



MannKind Corporation Reports First Quarter 2025 Financial Results and Provides Business Update

05/08/25

Conference call to provide corporate updates today at 9:00 am ET

- 1Q 2025 revenues of \$78M, +18% v. 1Q 2024
- 1Q 2025 net income of \$13M, + 24% v. 1Q 2024
- 1Q 2025 non-GAAP net income of \$22M, +43% v. 1Q 2024
- Advanced pipeline:
 - Expect to submit sBLA for Afrezza® in pediatric patients in mid-2025
 - MNKD-101: NTM global Phase 3 trial enrollment on track for interim analysis
 - MNKD-201: Expect to continue to next phase of global development in 2H 2025

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., May 08, 2025 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)** today reported financial results for the first quarter 2025 and provided a business update.

“The first quarter was marked by strong year-over-year NRx growth in Afrezza, substantial Tyvaso DPI-related revenues and continued progress in our Phase 3 trial of MNKD-101 (clofazimine inhalation suspension) in NTM lung disease,” said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. “We expect to file for approval of Afrezza in the pediatric population this summer and to continue developing our MNKD-201 (nintedanib DPI) program in IPF.”

1Q 2025 Business Update and Upcoming Milestones

Afrezza INHALE-1 Pediatric Phase 3 clinical trial

- Met with the FDA to obtain guidance on a supplemental Biologics License Application (sBLA) for the pediatric population expected to be filed in mid-2025
- Topline results from the full study pediatric data set with the safety extension expected in 2Q 2025

Clofazimine Inhalation Suspension (MNKD-101) Phase 3 global clinical trial (ICON-1)

- 85% of anticipated sites have been activated in five countries (U.S., Japan, Australia, South Korea, Taiwan)
- 55 patients randomized in four countries (U.S., Japan, Australia, South Korea)
- Expect to meet the interim enrollment target of 100 patients by YE 2025

Nintedanib DPI (MNKD-201)

- Planning to advance into the next phase of global development in 2H 2025

Endocrine Business Unit

- Afrezza INHALE-3 Phase 4 30-week data published in two articles in *Diabetes Technology & Therapeutics*
- Label application to update initial Afrezza conversion dose submitted to FDA; currently under review
- Afrezza performance 1Q 2025 compared to 1Q 2024: 20% NRx growth; 14% TRx growth

Corporate and Financial

- Cash, cash equivalents and investments as of March 31, 2025 totaled \$198 million
- Majority of revenue and future pipeline programs are derived from MannKind's U.S.-based manufacturing facility in Danbury, CT, mitigating potential tariff exposure

First Quarter 2025 Financial Results

Revenues

	Three Months Ended March 31,			
	2025	2024	\$ Change	% Change
Revenues				
				(Dollars in thousands)
Royalties	\$ 30,005	\$ 22,651	\$ 7,354	32%
Collaborations and services	29,376	24,848	\$ 4,528	18%
Afrezza	14,887	14,438	\$ 449	3%

V-Go	4,086	4,326	\$	(240)	(6%)
Total revenues	<u>\$ 78,354</u>	<u>\$ 66,263</u>	\$	12,091	18%

Total revenues increased \$12.0 million, or 18%, in the first quarter of 2025 compared to the same period in the prior year. Revenue increases were driven by higher royalties primarily due to increased patient demand for Tyvaso DPI[®] and higher revenue from collaborations and services due to increased product sold to United Therapeutics Corporation. Commercial product revenue remained consistent with the prior year period due to an increase in net revenue for Afrezza, mainly due to higher demand and price, partially offset by a decrease in net revenue for V-Go[®] due to lower demand.

Operating Expenses and Other Financial Highlights

- Research and development expenses were \$11.0 million for the first quarter of 2025 compared to \$10.0 million for the same period in 2024, an increase of 10%. The increase was primarily attributable to increased expenditures for development activities, including a Phase 3 clinical study for MNKD-101, clinical production scale up for MNKD-201, and personnel costs primarily due to additional headcount as a result of MannKind's transaction with Pulmatrix, Inc. in the third quarter of 2024, which bolstered our research capabilities and capacity.
- Selling, general and administrative expenses were \$25.0 million for the first quarter of 2025 compared to \$22.3 million for the same period in 2024, an increase of 12%. This increase was primarily attributable to increases in headcount, personnel costs and Afrezza promotional costs, partially offset by a loss of \$1.2 million in the prior year period for estimated returns associated with sales of V-Go that pre-dated MannKind's acquisition of the product.
- For the first quarter of 2025, MannKind reported net income of \$13.2 million, or \$0.04 earnings per share – basic, compared to net income of \$10.6 million, or \$0.04 earnings per share – basic, for the same period in 2024, an increase in net income of \$2.5 million, or 24%.
- For the first quarter of 2025, MannKind reported non-GAAP net income of \$21.6 million, or \$0.07 earnings per share – basic, compared to non-GAAP net income of \$15.1 million, or \$0.06 earnings per share – basic, for the same period in 2024, an increase in net income of \$6.5 million, or 43%. For a reconciliation of GAAP reported net income and net income per share for basic weighted average shares to these non-GAAP measures, please see Non-GAAP Measures below.

