# mannkind

CEO's corner Michael Castagna, PharmD Chief Executive Officer



I am really proud of how our team has executed so far in 2021, supporting the growth of Afrezza ® and preparing for the potential commercial launch of Tyvaso DPI™. With the issuance of the convertible debt in the first quarter and the pay-down and restructuring of our legacy debt in the second quarter, we have a stronger balance sheet with lower interest expense, which sets the company up for commercial growth and pipeline advancement for years to come.

company news

#### Tyvaso DPI (inhaled trepostinil) – currently being reviewed by the FDA for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD) - continues to

## be on track in terms of timeline and milestones. The on-site portion of the

tyvaso DPI

pre-approval inspection in Danbury was completed this August, and we have scaled up our staff and readied essential equipment and production lines to begin manufacturing pre-launch commercial product, pending FDA approval. Tyvaso DPI marks the second compound formulated with MannKind's Technosphere® technology to undergo FDA review, which is expected to be complete in October 2021. MannKind and United Therapeutics (UT) recently cemented a commercial supply agreement wherein MannKind will manufacture and supply Tyvaso DPI (inhaled treprostinil) and UT will purchase the product.

The non-clinical toxicology study was completed for MNKD-101 (Clofazimine Suspension for Inhalation), with reports pending. No drug-associated clinical signs were observed in this 28-day study. A Phase 1 clinical study in healthy volunteers is planned to start by year-end.

pipeline

We continue to work on several formulations for new collaborations, including the recently-announced partnership with NRx Pharmaceuticals to evaluate the feasibility of a dry powder version of ZYESAMI™ (Aviptadil) (see more in this newsletter's "In The News" section).

For a broader view of our <u>pipeline</u>, please visit our corporate website.

afrezza Afrezza experienced a 6% TRx growth (via Symphony) in 2Q 2021 vs. 1Q 2021, which we attribute to increased education and awareness efforts.

The Afrezza INHALE-1 Study for pediatric indication is nearing initiation. The protocol was reviewed with the FDA, and approval has been received from the



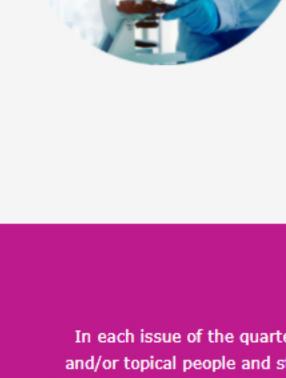
#### Institutional Review Boards (IRB). Initial investigator meetings are occurring in August 2021 and we are targeting the first patient visit in October 2021.

The INHALE-1 Study is a 26-week open-label, randomized clinical trial (with a 26-week extension) evaluating the efficacy and safety of Afrezza with basal

in the news

MannKind to explore dry powder formulation of ZYESAMI

### Intestinal Peptide (VIP) - an endogenous substance produced by the body that helps protect cells against inflammatory conditions. An intravenous formulation of ZYESAMI is currently in



Administration (FDA) for the treatment of Critical COVID-19 with Respiratory Failure. read more → spotlights In each issue of the quarterly Newsletter, we will look to Spotlight interesting and/or topical people and stories connected with MannKind. We hope you enjoy learning more about two key "Mannitarians" committed to – among other projects with their teams – furthering the Afrezza INHALE-1 Study.

We recently announced a partnership with NRx

formulation a dry powder formulation of ZYESAMI (Aviptadil), a synthetic form of human Vasoactive

Pharmaceuticals to evaluate the feasibility of

clinical trials, having been granted Fast Track

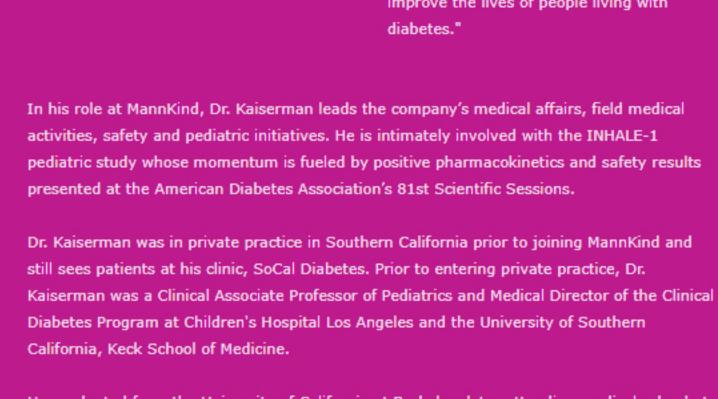
Designation by the U.S. Food and Drug

Dr. Kevin Kaiserman

## Dr. Kevin Kaiserman has dedicated his career of more than 25 years to improving

Vice President, Medical Affairs and Safety

the lives of children with diabetes whether it be in practice, volunteering, teaching, and currently at MannKind. A leading, board-certified pediatric



Foundation (JDRF), among others.

