
**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 27, 2026

MannKind Corporation

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-50865
(Commission File Number)

13-3607736
(IRS Employer
Identification No.)

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

06810
(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 filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- 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, par value \$0.01 per share	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.

Regulatory Update

In connection with the approval of the Biologics License Application (“BLA”) for Afrezza in June 2014, the U.S. Food and Drug Administration (“FDA”) required us to conduct a five-year, randomized, controlled trial in 8,000-10,000 patients with type 2 diabetes to assess the risk of pulmonary malignancy observed with Afrezza to that observed in a standard of care control group.

On May 27, 2026, the FDA informed us that we were released from this postmarketing requirement.

The only remaining postmarketing requirement for Afrezza is an assessment of its efficacy and safety in pediatric patients. In October 2025, the FDA accepted for review a supplemental BLA for Afrezza in children and adolescents between the ages of 4-17 who are living with type 1 or type 2 diabetes, with a PDUFA target action date of May 29, 2026.

Clinical Update

INHALE-1st: An additional eight sites have been activated to enroll participants into INHALE-1st, a study to evaluate the efficacy and safety of Afrezza plus basal insulin for youth aged 10-17 with newly-diagnosed type 1 diabetes. Up to 100 participants are expected to be enrolled in this study across 10 clinical sites. This single-arm, multi-center, clinical study will follow participants for 13 weeks during the main phase followed by an optional extension phase for participants continuing to use Afrezza in combination with basal insulin for up to 26 weeks. The primary endpoint is the percentage of participants with a continuous glucose meter who measured time in range of 70-180 mg/dL \geq 70% during 14 days prior to the 13-week visit. Data from this study is expected to be available in late 2027.

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,” “anticipate,” “potential” and similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements regarding the future development of Afrezza; expectations regarding our ongoing and planned clinical trials, including the expected number of patients to be enrolled and clinical sites for and timing for data readouts for INHALE-1st, and the expected PDUFA target action date for Afrezza in children and adolescents. These forward-looking statements are based upon our 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 associated with developing product candidates; risks and uncertainties related to unforeseen delays that may impact the timing of clinical trial enrollment and progression, and reporting data; risks associated with safety and other complications of our products and product candidates; risks associated with the regulatory review process; and other risks detailed in our filings with the Securities and Exchange Commission (“SEC”), including under the heading “Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, filed with the SEC on May 6, 2026. 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 we undertake no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this report.

SIGNATURES

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 28, 2026

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