# **MannKind Corporation**

Michael Castagna, Pharm D
Chief Executive Officer

Lytham Partners Virtual Investor Conference – June 24, 2020

## **Cautionary Statement**

This 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 forwardlooking. 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 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 vear ended December 31, 2019.



## Our strategy

Our strategy is focused on developing innovative medicines for both endocrine and orphan lung diseases.



## Corporate overview

#### Commercial-stage biopharma company with a differentiated delivery technology and robust product pipeline



Manufacturing Facility
Danbury, CT



Corporate Headquarters
Westlake Village, CA



#### Technosphere® Technology

Enables drug molecules to be delivered efficiently through the lungs, providing a faster onset of action. Technosphere can be applied to a number of important therapeutic areas.



#### Afrezza® Approved in U.S. & Brazil

Afrezza® is an ultra fast inhaled mealtime insulin positioned to be at the forefront of diabetes treatment and technology.

Net Revenue growth 6x between 1Q 2017 and 4Q 2019

#### Our Partnerships and Pipeline



Exclusive global license and \$105M+ collaboration agreement for the rights to our dry powder formulation of Treprostinil (TreT)





#### BluHale® - Inhalation Innovation

BluHale® helps make our simple inhaler even easier to use. The novel device is mounted on the inhaler and senses the change in pressure when a user inhales through the mouthpiece.



#### **Financial Position**

August 2019 recapitalization and UTHR milestones create a solid foundation moving forward.

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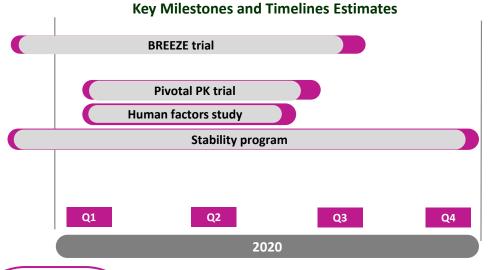
## **Our MNKD Pipeline**





## Completed 3<sup>rd</sup> Milestone and Received \$12.5M in Q2

-Critical Milestones for Treprostinil Dry Powder for Inhalation (TreT)



#### **BREEZE Trial**

Trial on hold due to COVID-19, but patients who switched are in the extension phase where they have the ability to up-titrate to higher maintenance dose.

14 sites have been activated and over additional sites are being evaluated.

#### **Program Status**

**CMC** 

Registration stability data is ongoing.

Manufacturing suite construction is

Protocol on human factors study

complete.

under final review.

#### **PK Trial**

First cohort of patients were dosed and there will be 2 additional cohorts.

Enrollment is on hold and a

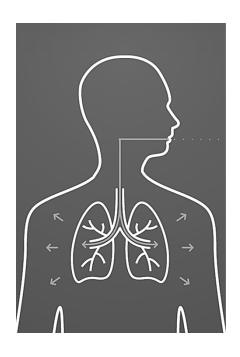
Enrollment is on hold and a tentative restart is in early July with a Covid-19 testing plan in place.

## Program Accomplishments

- Received 3 milestone payments for execution of planned deliverables on time and within scope.
- Manufactured clinical supplies and initiated BREEZE trial in 3Q, 2019 and PK trial in 1Q, 2020.
- Successfully completed Formative 1 study in human factors with positive feedback and input for summative validation study in 3Q, 2020.
- Initiated 12-month NDA (registration) stability program
- Continue to explore other PAH related partnerships based on our platform

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# Afrezza® oral inhalation insulin delivery: One-of-a-kind therapy



## What is Afrezza® made of?

Technosphere® + human insulin and water = Technosphere® Insulin Afrezza®

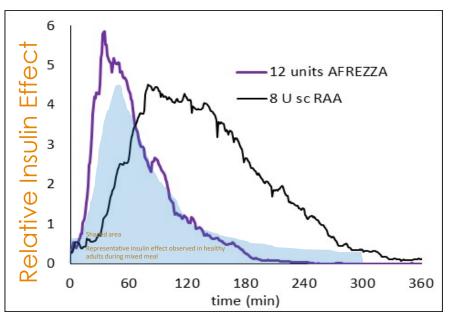
#### How is inhaled insulin delivered?

When the insulin is inhaled, the Technosphere particles dissolve rapidly and separate, and the FDKP and insulin are quickly absorbed across the lung membrane.

Delivering the insulin through the large surface area of the lungs allows for **ultra rapid absorption**.



