

# 4Q 2020 Earnings Call

February 25, 2021



# Cautionary Statement

Today's presentation includes forward-looking statements relating to the development, commercialization and benefits of our products and investigational product candidates, including AFREZZA®, that are subject to certain risks and uncertainties that could cause actual results to differ materially from those projected herein. The words "believe," "expect," "intend," "anticipate," "plan," variations of such words, and similar expressions identify forward-looking statements, but their absence does not mean that a statement is not forward-looking. These forward-looking statements are not guarantees of future performance and are subject to certain risks, uncertainties, and assumptions that are difficult for us to predict and include, without limitation, our ability to generate significant product sales, our ability to manage our existing cash resources or raise additional cash resources, stock price volatility, the impact of the COVID-19 pandemic on our business and other risks detailed in MannKind's filings with the Securities and Exchange Commission. For detailed information about the risks and uncertainties that could cause actual results to differ materially from those implied by, or anticipated in, these forward looking statements, please refer to our current and periodic reports filed with the Securities and Exchange Commission from time to time, including our annual report on Form 10-K for the year ended December 31, 2020.



# Today's Agenda

**4Q 2020 Highlights**

**Michael Castagna, CEO**

**Financial Review**

**Steven B. Binder, CFO**

**Pipeline Prioritization  
& 2021 Milestones**

**Michael Castagna, CEO**

**Analyst Q&A**



**mannkind**

# Michael Castagna

Chief Executive Officer

# Our strategy

- We have a therapeutic focus on two disease areas:
  - **Endocrine diseases**
  - **Orphan lung diseases**
- We will exploit our current proprietary technologies, but we will not be limited by them
- We will focus, execute and deliver

# 4Q 2020 Highlights

- **Orphan Lung Diseases**

- **United Therapeutics Collaboration – Tyvaso DPI** (formerly TreT)
  - Completed clinical and product stability studies
  - UTHR purchased a **Priority Review Voucher** for **\$105M**
- Bolstered pipeline with the **acquisition of QrumPharma** for **inhaled clofazimine**

- **Endocrine Diseases**

- **Afrezza**
  - Record quarterly Net Revenue of **\$10.1M, +30%** vs. 4Q 2019
    - Sequential quarterly growth of **+38%**
  - 2020 Net Revenue of **\$32.3M, +28%** vs 2019, despite COVID headwinds
  - Engaged with the FDA on the clinical protocol for the **Ph 3 pediatric study**
- Entered into an agreement to **co-promote Thyquidity**

- **Added key talent in 2H 2020**

- **Chief Scientific Officer, VP Regulatory, VP Medical, VP Reimbursement, Access & Value (1Q 2021)**

# Orphan Lung Diseases

# Tyvaso DPI Timeline & Milestones

Completed

- Clinical studies and stability testing completed
- UTHR purchased a Priority Review Voucher

- UTHR released top-line BREEZE & PK study results

4Q 2020

1Q 2021

2Q 2021

3Q 2021

4Q 2021

Anticipated

- Finalize NDA submission file

- UT to submit NDA to FDA for PAH & PH-ILD
- FDA acceptance of NDA submission

- Danbury begins manufacturing pre-launch commercial product

- PDUFA date



# Tyvaso DPI Top-Line Clinical Results Reported by UTHR\*

- **BREEZE Study**

- **Primary Objective Achieved:** Safety & tolerability; switch patients from Tyvaso to Tyvaso DPI
  - 49 of 51 (96%) patients completed the treatment phase
  - No study drug related serious adverse events
- **Secondary Objectives Achieved**
  - Improvement in 6 minute walk distance compared to baseline
  - Improvement in overall satisfaction with the Tyvaso DPI inhaler vs nebulizer
  - Improvement in patient-reported outcomes
- **Optional Extension Phase**
  - 49 of 51 patients who completed the treatment phase chose to continue treatment in the optional extension phase

