



MannKind Corporation Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business Update

02/26/25

Conference call to provide corporate updates today at 4:30 pm ET

- 2024 revenues of \$286M, +43% v. 2023; 4Q 2024 revenues of \$77M, +31% v. 4Q 2023
- 2024 net income of \$28M; Non-GAAP net income of \$68M
- 4Q 2024 net income of \$7M; Non-GAAP net income of \$23M
- Reduced debt principal by \$236M; remaining convertible debt of \$36M
- Year-end 2024 cash, cash equivalents and investments of \$203M
- Advanced pipeline:
 - Reported primary endpoint of INHALE-1 for Afrezza in pediatrics
 - Progressed MNKD-101 to Global Phase 3
 - Completed Phase 1 of MNKD-201

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., Feb. 26, 2025 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)** today reported financial results for the quarter and year ended December 31, 2024, and provided a business update.

"Throughout 2024, we accomplished the milestones we outlined at the beginning of the year, including delivering robust revenues as we exited the year with an annual run rate of \$300 million," said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. "We are thrilled to have welcomed Dominic Marasco as President, Endocrine Business Unit, positioning Afrezza for further growth, including a planned submission this summer to seek approval in the pediatric population. In our orphan lung clinical programs, nintedanib DPI is progressing to the next phase of development and our Phase 3 trial of clofazimine inhalation suspension in NTM lung disease is expected to meet the interim enrollment target by the end of 2025."

4Q 2024 Business Update and Upcoming Milestones

Afrezza® INHALE-1 Pediatric Phase 3 clinical trial

- Six-month safety and efficacy results announced
- Requested meeting with the U.S. Food and Drug Administration ("FDA") in 1H 2025 to discuss data submission for potential approval of Afrezza in the pediatric population
- Expect twelve-month data set with safety extension in 1H 2025
- Anticipate supplemental new drug application filing in 1H 2025 pending FDA feedback

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

- Approximately 70% of anticipated sites have been activated in four countries (U.S., Japan, Australia, South Korea)
- Patients randomized in two countries (U.S. and Australia)
- Expect to meet the interim enrollment target by YE 2025

Nintedanib DPI Phase 1 clinical trial (MNKD-201)

- Successfully completed Phase 1 trial, demonstrating nintedanib DPI was well tolerated with no serious adverse events or study drug discontinuation reported
- Expect to meet with the FDA in 1H 2025 to advance MNKD-201 into next phase of development

Commercial – Endocrine Business Unit

- Announced the appointment of Dominic Marasco as President, Endocrine Business Unit
- Afrezza INHALE-3 Phase 4 clinical trial 17-week data published in *Diabetes Care*; 30-week data manuscripts expected to be published in 1H 2025
- Inhaled insulin recognized as comparable to injectable insulin in the American Diabetes Association® *Standards of Care in Diabetes – 2025*
- Label application to update initial Afrezza conversion dose submitted to FDA
- Afrezza approved in India for adults; expect to ship in 4Q 2025 once Cipla obtains registration certificate and import license; earned \$1.1M regulatory milestone

Corporate and Financial: Strong Balance Sheet

- Cash, cash equivalents and investments as of December 31, 2024 totaled \$203 million
- Eliminated principal of \$236 million across three debt instruments during 2024 resulting in:
 - Remaining outstanding debt balance of \$36 million in 2.5% senior convertible notes due 2026

- o Utilized a combination of cash and stock to avoid potential dilution of 12 million shares of common stock
- o Interest expense savings of \$9 million through the respective maturity dates

Fourth Quarter and Full Year 2024 Financial Results

Revenues

	Three Months Ended December 31,			
	2024	2023	\$ Change	% Change
	(Dollars in thousands)			
Revenues				
Royalties	\$ 27,009	\$ 21,028	\$ 5,981	28 %
Collaborations and services	26,710	17,249	\$ 9,461	55 %
Afrezza	18,279	15,487	\$ 2,792	18 %
V-Go	4,778	4,708	\$ 70	1 %
Total revenues	<u>\$ 76,776</u>	<u>\$ 58,472</u>	\$ 18,304	31 %

