UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): May 24, 2022

MannKind Corporation
(Exact Name of Registrant as Specified in Charter)

Delaware	**000-50865**	**13-3607736**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

1 Casper Street, Danbury, Connecticut 06810
(Address of Principal Executive Offices) (Zip Code)

(818) 661-5000
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. of Form 8-K):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	MNKD	The Nasdaq Stock Market LLC

Item 8.01 Other Events.

On May 24, 2022, MannKind Corporation (the "Company") issued a press release, a copy of which is filed herewith as Exhibit 99.1 and is incorporated herein by reference, except the website addresses and hyperlinks contained in such press release are inactive textual references only and no information accessible through any such website address or hyperlink is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

Exhibit 99.1	Press release dated May 24, 2022
Exhibit 104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Forward-Looking Statements

Statements in Exhibit 99.1 to this report that are not statements of historical fact are forward-looking statements, including statements regarding the expected timing for Tyvaso DPI product availability. These forward-looking statements are based upon the Company's current expectations. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include risks and uncertainties regarding manufacturing pharmaceutical products. These and other risks are detailed in the Company's filings with the Securities and Exchange Commission ("SEC"), including under the heading "Risk Factors" in MannKind's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, filed with the SEC on May 5, 2022. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. All forward-looking statements are qualified in their entirety by this cautionary statement, and the Company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this report.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MannKind Corporation

Date: May 25, 2022

By: /s/ David Thomson, Ph.D., J.D.
David Thomson, Ph.D., J.D.
Executive Vice President, General Counsel and Secretary

EXHIBIT 99.1

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FOR IMMEDIATE RELEASE

MANNKIND'S TECHNOSPHERE® INHALATION PLATFORM UTILIZED IN FDA-APPROVED TYVASO DPI™

- *Tyvaso DPI represents the second FDA-approved product utilizing MannKind's Technosphere® inhalation technology*
- *First approval of a dry powder inhaled treatment for PAH and PH-ILD*
- *Manufacturing of Tyvaso DPI for United Therapeutics underway at MannKind's Connecticut facility with product availability expected in June 2022*

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., May 24, 2022 (Globe Newswire) – **MannKind Corporation (Nasdaq: MNKD)**, a company focused on the development and commercialization of innovative therapeutic products for patients with endocrine and orphan lung diseases, celebrated today that the U.S. Food and Drug Administration (FDA) has approved United Therapeutics' Tyvaso DPI™ (treprostinil) inhalation powder for the treatment of patients with pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD). Tyvaso DPI represents the second FDA-approved product utilizing MannKind's innovative Technosphere® inhalation technology and is the first and only approved dry powder inhaled treatment for these indications.

"We are elated that Tyvaso DPI has received approval from the FDA, which paves the way for patients to receive treprostinil in a new and convenient way," said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. "This approval exemplifies MannKind's commitment to developing products that give people control of their health and the freedom to live life. With Tyvaso DPI, patients can potentially fit in the palm of their hand a full day of dosing treprostinil from a Dreamboat® inhaler."

"This approval is a result of the hard work of the research, development, regulatory, and operations teams at MannKind and United Therapeutics," said Patrick Poisson, Executive Vice President of Technical Operations at United Therapeutics. "We are thrilled to provide a dry powder inhaled alternative to liquid nebulization of Tyvaso."

MannKind and United Therapeutics entered into a worldwide exclusive licensing and collaboration agreement in September 2018 for the development and commercialization of Tyvaso DPI. In August 2021, the two companies established a commercial supply agreement that has an initial term through 2031. A next-generation formulation of treprostinil, Tyvaso DPI incorporates the dry powder formulation technology and Dreamboat inhalation device technology used in MannKind's Afrezza® (insulin human) Inhalation Powder, which was

approved by the FDA in 2014. Tyvaso DPI is produced at MannKind's manufacturing facility in Connecticut.

PAH is a life-threatening high blood pressure in the arteries of the lungs, affecting the ability of the heart and lungs to work properly in afflicted patients. PAH affects an estimated 45,000 patients in the United States. ILD is a group of lung diseases in which marked scarring occurs within the lungs. It is often complicated by pulmonary hypertension (PH), which furthers symptoms and decreases survival. PH is estimated to affect at least 15% of patients with early-stage ILD (approximately 30,000 PH-ILD patients in the United States) and may affect up to 86% of patients with more severe ILD. Tyvaso® and Tyvaso DPI are the only therapies approved by the FDA to treat PH-ILD.

About TYVASO® (treprostinil) Inhalation Solution and TYVASO DPI™ (treprostinil) Inhalation Powder

Eyebrow (abbreviated) Indication

- For the treatment of pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability.
- For the treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability.

INDICATION

TYVASO (treprostinil) Inhalation Solution and TYVASO DPI (treprostinil) Inhalation Powder are prostacyclin mimetics indicated for the treatment of:

- Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability. Studies with TYVASO establishing effectiveness predominately included patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%).

  The effects diminish over the minimum recommended dosing interval of 4 hours; treatment timing can be adjusted for planned activities.