## Afrezza® Mimics Physiologic Insulin Response



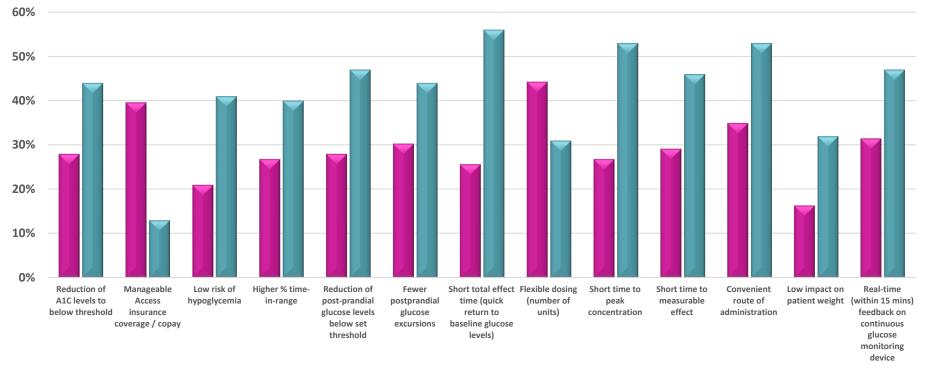
Caumo A. J Clin Endo Metab 85: 4396, 2000

RAA, rapid-acting analogue;

Afrezza [package insert]. MannKind Corporation; 2017. Figure adapted from: Baughman et al. Poster presented at: American Diabetes Association 76th Scientific Sessions; June 2016; New Orleans, LA. With permission.

## **Our Commercialization Efforts Are Making Impact:**

Market Research Shows Afrezza Performs Well Over Injectable Mealtime Insulin on 11 out of 13 Choice Drivers (% rated 6-7 on scale 1-7)

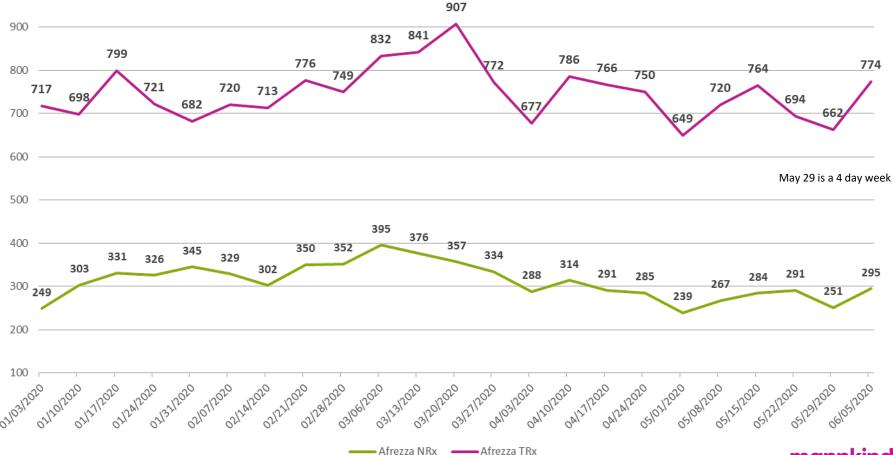


■ Standard of Care

**■** Afrezza



## NRx trends are stabilizing post COVID-19 Crisis



## Key Highlights of ADA Scientific Sessions (June 12-16)

- Afrezza's ultra rapid-acting profile may supersede the perceived precision of injected mealtime dosing and provides patients the ability to flexibly dose based on glycemic response
- Afrezza has a favorable weight profile: in T2D, treatment with Afrezza is associated with weight loss (compared to weight gain with injected mealtime insulin)
- In an MDI switch study, Afrezza improved A1c while maintaining Time In Range with no additional hypoglycemia in T2D
- Overall, 98% of those treated with Afrezza (vs. 99% treated with injected mealtime insulin)
   had either no change (≥15%) or a transient change in FEV₁ over 2 years

## Results: Mean Change in Weight

- TI was associated with a reduction in body weight from baseline, whereas both insulin aspart and biaspart were associated with weight gain
  - Difference estimate between TI and aspart:
     0.83kg (P<0.01)</li>
  - Difference estimate between TI and biaspart: 1.44kg (P<0.0001)</li>
- Weight changes were independent of HbA1C changes

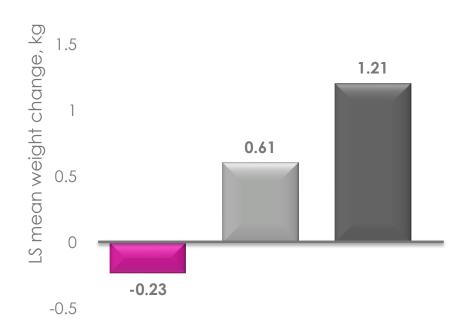


Figure 1. Weight Change from Baseline Week 24/26



## Inhaled and Background Basal Insulins Improved A1c and QOL in Patients with T2D: an Observational Study

Authors: M Kipnes, A Salhin, J Vadakekalam, V Pamar, WF Trigoso, F Akhrass, T Ryan

#### Background:

Investigator Initiated Trial conducted at the Diabetes & Glandular Disease Clinic PA., San Antonio, TX

### **Objective:**

To determine the clinical impact of conversion from SC prandial analog to TI in people with type 2 diabetes