- **PK Study**

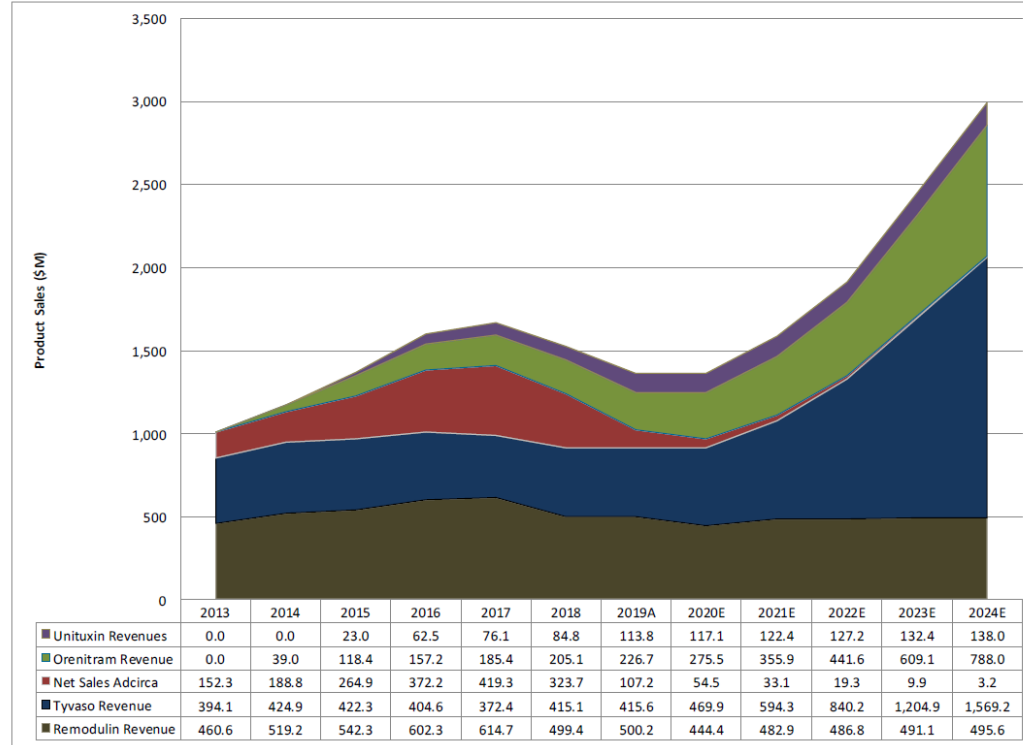
- **Primary Objective Achieved:** evaluate the systemic exposure and PK of treprostinil administered as Tyvaso DPI and Tyvaso Inhalation Solution
  - Patients demonstrated comparable systemic treprostinil exposure
  - Between-patient variability for AUC and Cmax was ~50% less for Tyvaso DPI

- **Safety**

- Adverse event profile was consistent with known prostacyclin effects and previous studies of Tyvaso Inhalation Solution

# A Peek Into the Future: Tyvaso DPI Potential (Blue) per Latest Oppenheimer & Co Research

Exhibit 13: UTHR Product Sales



# Acquisition of QrumPharma & Inhaled Clofazimine

- **Purchased Qrum in December 2020 for ~\$12.75M**
- **Inhaled clofazimine in development pre-IND**
  - Initial target is **nontuberculous mycobacterium (NTM) lung disease**
    - Significant unmet medical need - no current effective medication for NTM
  - Obtained **FDA orphan drug** & **QIDP** designations
  - Expected to enter Phase 1 in late 2021
  - NIH currently funding development in TB
- **Thomas Hofmann, MD, PhD, joined MNKD as Chief Scientific Officer**
  - Dr. Hofmann is a pediatric pulmonologist and has extensive experience with inhaled drug discovery and development

