competitor DPI)

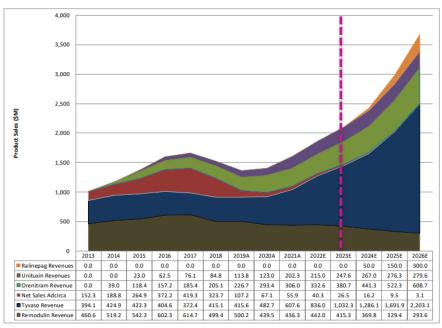
Higher doses of Tyvaso DPI up to 150 mcg were safe and well tolerated

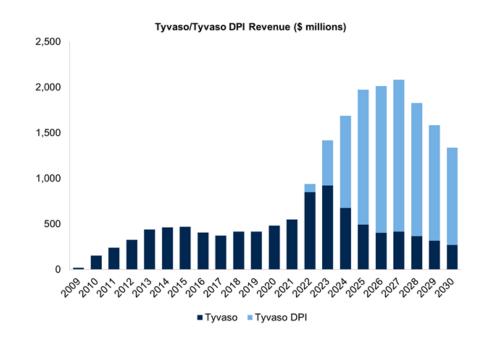


<sup>\*</sup>Data plotted from publicly available information

## Tyvaso DPI Potential: Analyst Projections

#### **Exhibit 6: UTHR US Product Sales**





Source: Company reports. Oppenheimer & Co. & estimates

Source: OpCo Research Report on UTHR November 3, 2022

Source: RBC Capital Markets Estimate, November 15, 2022



### **Orphan Lung Indication Overview**

MannKind's pipeline is differentiated and addresses multiple high-unmet need indications worth a combined market size of over \$25B.

Indication (Program/ molecule)	Unmet Need	Market Opportunity (WW 2030)	Commentary
<b>NTM</b> (MNKD-101/ Clofazimine)		\$3.7B	<ul> <li>NTM infections cause devastating lung disease</li> <li>~58k cases of NTM diagnosed in the US</li> <li>Global Opportunity especially in Asia Pacific</li> </ul>
IPF (MNKD-201/ nintedanib)		\$11.OB	<ul> <li>IPF is debilitating with a median survival of 3-5 years</li> <li>Approved IPF products come with AEs that impact compliance</li> <li>~100K cases of IPF in the US</li> </ul>
CF (MNKD-301/ dornase alfa)		\$12.7B	<ul> <li>All treatment options to date are non-curative and more recent CFTR therapies depend on patient subtype</li> <li>~40k pts living with CF in the US</li> </ul>

Sources: Global Data

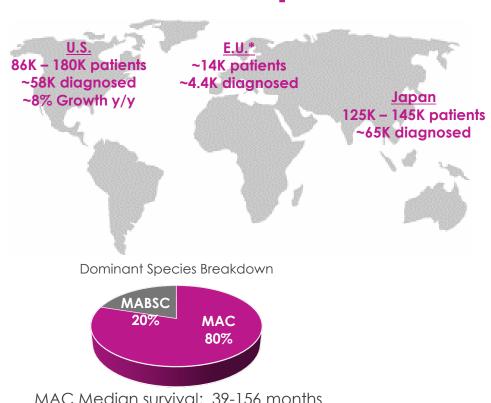






High Need

## NTM Landscape & Unmet Need





#### Treated by Pulmonary and ID with:

- 1. clarithromycin or azithromycin<sup>†</sup>
- 2. rifampin or rifabutin<sup>†</sup>
- 3. Ethambutol<sup>†</sup>
- 4. Arikayce® (only FDA approved)
- AEs = Gl issues, liver function, optic neuritis, QT prolongation

#### **Demographics:**

- Women
- 65+



## MNKD-101 Update

- Novel, proprietary suspension for inhalation, orphan and QIDP designation in the US (12 years exclusivity)
- Activity against: tuberculosis, staph (MRSA), fungal infections, MAC, MABSC. POC already shown in NTM
- Synergistic activity with other antimicrobials
- Low systemic exposure and better lung penetration expect fewer side effects than oral dosage form
- Phase 1 complete, no tox signal to date
- Expected Dosing: 28 days every 3 months

