

### CEO's corner

**Michael Castagna, PharmD**

Chief Executive Officer



“ The MannKind team continues to stay focused and execute our corporate objectives of preparing for the commercial launch of Tyvaso DPI <sup>™</sup>, moving our pipeline forward and growing Afrezza <sup>®</sup>. We are motivated by the recently completed animal toxicology studies of inhaled clofazimine that supports moving this unique chemical entity into Phase 1 clinical trials by year-end. ”

### company news



#### TYVASO DPI

In support of the commercial launch of Tyvaso DPI (inhaled treprostinil) by United Therapeutics, MannKind is building pre-launch inventory at our manufacturing facility in Danbury, Conn.

In October, the company learned that the U.S. Food and Drug Administration (FDA) issued a complete response to United Therapeutics Corporation regarding the New Drug Application (NDA) for Tyvaso DPI.

The complete response did not pertain to MannKind, and no issues were cited by the FDA as it relates to our facility for manufacturing, testing and packaging of finished Tyvaso DPI, including its associated device. The FDA noted only one deficiency related to an open inspection issue at a third-party analytical testing center.

The draft labeling received from the FDA included the same indications as Tyvaso Inhalation Solution -- pulmonary arterial hypertension and pulmonary hypertension associated with interstitial lung disease – and does not contain any

contraindications or a boxed warning. United Therapeutics has stated that it expects approval and launch by summer 2022, or earlier.



## PIPELINE

Pre-IND toxicology studies were completed for MNKD-101 (Clofazimine Suspension for Inhalation). These results provide us the rationale to move forward with a Phase 1 clinical study by year-end.

Formulation work on MNKD-201 for idiopathic pulmonary fibrosis (IPF) is also nearing completion. IPF is the most common type of idiopathic interstitial lung disease (ILD).

According to the National Institutes of Health (NIH), about 100,000 people in the United States have IPF, and approximately 30,000 to 40,000 new cases are found each year.

In June, MannKind announced an agreement with Thirona Bio, Inc., for Thirona 5712, a TGF-beta receptor kinase (ALK-5) inhibitor for which we are creating a Technosphere<sup>®</sup> dry-powder formulation. The agreement with Thirona allows MannKind to exercise certain rights to seek a full license to the compound to treat fibrotic pulmonary diseases.

MannKind maintains a goal of launching a new product or indication from its pipeline every year between 2025 and 2030. For a broader view of our [pipeline](#), please visit our corporate website.



## AFREZZA

MannKind announced in October its first patient enrollment in the INHALE-1 study. This multi-center study will assess the efficacy and safety of Afrezza in patients aged 4-17 living with type 1 or type 2 diabetes. The "In The News" section below shares more about the INHALE-1 Study.

Afrezza experienced a 16% TRx growth (via Symphony) in 3Q 2021 vs. 3Q 2020. The fourth quarter will see multiple initiatives aimed at growing Afrezza, including: launching a primary care outreach pilot program, an additional program to help improve patient retention during the first 12 weeks of treatment, and implementing a "Seeing is Believing" Afrezza Challenge with Continuous Glucose Monitoring (CGM) devices.

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## in the news



## 1st patient enrolled in INHALE-1 Study of Afrezza for pediatric population

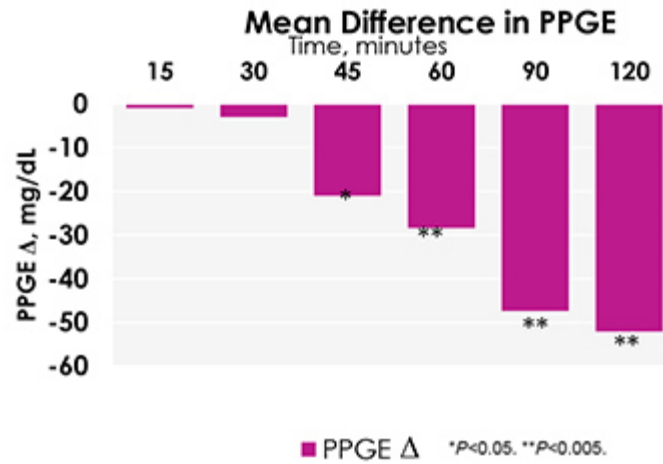
MannKind is often asked about Afrezza for pediatrics, and we are delighted to share our latest efforts in hopes of bringing its Technosphere Insulin (TI) to a younger generation. On October 4th, MannKind announced its first patient enrollment for the INHALE-1 study of Afrezza in the pediatric population. This multi-center study will evaluate the efficacy and safety of Afrezza in combination with basal insulin vs. multiple daily injections of insulin in children and adolescents aged 4-17 who are living with type 1 or type 2 diabetes.

In all, approximately 260 patients are planned to be enrolled at more than 30 sites across the United States.

For more information about INHALE-1, visit [go.afrezza.com/INHALE1](http://go.afrezza.com/INHALE1). Read more about the INHALE-1 announcement [here](#).

## Higher TI dose resulted in ~ 50 mg/dL improvement in PPGE @ 120 minutes

It's no secret that mealtime control of glucose for patients living with diabetes remains a critical goal. MannKind recently presented data at the 21st Annual Diabetes Technology Meeting (DTM) regarding a feasibility study that demonstrated a higher Afrezza dose – approximately double the estimated mealtime subcutaneously (SC) injection dose – than the dose determined from the current prescribing information reduced postprandial glucose excursions (PPGE) without any severe hypoglycemia in the first two hours. The higher dose of Afrezza resulted in approximately 50 mg/dL improvement in PPGE at 120 minutes. For greater details, read more [here](#).