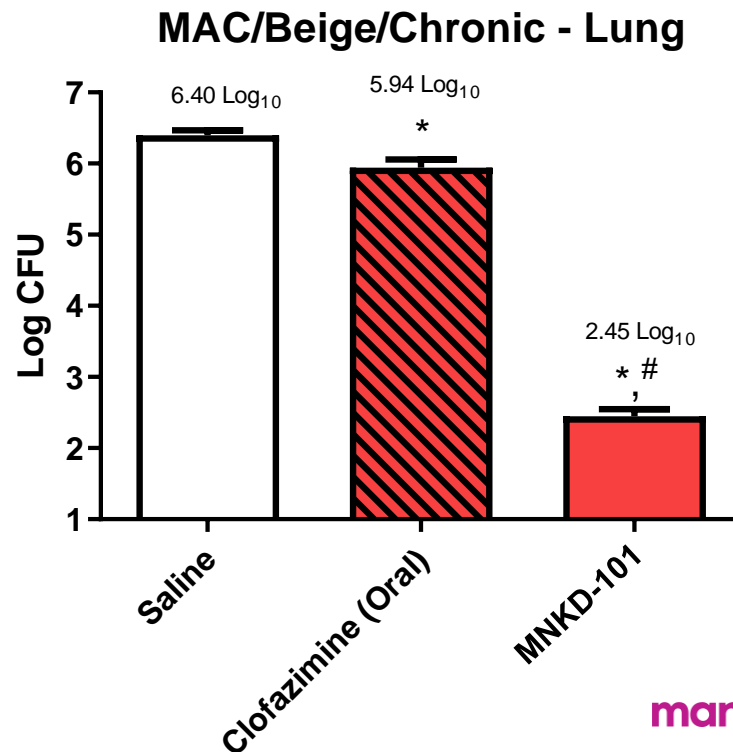
# MNKD 101 (Clofazimine Suspension for Inhalation)

## Reasons to be excited

- Highly potent MIC activity versus Nontuberculous Mycobacteria
  - Activity in both MABSC and MAC type NTM
- Efficient lung tissue penetration and long half life
  - Low dose and non continuous dosing may be possible
- Positive animal efficacy data
  - NTM mouse models with MABSC and MAC
- GLP tox studies ongoing and on schedule

# Chronic NTM-PD Treatment with MNKD-101 Superior to Oral Clofazimine After 28 Days

- 28 days infection; 14 treatments Q2D
- Minimal reduction in bacterial recovery from traditional oral clofazimine
  - Consistent with previous studies
- Strong reduction in bacterial recovery in MNKD-101 vs. saline control (4 log; 99.99% reduction)
- Statistically significant improvement vs. oral clofazimine (3.5 log; 99.97% reduction)