Conference Call

MannKind will host a conference call and presentation webcast to discuss these results today at 9:00 a.m. Eastern Time. The webcast will be accessible via a link on MannKind's website. A replay will also be available in the same location within 24 hours after the call and accessible for approximately 90 days.

About MannKind

MannKind Corporation (Nasdaq: MNKD) focuses on the development and commercialization of innovative inhaled therapeutic products and devices to address serious unmet medical needs for those living with endocrine and orphan lung diseases.

We are committed to using our formulation capabilities and device engineering prowess to lessen the burden of diseases such as diabetes, nontuberculous mycobacterial (NTM) lung disease, pulmonary fibrosis, and pulmonary hypertension. Our signature technologies – dry-powder formulations and inhalation devices – offer rapid and convenient delivery of medicines to the deep lung where they can exert an effect locally or enter the systemic circulation, depending on the target indication.

With a passionate team of Mannitarians collaborating nationwide, we are on a mission to give people control of their health and the freedom to live life.

Please visit mannkindcorp.com to learn more, and follow us on [LinkedIn](#), [Facebook](#), [X](#) or [Instagram](#).

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 MannKind's expectations about the development of Afrezza for the pediatric population, MNKD-101 and MNKD-201, including the expected timing for regulatory filings and patient enrollment timelines. Words such as "believes," "anticipates," "plans," "expects," "intend," "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, risks associated with developing product candidates; risks and uncertainties related to unforeseen delays that may impact the timing of clinical trials and reporting data; risks associated with the regulatory review process; and 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, filed with the SEC on February 26, 2025, as updated by the "Risk Factors" in its Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2025, being filed with the SEC later today. 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.

Tyvaso DPI is a trademark of United Therapeutics Corporation.

AFREZZA, MANNKIND, and V-GO are registered trademarks of MannKind Corporation.

**MANNKIND CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS**

	Three Months Ended March 31,	
	2025	2024
	(In thousands except per share data)	
Revenues:		
Commercial product sales	\$ 18,973	\$ 18,764
Collaborations and services	29,376	24,848
Royalties	30,005	22,651
Total revenues	78,354	66,263
Expenses:		
Cost of goods sold – commercial	3,768	3,819
Cost of revenue – collaborations and services	13,748	14,779
Research and development	11,022	10,013
Selling, general and administrative	25,014	22,329
Loss (gain) on foreign currency transaction	2,509	(1,399)
Total expenses	56,061	49,541
Income from operations	22,293	16,722
Other income (expense):		
Interest income, net	1,956	3,434
Interest expense on liability for sale of future royalties	(3,577)	(4,248)
Interest expense on financing liability	(2,410)	(2,447)
Interest expense	(4,645)	(2,567)
Total other expense	(8,676)	(5,828)
Income before income tax expense	13,617	10,894
Income tax expense	459	264
Net income	\$ 13,158	\$ 10,630
Net income per share – basic	\$ 0.04	\$ 0.04
Weighted average shares used to compute net income per share – basic	303,481	270,356
Net income per share – diluted	\$ 0.04	\$ 0.04
Weighted average shares used to compute net income per share – diluted	320,897	324,733

**MANNKIND CORPORATION AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS**

	March 31, 2025		December 31, 2024	
	(In thousands except share and per share data)			
ASSETS				
Current assets:				
Cash and cash equivalents	\$	47,312	\$	46,339
Short-term investments		134,229		150,917
Accounts receivable, net		28,900		11,804
Inventory		28,892		27,886