## Sale-leaseback transaction results in \$102.25M in non-dilutive proceeds

On November 8th, MannKind officially closed its sale-leaseback transaction with an affiliate of Creative Manufacturing Properties that resulted in \$102.25 million in non-dilutive gross proceeds. Simultaneous with closing of the purchase and sale agreement, MannKind entered into a 20-year lease agreement with the purchaser, with multiple renewal options available.

The real property sale includes 263,900 square feet of MannKind's manufacturing space at 1 Casper Street in Danbury, Conn., but does not include its research and development facility. MannKind continues as the sole operator of the entire Connecticut facility. The location is where MannKind produces Afrezza and Tyvaso DPI.



## spotlights

In each issue of the quarterly MNKD Newsletter, we will look to Spotlight interesting and/or topical people and stories connected with MannKind. We hope you enjoy learning more about a new addition to our team:

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### Ben Harris Executive Director, Marketing



Many weekends, between kids' soccer, football, and baseball games, you're bound to find Ben Harris lacing up his sneakers to hit the pavement for a training session. He has logged many miles competing in everything from the LA Marathon to the Malibu Triathlon – and has even tackled three 100-mile cycling events with JDRF, Ride to Cure Diabetes.

These days the he can add logging steps at MannKind as its newly-appointed Executive Director of Marketing based in Westlake Village, Calif., where he will lead strategy and execution of the Afrezza brand plan, including healthcare provider, consumer, and digital marketing efforts.

Ben will also partner closely with internal cross-functional teams to lead the development and execution of the commercial strategies and brand-level operational plans to maximize the value of Afrezza.

As a passionate advocate in the diabetes space, Ben joins MannKind following a distinguished career at Medtronic where he held a number of roles across both Sales and Marketing. He most recently served as Global Marketing Head, Digital Platforms for Diabetes where he was responsible for Medtronic's engagement platforms and driving patient experience.

A graduate of Purdue University, Ben and his wife Laura are proudly raising four children in SoCal. Be ready for Ben to call upon the MannKind team to join him on the next JDRF ride: "We have miles to go with diabetes, and we will do it together."

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### Raising our voice for National Diabetes Month

In honor of World Diabetes Day on November 14th, MannKind joined its patients, employees, colleagues, and the medical and scientific communities in elevating the progressive conversation about diabetes. New figures reveal that 537 million adults

worldwide – or 1 in 10 adults – are living with diabetes. Diabetes is an alarming growing concern for those under the age of 20 as well with an estimated 210,000 youth diagnosed with diabetes in the U.S. alone.

We get it – those are a lot of numbers to digest and our tendency is to scroll – but the reality is that we all likely know someone that is living with Type 1 or Type 2 diabetes. These often are private or quiet conversations, but talking about diabetes care, education and access to medicines more broadly is essential.

It's a passion project for MannKind as our team of dedicated scientists and medical professionals understand how serious medical conditions can impact people's lives because many of us live with these conditions ourselves. MannKind is dedicated to making a difference, to changing the way diabetes is treated, and giving people control of their health and the freedom to live life more humann<sup>SM</sup>.

We are proud of the advances made thus far, but are committed to pushing boundaries into the future. MannKind is grateful to all that raise their voice, innovate, and advocate for the diabetes community. We invite you to join the dialogue and shine a light on diabetes this month – National Diabetes Month – and always.



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## MannKind proud of recent honors for innovation, company culture, and growth

MannKind is humbled and grateful for recent recognitions related to its innovation, company culture, and growth. The accolades included MannKind being honored for its contributions to the diabetes community by the Joslin Diabetes Center at the High Hopes Gala held virtually on November 13th. We celebrate this honor with our dedicated employees who love what they do – and it shows, as MannKind picked up its fourth corporate culture award this year from Comparably as a winner of Best Company Happiness 2021.

From a growth perspective, MannKind celebrates landing on the 2021 Deloitte

Technology Fast 500™ list. Now in its 27th year, the Fast 500 provides a ranking of the most innovative and fastest-growing companies in North America. MannKind ranked 284th with its 455% fiscal year revenue growth during the period (2017 to 2020). The Pacific Coast Business Times recently announced their list for 50 Fastest Growing Companies, and MannKind was named 11th as ranked by revenue growth from 2018 to 2020.



**\$181.1M**

Cash as of  
September 30, 2021

**\$22.8M**

Total revenue for 3Q  
of 2021

**48% ^**

Increase in total  
revenue\*

\* In comparison to 3Q 2020.

[see 2021 q3 financial results](#) | [→](#)

### stock performance\*

Equity/Index	Price: 12/31/19	Price: 12/31/20	Price: 11/26/21
<b>MNKD</b>	\$1.29	\$3.13	\$4.64
<b>R3000 P&amp;B Index</b>	\$3,052.90	\$3,459.40	\$3,704.70

Equity/Index	% Change - 3 Yrs 11/27/18 - 11/26/21	% Change - 1 Yr 11/27/20 - 11/26/21	% Change - 6 Mos 1/1/21 - 11/26/21
<b>MNKD</b>	+161.6%	+50.3%	+47.9%
<b>R3000 P&amp;B Index</b>	+33.6%	+11.6%	+7.1%

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

# Events

december  
13-16



**Lytham Partners Winter Investor  
Conference - 2022 Vision Event**

january  
10-13



**H.C. Wainwright BioConnect 2022  
Conference**

february  
14-18



**Virtual 11th Annual SVB Leerink Global  
Healthcare Conference 2022**

~2h Feb  
1h Mar



**MannKind 4Q/Year End 2021 Earnings  
Call**

## Connect with us.

Reach out anytime. We'd love to hear from you.

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[general inquiries contact](#) | →

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