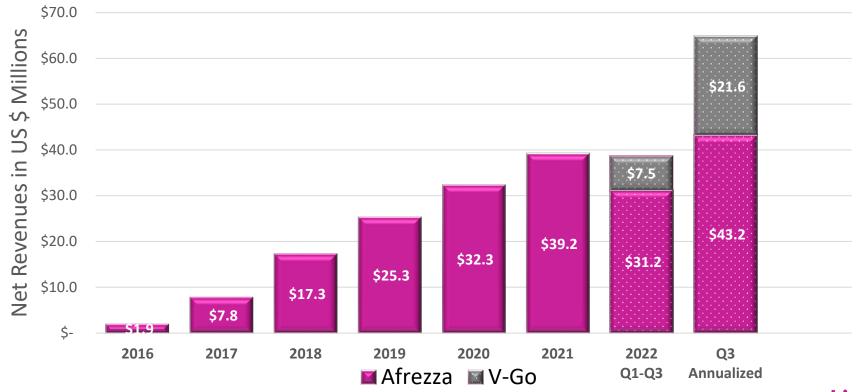
Expect to progress to a Phase 2/3 study in 2023



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## **Endocrine Diseases**

### Net Revenue From 2016 Through 3Q, 22 – **Commercial Products**



# Afrezza: 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

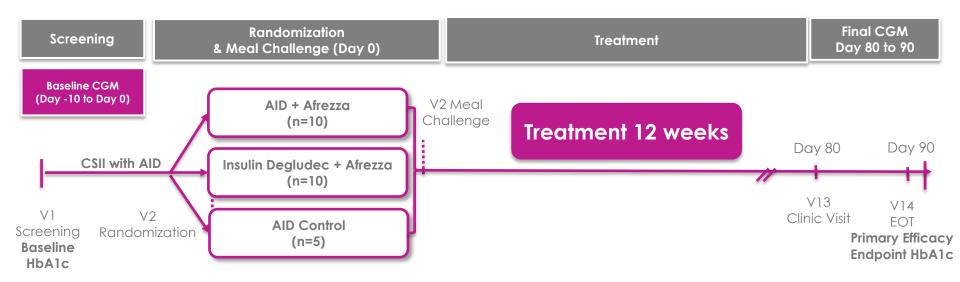
8 units

12 units



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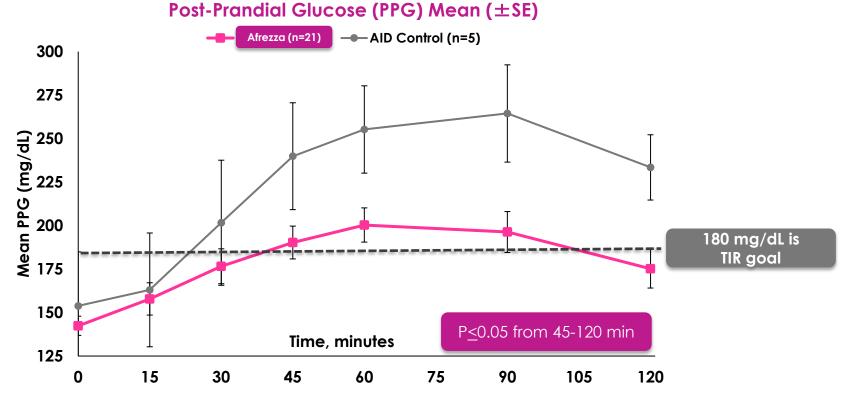
## ABC Study Overview (aka Pump Switch)