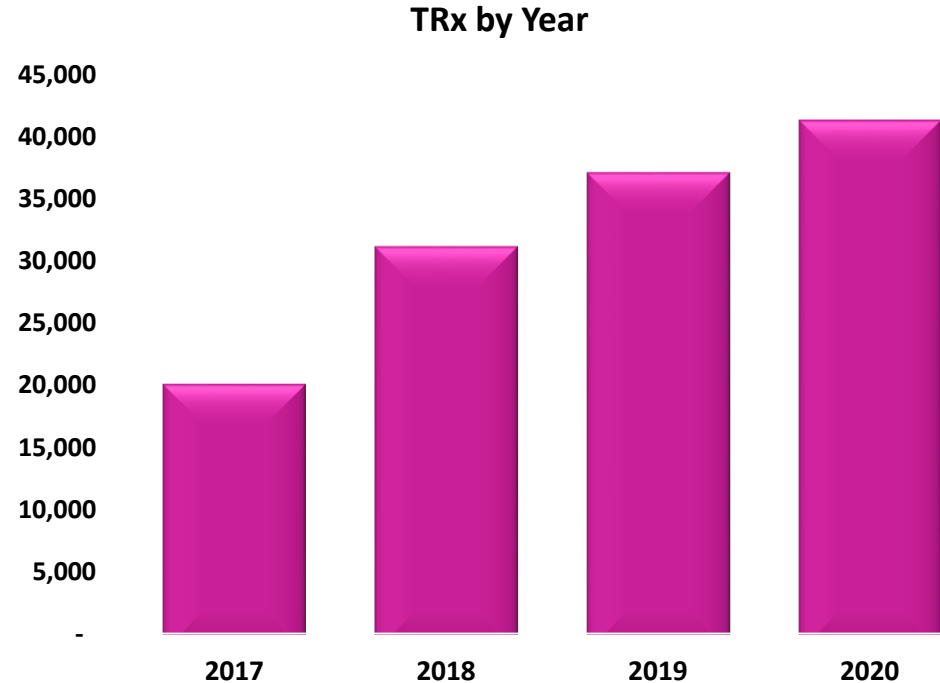


Banaschewski *et al.* 2019 J Cystic Fibrosis

# Endocrine Diseases

# Foundation of Afrezza is Established and Should Continue to Expand in 2021+

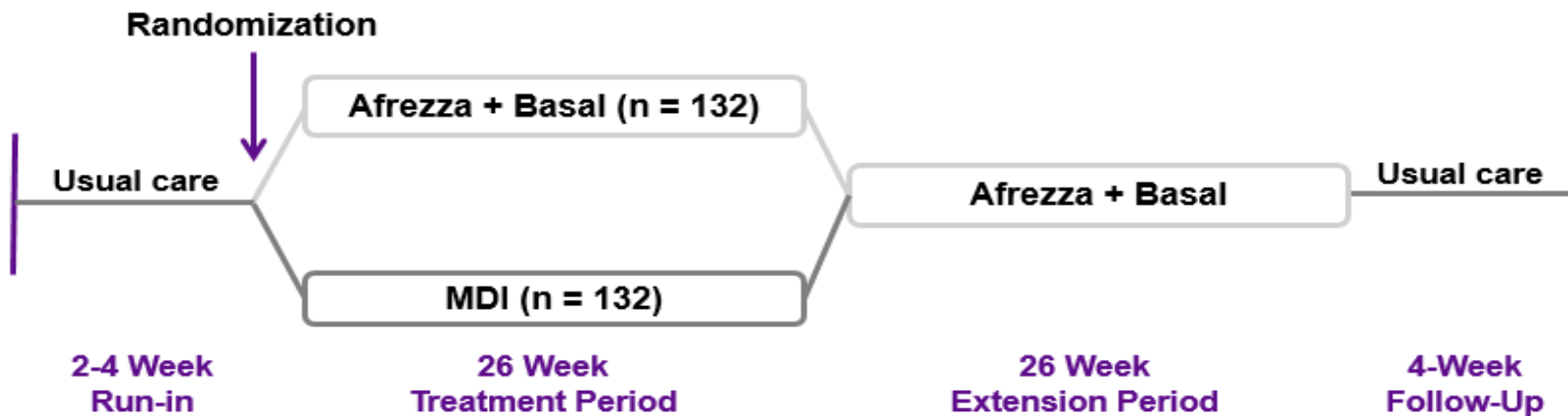
- Clinical efficacy, safety and dosing datasets have been presented and published
- Base of prescribers is ~3,000+ doctors
- Commercial and medical teams are stable and talent is expanding
- The safety profile is well established
- Moving toward expansion indications for pediatrics and possible gestational diabetes



# Preliminary Design of Afrezza Pediatric Study

**Study Design:** 26-week primary treatment phase, with 26-week extension, open-label, randomized clinical trial evaluating efficacy and safety of Afrezza with basal versus MDI in pediatrics (ages 4-17) with T1 or T2

**Primary Objective:** Non-inferior to MDI as defined by A1c at 26 weeks



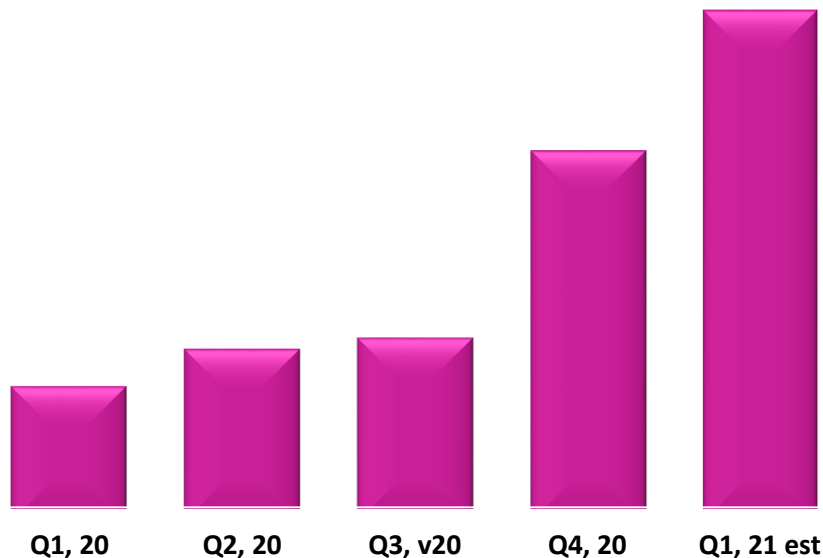


# Afrezza Key Priorities for 2021

- Increase awareness
- Prepare BluHale for consumer launch
- Successfully launch new reimbursement model
- Strengthen advocacy for inhaled insulin