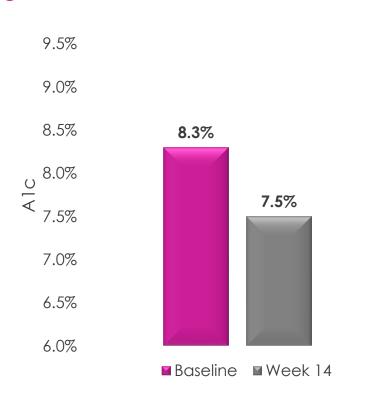


<sup>1.</sup> Rosensock et al. Lancet. 2010;375:2244-2253

<sup>2.</sup> Bode et al. Diabetes Care. 2015;38:2266-2273

## Results

## Significant Reduction in HbA1C with Afrezza® of -0.8% over 14 weeks



Subjects (N=25)	Mean A1c			
Baseline	8.3%			
Endpoint (Week 14)	7.5%			
Change from baseline	-0.8% (P=0.0004)			

#### **SUMMARY:**

When compared to SC prandial insulin over 14 weeks, patients treated with Afrezza® in combination with basal insulin achieved:

- Improved glucose control
- Acceptable TIR maintenance
- Improved QoL
- No significant increase in hypoglycemia



# 2020 Afrezza Commercial Strategy Is Focused on Placing Key Bets to Drive Wider Adoption



- Increased focus of resources on Type 1 diabetes, including:
  - Sales and Marketing efforts
  - Physician targeting
  - Advocacy relations
  - Data generation and publications



- Specialty pharmacy network that provides:
  - Reimbursement support
  - Pharmacy fulfillment support
  - Patient persistency tactics (e.g., texts, e-mails, phone calls)



 Patient training pilot program to support patients in successfully starting Afrezza



Launch BluHale® PRO

## In addition to new sales reps, we have brought new additions to the sales leadership team





## BluHale PRO will launch in Q3,2020

## the device: 1.0



BluHale Pro is an accessory device for dreamboat inhaler. It mounts onto the inhaler to measure the effort exerted by patients during inhalation.

## the future: 2.0

BluHale 2.0 will have dose detection integration for consumers



## the app



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Available for both Android and IOS devices. Connecting the device to the app allows healthcare providers to train their patients on how to use their inhaler in real-time.

### the feedback



#### Increased patience confidence levels.

Patients feel more comfortable using the inhaler when they receive their first prescription after practicing with the BluHale device.



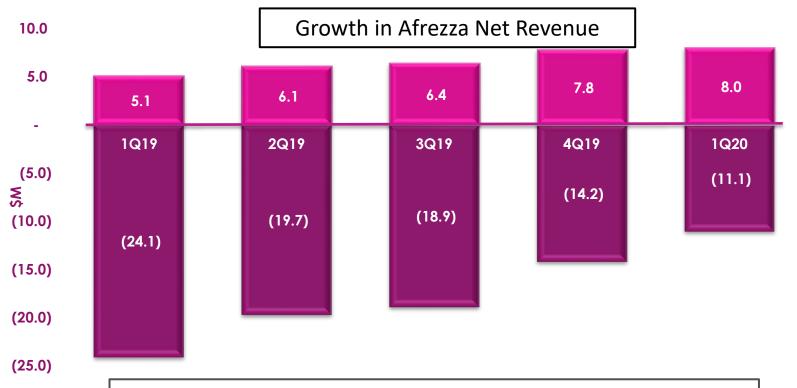
## Afrezza Quarterly Net Revenue is up ~7X since 1Q,17



<sup>\*</sup>Please see GAAP to Non-GAAP reconciliation at end of presentation



## **Operating Cash Efficiency Continues to Improve**



Reduction in Non-GAAP Net Cash Used in Operating Activities\*





			Price Target	
SVB Leerink		Outperform	\$	3.00
		•	·	
Cantor Fitzgerald		Overweight	\$	3.00
BTIG		Buy	\$	4.00
	-			
H. C. Wainwright & Co		Buy	\$	2.50
_				
Oppenheimer		Outperform	\$	2.50

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# The Transformation of Our Revenue Growth Drivers Should Deliver Future Shareholder Value

Pipeline Royalties and In-license

Afrezza International expansion

**US Afrezza** 

**Technosphere Platform** 





Thank You



## **GAAP to Non-GAAP Reconciliations**

(\$M)	4Q 2017	
<b>GAAP Afrezza Net Revenue</b>	4.5	
Adjustment for Change in Estimate	(1.4)	
Non-GAAP Afrezza Net Revenue	3.1	

	(\$M)	1Q 2019	2Q 2019	3Q 2019	4Q 2019	1Q 2020
GAAP Net Cash Used in Operating Activities		(11.6)	(19.7)	(52.1)	(5.1)	(11.1)
Milestone received from UTHR		(12.5)			(12.5)	
Payment-in-kind interest on promissory notes				32.8		
Deerfield Milestone					3.4	
Warrant Purchase				0.4		
Non-GAAP Net Cash Used in Operating Activiti	ies	(24.1)	(19.7)	(18.9)	(14.2)	(11.1)