Data submitted for presentation at ATTD and ADA 2023

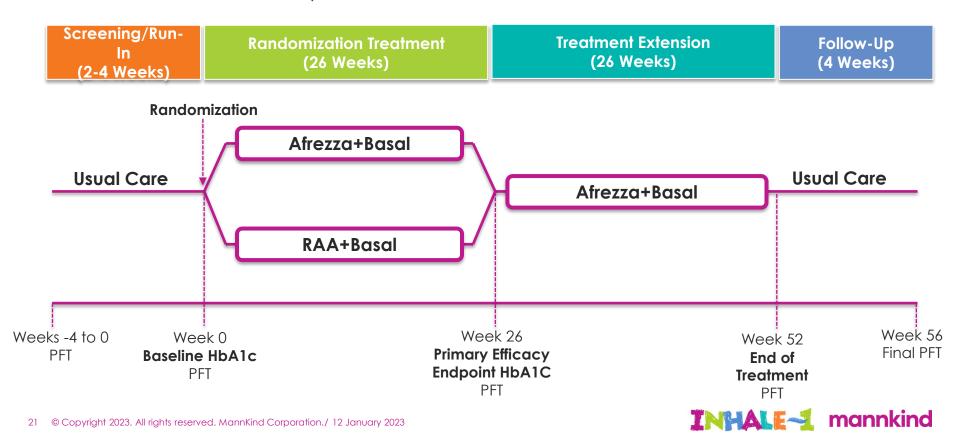


## ABC Study: First dose in office is significantly better than AID mealtime insulin bolus in first 120 minutes



### Pediatric Study Expected to Complete Enrollment in 2023

Each 10% market share is ~\$150M in Revenue Potential...



## MNKD Strengthens Commitment to Innovative Mealtime Diabetes Solutions with V-Go® Acquisition in Q2, 2022

- 2<sup>nd</sup> diabetes product for Endocrine Business Unit
  - Creates synergies across the BU
- Purchase price was \$15M including:
  - Intellectual property
  - \$11M of inventory & \$3M of equipment
- Expected 1st year net revenue run-rate of \$18M \$22M
- Integration into the Afrezza Sales Force in Q1 23
- Expected to be accretive in 2023







## V-Go: Expanding Beyond Insulin

With minimal investment, V-Go can potentially be fitted with other low volume SC injectables to expand into new markets.

#### **Market Opportunities**

**Biosimilars** 

- Buy and Bill
- Clinical Improvement with slow infusion

#### **V-Go Platform Expansion Overview**

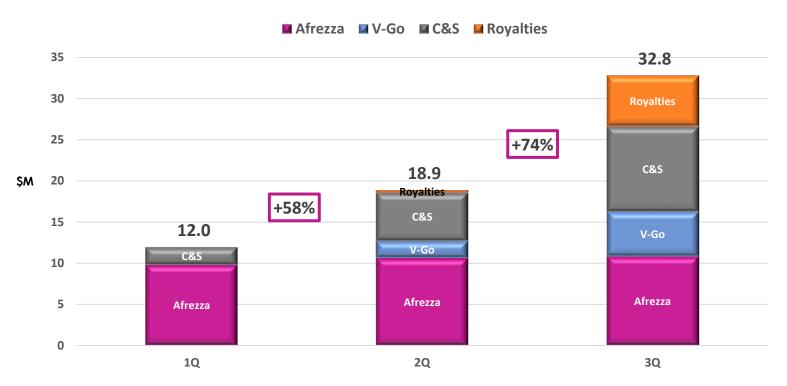
- Can eliminate need to take multiple/daily shots
- Continuous SC dosing (i.e., basal only)
- On-demand bolus feature
- Ex-US opportunity



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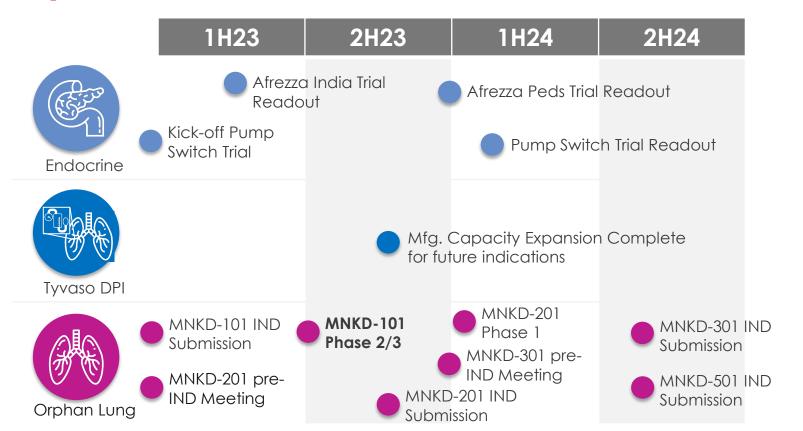
## Summary

# The New MannKind: 2022 Quarterly Commercial Revenue Acceleration





## Pipeline momentum over next 24 months



## MNKD Future is Exciting...

- Four sources of growing revenue
- Long-Term IP protection
- Emerging Pipeline
- Indication expansion for FDA approved assets with billions in potential
- Sustainable growth that is well funded