Cash Pay + Free Goods (TRx)



# Co-Promotion of Thyquidity

- **Thyquidity is indicated for hypothyroidism**
  - Adult and pediatric endocrinologists have a high concentration of prescriptions
- **MNKD will use its sales force to promote Thyquidity in a secondary position**
  - Expands our footprint into pediatric endocrinology
- **Financial Impact**
  - Quarterly payments to MNKD for promotional activity
  - Royalties on gross profit of Thyquidity
- **Launched this week**



# Steven B Binder

Chief Financial Officer

# 4Q Afrezza U.S. Revenue Increased +30%

	4Q 2020	4Q 2019	% Chg	YTD 2020	YTD 2019	% Chg
Net Revenue - Afrezza	10.1	7.8	30%	32.3	25.3	28%
GTN %	38%	44%		41%	42%	
Revenue - Collaborations and Services	8.4	8.2	2%	32.8	37.7	-13%
Total Revenues	18.4	16.0	15%	65.1	63.0	3%

	4Q 2020	4Q 2019	% Chg
Net Revenue - Afrezza	10.1	7.8	30%
End Free Goods Program	(1.1)	-	
Non-GAAP Net Revenue - Afrezza	8.9	7.8	15%

## Free Goods Program Termination:

- Impact on TRx is ~ -15% decrease
- 4Q 2020 Net Sales benefit from reversal of \$1.1M accrual

# Afrezza GTNs Trending Lower

	(\$M)	1Q 2020	2Q 2020	3Q 2020	4Q 2020
<b>Afrezza Gross Revenue</b>		13.9	11.7	12.4	16.2
<b>Gross-to-Nets</b>		<u>(5.9)</u>	<u>(4.9)</u>	<u>(5.1)</u>	<u>(6.2)</u>
<b>Afrezza Net Revenue</b>		<u><u>8.0</u></u>	<u><u>6.8</u></u>	<u><u>7.3</u></u>	<u><u>10.1</u></u>
<b>GTN %</b>		<b>43%</b>	<b>42%</b>	<b>41%</b>	<b>38%</b>

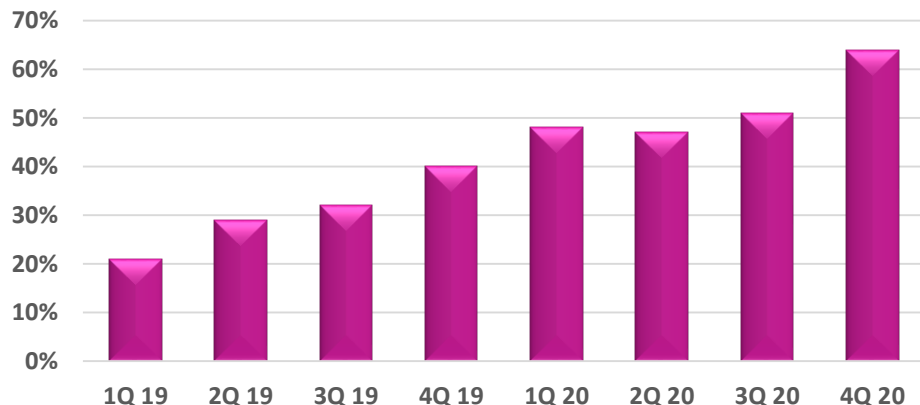
## Primary reasons for lower GTN %:

- Shift to specialty pharmacies – favorable impact on distribution fees
- 4Q 2020 Free Goods Program termination

