MannKind Provides Business Updates and 2026 Growth Drivers

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DANBURY, Conn. and WESTLAKE VILLAGE, Calif., Jan. 08, 2026 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)**, a biopharmaceutical company dedicated to transforming chronic disease care through innovative, patient-centric solutions for cardiometabolic and orphan lung diseases, today provided business updates and outlined anticipated growth drivers for 2026, including progress across its commercial programs and clinical development initiatives.

“MannKind closed 2025 on a high note, marked by milestones that reinforce our growth trajectory—including the acquisition of scPharmaceuticals and a record-setting fourth quarter surpassing $100 million in net revenue,” said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. “With two high-potential launches on the horizon, 2026 is shaping up to be a catalyst-rich year that positions MannKind for long-term value creation.”

Major Catalysts Driving 2026:

Afrezza® (insulin human) Inhalation Powder

- FDA decision on Afrezza label update (dose conversion) anticipated with a PDUFA target action date of January 23, 2026
  - Would update the initial dose for mealtime insulin when switching from subcutaneous rapid-acting insulin
- FDA accepted for review the supplemental Biologics License Application (sBLA) for Afrezza® Inhalation Powder in children and adolescents living with type 1 or type 2 diabetes with a PDUFA target action date of May 29, 2026
  - If approved, it would be the first needle-free insulin option for pediatric patients in 100+ years of insulin therapy

FUROSCIX® (furosemide injection) for Subcutaneous Use

- Supplemental New Drug Application (sNDA) for FUROSCIX ReadyFlow ™ Autoinjector accepted for review by U.S. Food and Drug Administration (FDA) with a PDUFA target action date of July 26, 2026
  - If approved, it would deliver an IV-equivalent diuretic dose (subcutaneous furosemide injection 80 mg/ml) in under 10 seconds

Pipeline

- Nintedanib DPI (MNKD-201) saw its first patient enrolled in December for the INFLO-1 Phase 1b study (U.S.) and anticipates first patient in for INFLO-2 Phase 2 (global) in Q2 2026
- Advancing Bumetanide DPI (MNKD-701) pre-clinical development

United Therapeutics Collaborations

- Tyvaso DPI bridging study anticipated following 1H 2026 readout of TETON-1 study
- Formulating a second dry powder investigational molecule under the expanded collaboration with United Therapeutics using MannKind’s proprietary Technosphere ® platform

About MannKind
MannKind Corporation (Nasdaq: MNKD) is a biopharmaceutical company dedicated to transforming chronic disease care through innovative, patient-centric solutions. Focused on cardiometabolic and orphan lung diseases, we develop and commercialize treatments that address serious unmet medical needs, including diabetes, pulmonary hypertension, and fluid overload in heart failure and chronic kidney disease.

With deep expertise in drug-device combinations, MannKind aims to deliver therapies designed to fit seamlessly into daily life.

Learn more at mannkindcorp.com.

Forward-Looking Statements
Statements in this press release that are not statements of historical fact are forward-looking statements that involve risks and uncertainties. These statements include, without limitation, statements regarding potential product launches, ongoing clinical trials and preclinical studies, expected initiation and patient enrollment timelines, and the expected timing for trial results; the development of a new dry powder inhalation therapy and investigational molecule under the expanded collaboration with United Therapeutics and the planned preclinical studies thereof; the expected timing for regulatory events related to Afrezza and the FUROSCIX ReadyFlow Autoinjector; and other statements about future events. Words such as “believes,” “anticipates,” “plans,” “expects,” “intends,” “will,” “goal,” “potential,” and similar expressions are intended to identify forward-looking statements. 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, the risk that unforeseen delays that may impact the timing of clinical trials and reporting data, the risk that issues

develop in the review by the FDA that subject us to unanticipated delays or prevent us from obtaining the desired regulatory approval as well as other risks; detailed in MannKind's filings with the Securities and Exchange Commission ("SEC"), including under the "Risk Factors" heading of its Annual Report on Form 10-K for the year ended December 31, 2024, and subsequent periodic reports on Form 10-Q and current reports on Form 8-K. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. 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 press release.

FUROSCIX is a registered trademark of scPharmaceuticals Inc, a subsidiary of MannKind Corporation.

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