Prepaid expenses and other current assets	34,404	31,360
Total current assets	<u>273,737</u>	<u>268,306</u>
Restricted cash	739	737
Long-term investments	16,681	5,482
Property and equipment, net	83,781	85,365
Goodwill	1,931	1,931
Other intangible assets	5,217	5,265
Other assets	28,055	26,757
Total assets	<u>\$ 410,141</u>	<u>\$ 393,843</u>

LIABILITIES AND STOCKHOLDERS' DEFICIT

Current liabilities:

Accounts payable	\$ 5,041	\$ 6,792
Accrued expenses and other current liabilities	40,103	40,293
Senior convertible notes – current	36,109	—
Liability for sale of future royalties – current	12,802	12,283
Financing liability – current	10,125	10,062
Deferred revenue – current	11,757	12,407
Total current liabilities	<u>115,937</u>	<u>81,837</u>
Liability for sale of future royalties – long term	137,420	137,362
Financing liability – long term	93,665	93,877
Deferred revenue – long term	47,360	51,160
Recognized loss on purchase commitments – long term	60,713	58,204
Operating lease liability	11,141	11,645
Milestone liabilities	2,523	2,523
Senior convertible notes	—	36,051
Total liabilities	<u>468,759</u>	<u>472,659</u>

Stockholders' deficit:

Undesignated preferred stock, \$0.01 par value – 10,000,000 shares authorized; no shares issued or outstanding as of March 31, 2025 or December 31, 2024	—	—
Common stock, \$0.01 par value – 800,000,000 shares authorized; 303,918,969 and 302,959,782 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	3,039	3,029
Additional paid-in capital	3,125,830	3,118,865
Accumulated other comprehensive income	1,174	1,109
Accumulated deficit	<u>(3,188,661)</u>	<u>(3,201,819)</u>
Total stockholders' deficit	<u>(58,618)</u>	<u>(78,816)</u>
Total liabilities and stockholders' deficit	<u>\$ 410,141</u>	<u>\$ 393,843</u>

Non-GAAP Measures

To supplement MannKind's condensed consolidated financial statements presented under GAAP, we are presenting non-GAAP financial measures for net income and net income per share – basic. We are providing these non-GAAP financial measures, which are among the indicators management uses as a basis for evaluating our financial performance, to disclose additional information to facilitate the comparison of past and present operations. We believe that these non-GAAP financial measures, when considered together with our GAAP financial results, provide management and investors with an additional understanding of our business operating results, including underlying trends.

These non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable GAAP measures; should be read in conjunction with our condensed consolidated financial statements prepared in accordance with GAAP; have no standardized meaning prescribed by GAAP; and are not prepared under any comprehensive set of accounting rules or principles. In addition, from time to time in the future, there may be other items that we may exclude for purposes of our non-GAAP financial measures; and we may cease to exclude items that we have historically excluded for purposes of our non-GAAP financial measures. Likewise, we may determine to modify the nature of its adjustments to arrive at our non-GAAP financial measures. Because of the non-standardized definitions of non-GAAP financial measures, the non-GAAP financial measures as used by us in this Quarterly Report on Form 10-Q have limits in their usefulness to investors and may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies.

The following table reconciles our financial measures for net income and net income per share ("EPS") for basic weighted average

shares as reported in our condensed consolidated statements of operations to a non-GAAP presentation:

	Three Months Ended March 31,			
	2025		2024	
	Net Income	Basic EPS	Net Income	Basic EPS
	(In thousands except per share data)			
GAAP reported net income	\$ 13,158	\$ 0.04	\$ 10,630	\$ 0.04
Non-GAAP adjustments:				
Sold portion of royalty revenue ⁽¹⁾	(3,000)	(0.01)	(2,265)	(0.01)
Interest expense on liability for sale of future royalties	3,577	0.01	4,248	0.03
Stock compensation	5,385	0.02	3,885	0.01
Loss (gain) on foreign currency transaction	2,509	0.01	(1,399)	(0.01)
Non-GAAP adjusted net income	<u>\$ 21,629</u>	<u>\$ 0.07</u>	<u>\$ 15,099</u>	<u>\$ 0.06</u>
Weighted average shares used to compute net income per share – basic	303,481		270,356	

(1) Represents the non-cash portion of the 1% royalty on net sales of Tyvaso DPI which is remitted to the royalty purchaser and recognized as royalties from collaborations in our consolidated statements of operations.

MannKind Contacts:
Investor Relations
Ana Kapur
(818) 661-5000
Email: ir@mnkd.com

Media Relations
Christie Iacangelo
(818) 292-3500
Email: media@mnkd.com

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Source: MannKind