Please see GAAP to Non GAAP reconciliation at the end of the presentation

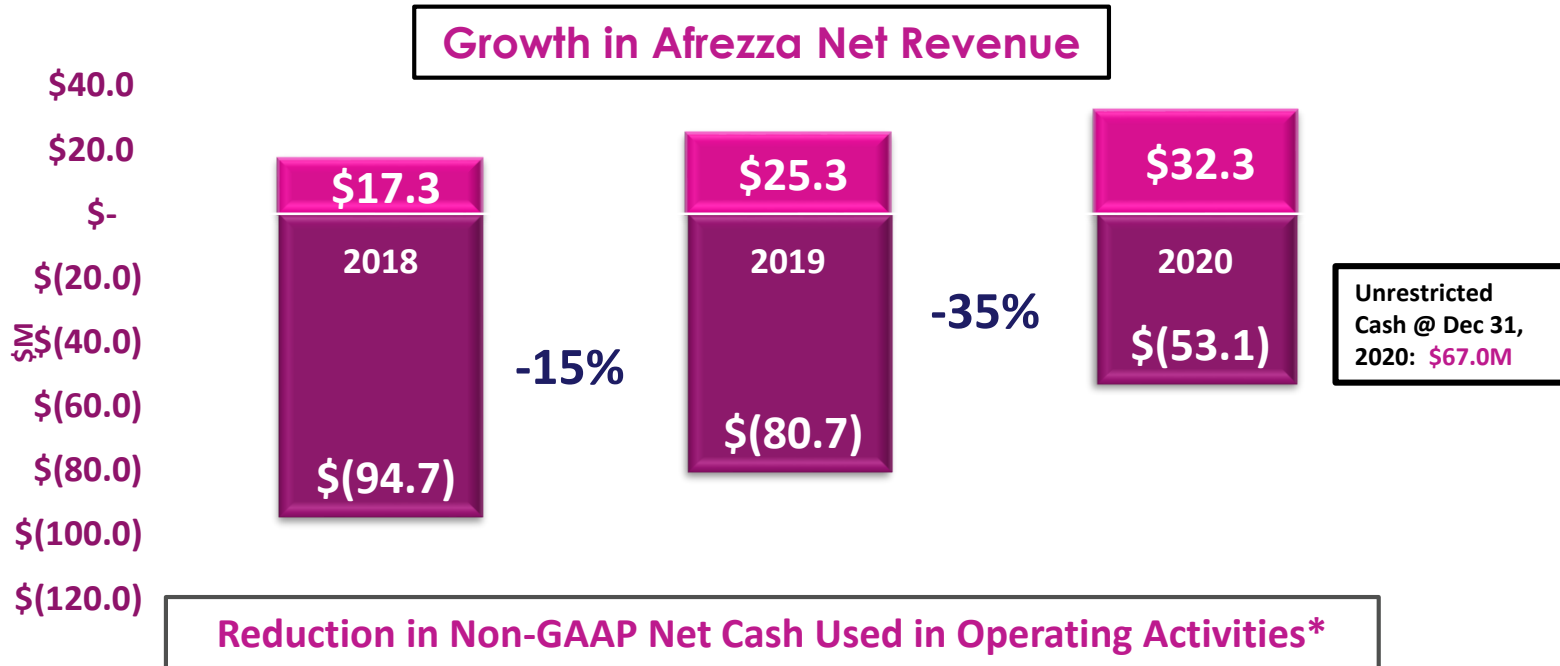
# Afrezza Gross Margin Hits 64% for 4Q 2020

	(\$M)	1Q 2019	2Q 2019	3Q 2019*	4Q 2019	1Q 2020	2Q 2020	3Q 2020	4Q 2020
Net Revenue - Afrezza		5.1	6.1	6.4	7.8	8.0	7.0	7.3	10.1
Cost of Goods Sold - Afrezza		(4.0)	(4.3)	(4.3)	(4.6)	(4.2)	(3.7)	(3.6)	(3.7)
Gross Profit - Afrezza		1.1	1.7	2.1	3.1	3.8	3.3	3.7	6.4
Gross Margin - Afrezza		21%	29%	32%	40%	48%	47%	51%	64%



\* 3Q 2019 Afrezza COGS, Gross Profit and Gross Margin exclude \$2.75M AMPH Amendment Fees. Please see GAAP to Non-GAAP reconciliation at end of presentation.