Karen Jaffe

Endocrinology.

diabetes." In his role at MannKind, Dr. Kaiserman leads the company's medical affairs, field medical activities, safety and pediatric initiatives. He is intimately involved with the INHALE-1

endocrinologist, Dr. Kaiserman joined

Mannitarians embodied a purpose aligned to his: "I think the MannKind mission and

focus is very much in line with what I've

devoted my career to. The entire team is

improve the lives of people living with

committed in a very unified way in trying to

MannKind in 2020, as he saw that

He graduated from the University of California at Berkeley, later attending medical school at Eastern Virginia Medical School. Dr. Kaiserman completed his internship and residency at the UCLA Department of Pediatrics and his fellowship at the UCLA Division of Pediatric A renowned speaker and thought leader in the field of diabetes, Dr. Kaiserman has participated in numerous publications and research studies. He has served on multiple

**Operations and Quality Assurance** Nothing motivates Karen Jaffe more than a good challenge. She powerfully believes there are no bad ideas. And she is driven to help make Afrezza as successful as it

in her mind.

boards such as the American Diabetes Association-Greater Los Angeles Chapter, and

continues to sit on Boards for organizations such as the Juvenile Diabetes Research

A passion project outside of work for Dr. Kaiserman is Camp Conrad-Chinnock, which hosts a

California. In addition to being a medical director for the camp, he is a proud board member

summer camp for youth and families with diabetes in the San Bernardino Mountains of

of the Diabetes Camping and Educational Services (DCES).

Vice President, Regulatory Affairs, Clinical



Goldendoodle Simba.

technology project management and regulatory strategy that supports MannKind's innovative product and medical device development. An engineer by training – she holds a BS from Georgia Tech and Master's in Electrical Engineering (MSEE) from Cornell University. She also obtained an MBA from New York University and went on to earn another master's degree in Medical Regulatory Sciences (MRSc) from the University of Southern California (USC). Her career path has included (among others) stints as VP RA/QA/CA for Keystone Heart, Ltd, Senior Director of RA/QA for NuVasive Specialized Orthopedics and Obalon Therapeutics, as well as consulting for Edwards LifeSciences, and holds two patents in Pharmacovigilance.

Cash as of

of 2021

June 30, 2021

Total revenue for 2Q

Price: 8/23/21

% Change - 6 Mos

1/1/21 - 8/23/21

\$4.48

\$3,982.70

+43.1%

+15.1%

possibly can be. "For me, there's a personal

project that brings purpose to the forefront

passion for realizing Al's (Mann) dream," she explains. So the INHALE-1 Study is a

Increase in total 54% ^ revenue\* \*In comparison to 2Q 2020.

Jaffe can be found living life more human by enjoying outdoors activities with her family. She

financial & stock performance

\$201.4M

\$23.3M

is an avid skier, swimmer, spinner, hiker and kayaker – the last activity done often with her

P&B Index \* Stock price return over the course of 2020-21 for both MannKind and the Russell 3000 Pharmaceuticals & Biotech index provided via Bloomberg.

Valley →

Conference →

Meeting →

H.C. Wainwright 23rd Annual Global september HCW Investment Conference → 13-14

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DESCRIPTION OF THE REAL PROPERTY.

2021 events

sep. 27oct. 1

21st Annual Diabetes Technology

MannKind 3Q 2021 Earnings Call →

Reach out anytime. We'd love to hear from you. general inquiries contact contact investor relations

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insulin vs multiple daily injections (MDI) of insulin in pediatric patients (aged 4-17) living with type 1 diabetes (T1D) or type 2 diabetes (T2D).

see 2021 q2 financial results

Price: 12/31/19

% Change - 3 Yrs

8/24/18 - 8/23/21

\$1.29

\$3,052.90

+300.0%

+39.2%

stock performance\*

Equity/Index

MNKD

R3000

MNKD

R3000

september

23-25

september

27-29

november

4-6

1H

november

MannKind Corporation

30930 Russell Ranch Road, Suite 300

Westlake Village, CA 91362 USA

P&B Index

Equity/Index

+23.4%

SVB Leerink Healthcare Summit Napa

Price: 12/31/20

% Change - 1 Yr

8/24/20 - 8/23/21

\$3.13

\$3,459.40

+165.1%

Cantor Virtual Global Healthcare EASD 51st Annual Meeting →

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