mannkind

August 2021 MNKD Newsletter

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

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 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.

pipeline

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.

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 pipeline, 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 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).

in the news

MannKind to explore dry powder formulation of ZYESAMI

We recently announced a partnership with NRx Pharmaceuticals to evaluate the feasibility of formulation a dry powder formulation of ZYESAMI (Aviptadil), a synthetic form of human Vasoactive 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 clinical trials, having been granted Fast Track Designation by the U.S. Food and Drug 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.

Dr. Kevin Kaiserman
Vice President, Medical Affairs and Safety

Dr. Kevin Kaiserman has dedicated his career of more than 25 years to improving the lives of children with diabetes – whether it be in practice, volunteering, teaching, and currently at MannKind.

A leading, board-certified pediatric endocrinologist, Dr. Kaiserman joined MannKind in 2020, as he saw that 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 committed in a very unified way in trying to improve the lives of people living with 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 pediatric study whose momentum is fueled by positive pharmacokinetics and safety results presented at the American Diabetes Association's 81st Scientific Sessions.

Dr. Kaiserman was in private practice in Southern California prior to joining MannKind and still sees patients at his clinic, SoCal Diabetes. Prior to entering private practice, Dr. Kaiserman was a Clinical Associate Professor of Pediatrics and Medical Director of the Clinical Diabetes Program at Children's Hospital Los Angeles and the University of Southern California, Keck School of Medicine.

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 Endocrinology.

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 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 Foundation (JDRF), among others.

A passion project outside of work for Dr. Kaiserman is Camp Conrad-Chinnock, which hosts a summer camp for youth and families with diabetes in the San Bernardino Mountains of California. In addition to being a medical director for the camp, he is a proud board member of the Diabetes Camping and Educational Services (DCES).

Karen Jaffe
Vice President, Regulatory Affairs, Clinical 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 possibly can be. "For me, there's a personal passion for realizing Al's (Mann) dream," she explains. So the INHALE-1 Study is a project that brings purpose to the forefront in her mind.

Jaffe's first introduction to MannKind came in 2011 when she served for two years directing regulatory affairs at the Alfred Mann Biomedical Engineering Institute. She went on to serve as vice president of regulatory affairs at Keystone Heart before becoming a Mannitarian.

Born in Canada and raised in Augusta, Georgia, Jaffe joined the company with 25 years of 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.

Jaffe can be found living life more human by enjoying outdoors activities with her family. She is an avid skier, swimmer, spinner, hiker and kayaker – the last activity done often with her Goldendoodle Simba.

financial & stock performance

$201.4M Cash as of June 30, 2021

$23.3M Total revenue for 2Q of 2021

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

see 2021 q2 financial results →

stock performance*

Equity/Index	Price: 12/31/19	Price: 12/31/20	Price: 8/23/21
MNKD	$1.29	$3.13	$4.48
R3000 P&B Index	$3,052.90	$3,459.40	$3,982.70

Equity/Index	% Change - 3 Yrs 8/24/18 - 8/23/21	% Change - 1 Yr 8/24/20 - 8/23/21	% Change - 6 Mos 1/1/21 - 8/23/21
MNKD	+300.0%	+165.1%	+43.1%
R3000 P&B Index	+39.2%	+23.4%	+15.1%

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

2021 events

- september 13-14 — H.C. Wainwright 23rd Annual Global Investment Conference →
- september 23-25 — SVB Leerink Healthcare Summit Napa Valley →
- september 27-29 — Cantor Virtual Global Healthcare Conference →
- sep. 27- oct. 1 — EASD 51st Annual Meeting →
- november 4-6 — 21st Annual Diabetes Technology Meeting →
- 1H november — MannKind 3Q 2021 Earnings Call →

Connect with us.

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

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