# Improving Operating Efficiency and Cash Balance



Avg. Qtrly Non-GAAP Net Cash Used in Operating Activities	\$23.7M	\$20.2M	\$13.3M
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# Sale-Leaseback of Danbury Manufacturing Facility

- **Non-Binding Letter of Intent**
  - Due diligence and definitive agreement expected to be completed by end of 1Q 2021
- **Sale expected to be funded in 2Q 2021**
  - Sales price expected range of ~\$95M-\$105M
- Use proceeds for **general corporate purposes**
  - May pay down a portion of the senior secured debt





**Michael Castagna**

**Chief Executive Officer**

# **Pipeline Prioritization, Technosphere Platform and 2021 Milestones**

# MNKD Pipeline and Collaborations

Endocrine

Orphan Lung

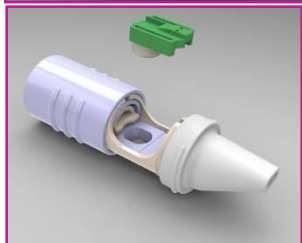
Third-Party Programs

product	formulation	pre-IND	phase 1	phase 2	phase3/ pivotal	marketed
<b>Afrezza® (insulin human) Inhalation Powder</b> <i>USA, Brazil (with Biommm)</i>	T1 and T2 diabetes mellitus (adults)					
<b>Thyquidity™ (levothyroxine solution) oral solution 100mL</b> <i>USA (co-promotion with Vertice)</i>	Hypothyroidism					
<b>Pediatric Afrezza® (insulin human) Inhalation Powder</b> <i>Indication Expansion</i>	T1 and T2 diabetes mellitus (pediatrics)					
<b>Afrezza® (insulin human) Inhalation Powder</b> <i>International Expansion: India (Cipla) and Australia (AMSL)</i>	T1 and T2 diabetes mellitus (adults)					
<b>Tyvaso DPI™</b> <i>(collaboration with United Therapeutics)</i>	PAH / PH-ILD					
<b>MNKD-101</b>	NTM					
<b>MNKD-201</b>	IPF					
<b>MNKD-301</b>	Cystic fibrosis					
<b>MNKD-701</b>	Undisclosed					
<b>Cannabidiol Technosphere®</b> <i>(licensed to Receptor Life Sciences, milestones and royalty payments)</i>	Panic attack (POC)					
<b>Small molecule enzyme inhibitor</b> <i>(sold to Fosun Pharma, MNKD eligible for royalty payments)</i>	Solid tumors-Fast Tracked by FDA					

PAH pulmonary arterial hypertension  
 PH-ILD pulmonary hypertension associated with interstitial lung disease  
 NTM nontuberculous mycobacterial lung disease  
 IPF idiopathic pulmonary fibrosis