  While there are long-term data on use of treprostinil by other routes of administration, nearly all clinical experience with inhaled treprostinil has been on a background of an endothelin receptor antagonist (ERA) and/or a phosphodiesterase type 5 (PDE-5) inhibitor. The controlled clinical experience with TYVASO was limited to 12 weeks in duration.

- Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. The study with TYVASO establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF), combined pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%).

IMPORTANT SAFETY INFORMATION
WARNINGS AND PRECAUTIONS

- TYVASO and TYVASO DPI are pulmonary and systemic vasodilators. In patients with low systemic arterial pressure, either product may produce symptomatic hypotension.
- Both products inhibit platelet aggregation and increase the risk of bleeding.
- Co-administration of a cytochrome P450 (CYP) 2C8 enzyme inhibitor (e.g., gemfibrozil) may increase exposure (both C_{max} and AUC) to treprostinil. Co-administration of a CYP2C8 enzyme inducer (e.g., rifampin) may decrease exposure to treprostinil. Increased exposure is likely to increase adverse events associated with treprostinil administration, whereas decreased exposure is likely to reduce clinical effectiveness.
- Like other inhaled prostaglandins, TYVASO and TYVASO DPI may cause acute bronchospasm. Patients with asthma or chronic obstructive pulmonary disease (COPD), or other bronchial hyperreactivity, are at increased risk for bronchospasm. Ensure that such patients are treated optimally for reactive airway disease prior to and during treatment with TYVASO and TYVASO DPI.

DRUG INTERACTIONS/SPECIFIC POPULATIONS

- The concomitant use of either product with diuretics, antihypertensives, or other vasodilators may increase the risk of symptomatic hypotension.
- Human pharmacokinetic studies with an oral formulation of treprostinil (treprostinil diolamine) indicated that co-administration of the cytochrome P450 (CYP) 2C8 enzyme inhibitor, gemfibrozil, increases exposure (both C_{max} and AUC) to treprostinil. Co-administration of the CYP2C8 enzyme inducer, rifampin, decreases exposure to treprostinil. It is unclear if the safety and efficacy of treprostinil by the inhalation route are altered by inhibitors or inducers of CYP2C8.
- Limited case reports of treprostinil use in pregnant women are insufficient to inform a drug-associated risk of adverse developmental outcomes. However, pulmonary arterial hypertension is associated with an increased risk of maternal and fetal mortality. There are no data on the presence of treprostinil in human milk, the effects on the breastfed infant, or the effects on milk production.
- Safety and effectiveness in pediatric patients have not been established.
- Across clinical studies used to establish the effectiveness of TYVASO in patients with PAH and PH-ILD, 268 (47.8%) patients aged 65 years and over were enrolled. The treatment effects and safety profile observed in geriatric patients were similar to younger patients. In general, dose selection for an elderly patient should be cautious, reflecting the greater frequency of hepatic, renal, or cardiac dysfunction, and of concomitant diseases or other drug therapy.

ADVERSE REACTIONS

- Pulmonary Arterial Hypertension (WHO Group 1)

  In a 12-week, placebo-controlled study (TRIUMPH I) of 235 patients with PAH (WHO Group 1 and nearly all NYHA Functional Class III), the most common adverse reactions seen with TYVASO in ≥4% of PAH patients and more than 3% greater than placebo were cough (54% vs 29%), headache (41% vs 23%), throat irritation/pharyngolaryngeal pain (25% vs 14%), nausea (19% vs 11%), flushing (15% vs <1%), and syncope (6% vs <1%). In addition, adverse reactions occurring in ≥4% of patients were dizziness and diarrhea.

In a 3-week, open-label, single-sequence, safety and tolerability study (BREEZE) conducted in 51 patients on stable doses of TYVASO who switched to a corresponding dose of TYVASO DPI, the most commonly reported adverse events seen with TYVASO DPI in ≥4% of PAH patients during the 3-week treatment phase included cough (35.3%), headache (15.7%), dyspnea (7.8%), and nausea (5.9%).

- Pulmonary Hypertension Associated with ILD (WHO Group 3)
  In a 16-week, placebo-controlled study (INCREASE) of 326 patients with PH-ILD (WHO Group 3), adverse reactions with TYVASO were similar to the experience in studies of PAH.

Please see Full Prescribing Information for TYVASO or TYVASO DPI, Instructions for Use manuals for TD-100 and TD-300 TYVASO® Inhalation System and TYVASO DPI™ Inhalation Powder, and additional information at www.TYVASOHCP.com or call 1-877-UNITHER (1-877-864-8437).

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About MannKind Corporation
MannKind Corporation (Nasdaq: MNKD) focuses on the development and commercialization of therapeutic and convenient products for patients with endocrine and orphan lung diseases. MannKind is currently commercializing Afrezza® (insulin human) Inhalation Powder, the Company's first FDA-approved product and the only inhaled ultra rapid-acting mealtime insulin in the United States, where it is available by prescription from pharmacies nationwide. Afrezza is also available by prescription in Brazil, where it is commercialized by the Company's partner, Biomm SA. MannKind was established in 1991, and is located in Danbury, Conn., and Westlake Village, Calif. The Company also employs field sales and medical representatives across the U.S. Please visit mannkindcorp.com to learn more.

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