

**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): June 16, 2021

MannKind Corporation
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

000-50865
(Commission
File Number)

13-3607736
(IRS Employer
Identification No.)

30930 Russell Ranch Road, Suite 300
Westlake Village, CA
(Address of principal executive offices)

91362
(Zip Code)

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

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

Check the appropriate box below if the Form 8-K 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))

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	MNKD	The Nasdaq Stock Market LLC

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

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.

Item 8.01 Other Events.

On June 16, 2021, MannKind Corporation (“MannKind”) and United Therapeutics Corporation (“United Therapeutics”) announced that the U.S. Food and Drug Administration (“FDA”) accepted for priority review the New Drug Application (“NDA”) submitted by United Therapeutics for Tyvaso DPI™ (inhaled treprostinil) for the treatment of pulmonary arterial hypertension and pulmonary hypertension associated with interstitial lung disease. The development marks the second compound formulated with MannKind’s Technosphere® technology to be reviewed by the FDA, which is expected to be complete in October 2021. The FDA has also indicated that they have not identified any potential review issues at this time.

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. MannKind and United Therapeutics are also developing BluHale®, a Bluetooth-connected accessory for the Tyvaso DPI inhaler with a companion mobile application intended to help patients track information about their inhaler use.

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 its communications with United Therapeutics, the FDA indicated that approval of the NDA will be subject to an inspection of the Tyvaso DPI manufacturing facility operated by MannKind; the FDA and MannKind have jointly targeted the third quarter of 2021 to complete the inspection.

MannKind is entering an expansion phase as it prepares to transition from producing clinical supply to building pre-launch inventory of Tyvaso DPI, pending FDA approval. MannKind’s manufacturing and R&D facility in Danbury is scaling up by hiring more than 100 positions, as well as readying essential equipment and production lines. A variety of MannKind jobs in commercial manufacturing, engineering, quality control, warehouse operations, maintenance, and more are currently open and planned to be filled this year.

Forward-looking Statements

Statements in this report that are not statements of historical fact are forward-looking statements. Words such as “plans,” “expects,” “intend,” “will,” “targeted,” “potential” and similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements regarding: the expected timing for the FDA’s completion of its review of the NDA for Tyvaso DPI; the development of BluHale as an accessory for the Tyvaso DPI inhaler and its intended benefits; the targeted timing for the FDA’s completion of its inspection of MannKind’s Tyvaso DPI manufacturing facility; MannKind’s transition from producing clinical supply to building pre-launch inventory of Tyvaso DPI, pending FDA approval; if MannKind fails as an effective manufacturing organization, MannKind may be unable to support commercialization of Tyvaso DPI; and MannKind’s planned hiring. These forward-looking statements are based upon MannKind’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, without limitation: risks and uncertainties regarding the regulatory approval process; risks inherent in product development; risks associated with an inspection by a regulatory agency; and challenges that may be encountered during the scale-up of manufacturing operations, including attracting and retaining qualified personnel. These and other risks are detailed in MannKind’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, 2021, filed with the SEC on May 12, 2021. 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 MannKind undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

MANKIND CORPORATION

Dated: June 16, 2021

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