# Growth of the Technosphere® Platform

## Reusable Dreamboat® Family



## Single-use Cricket® Family



5  
Formulations

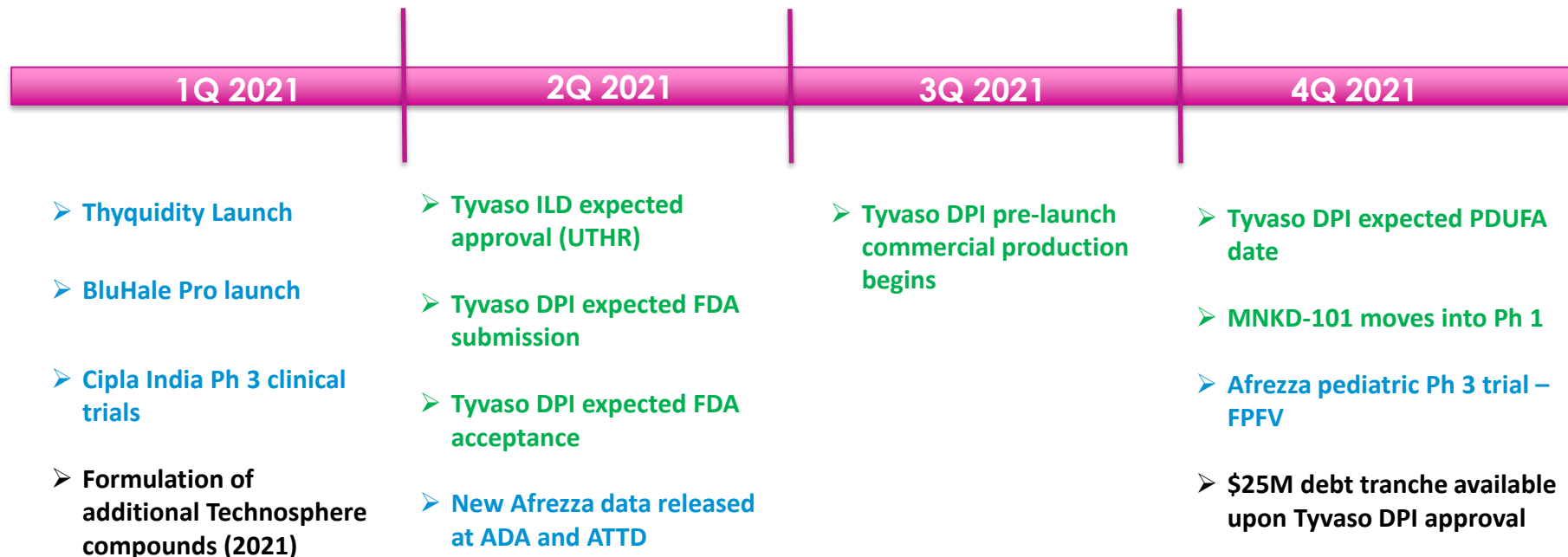
2020

10+  
Formulations  
expected for  
2021, majority  
are external

2021

Technosphere® Platform

# 2021 Milestones



**KEY:**

Endocrine Diseases

Orphan Lung Diseases

Not identified/Corporate

# Thank you

Contact: [IR@mannkindcorp.com](mailto:IR@mannkindcorp.com)

# GAAP to Non-GAAP Reconciliations

	(\$M)	4Q 2020
Afrezza Gross Revenue	16.2	
Free Goods Accrual Reversal	(1.1)	
Non-GAAP Afrezza Gross Revenue	15.1	
Gross-to-Nets	(6.2)	
Non-GAAP Afrezza Net Revenue	8.9	
<b>Non-GAAP GTN%</b>		<b>41%</b>

	(\$M)	4Q 2020
Afrezza Gross Revenue	16.2	
Free Goods Accrual Reversal	(1.1)	
Non-GAAP Afrezza Gross Revenue	15.1	
Afrezza Net Revenue	10.1	
Free Goods Accrual Reversal	(1.1)	
Non-GAAP Afrezza Net Revenue	8.9	
Cost of Goods Sold	(3.7)	
Non-GAAP Gross Profit - Afrezza	5.3	
<b>Non-GAAP Gross Margin- Afrezza</b>		<b>59%</b>

	(\$M)	3Q 2019
Net Afrezza Revenue	6.4	
Cost of Goods Sold	(7.1)	
<b>GAAP Gross Profit</b>		<b>(0.7)</b>
Exclude Amphastar Amendment Fee	2.8	
<b>Non-GAAP Gross Profit</b>		<b>2.1</b>
<b>Non-GAAP Gross Margin</b>		<b>32%</b>
<b>GAAP Cost of Goods Sold</b>		<b>(7.1)</b>
Exclude Amphastar Amendment Fee	2.8	
<b>Non-GAAP Cost of Goods Sold</b>		<b>(4.3)</b>

	YTD 2018	YTD 2019	YTD 2020
<b>GAAP Net Cash Used in Operating Activities</b>	<b>(37.7)</b>	<b>(88.5)</b>	<b>(28.1)</b>
License fee received from Cipla	(2.0)		
Upfront Payment from UTHR	(45.0)		
Milestone received from UTHR		(25.0)	(25.0)
Research fee received from UTHR	(10.0)		
PIK interest on promissory notes		32.8	
<b>Non-GAAP Net Cash Used in Operating Activities</b>	<b>(94.7)</b>	<b>(80.7)</b>	<b>(53.1)</b>