	Year Ended December 31,			
	2024	2023	\$ Change	% Change
	(Dollars in thousands)			
Revenues				
Royalties	\$ 102,335	\$ 71,979	\$ 30,356	42 %
Collaborations and services	100,840	52,954	\$ 47,886	90 %
Afrezza	64,041	54,914	\$ 9,127	17 %
V-Go	18,288	19,115	\$ (827)	(4 %)
Total revenues	<u>\$ 285,504</u>	<u>\$ 198,962</u>	\$ 86,542	43 %

Total revenues for the fourth quarter and full year 2024 rose due to increases in revenue from royalties, collaborations and services, and commercial sales. The rise in royalties was primarily due to higher patient demand for Tyvaso DPI. Collaborations and services revenue grew due to increased manufacturing of Tyvaso DPI for United Therapeutics Corporation ("UT"). Net revenues for Afrezza and V-Go increased primarily as a result of improved gross-to-net percentages and higher demand and, to a lesser extent, pricing for Afrezza, partially offset by a decrease in V-Go product demand.

Operating Expenses and Other Financial Highlights

- Cost of revenue – collaborations and services was \$14.8 million for the fourth quarter of 2024, compared to \$12.0 million for the same period in 2023, an increase of 24%. For the full year 2024, cost of revenue – collaborations and services was \$59.2 million, compared to \$41.9 million, an increase of 41%. These increases are primarily the result of increased manufacturing volume of Tyvaso DPI.
- Research and development ("R&D") expenses were \$11.1 million for the fourth quarter of 2024 compared to \$9.2 million for the same period in 2023, an increase of 21%. For the full year 2024, R&D expenses were \$45.9 million compared to \$31.3 million, an increase of 47%. The increases were primarily attributable to development activities including the ICON-1 clinical study, a Phase 1 clinical study of MNKD-201, and personnel costs primarily due to increased headcount resulting from the Pulmatrix Transaction.
- Selling, general and administrative ("SG&A") expenses were \$24.0 million for the fourth quarter of 2024 compared to \$20.5 million for the same period in 2023, an increase of 17%. For the full year 2024, SG&A expenses remained consistent compared to the same period in 2023. This was primarily attributable to a loss of \$1.4 million for estimated returns associated with sales of V-Go that pre-date MannKind's acquisition of the product and increases in personnel costs, professional fees and promotional activities, offset by a decrease in selling expenses related to sales force restructuring activities completed during the first quarter of 2024.
- For the fourth quarter of 2024, MannKind reported net income of \$7.4 million, or \$0.03 earnings per share – basic, compared to net income of \$1.4 million, or \$0.01 earnings per share – basic, for the same period in 2023. For the full year 2024, MannKind reported net income of \$27.6 million, or \$0.10 earnings per share – basic, compared to net loss of \$11.9 million, or \$0.04 loss per share – basic for the same period in 2023.
- For the fourth quarter of 2024, MannKind reported non-GAAP net income of \$23.0 million, or \$0.08 earnings per share – basic, compared to non-GAAP net income of \$7.1 million, or \$0.02 earnings per share – basic, for the same period in 2023. For the full year 2024, MannKind reported non-GAAP net income of \$67.7 million, or \$0.25 earnings per share – basic, compared to non-GAAP net income of \$5.9 million, or \$0.03 earnings per share – basic for the same period in 2023. For a reconciliation of GAAP reported net income (loss) and net income (loss) per share for basic weighted average shares to these non-GAAP measures, please see the end of this press release.

Conference Call

MannKind will host a conference call and presentation webcast to discuss these results today at 4:30 p.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 data readouts, regulatory filings, meetings with the FDA and patient enrollment timelines; expectations regarding the commercialization of Afrezza in India, including the estimated timing for the shipment of product; and MannKind being positioned for further growth. 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 safety and other complications of our products and product candidates; risks associated with the regulatory review process; risks associated with competition; 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, being filed with the SEC later today, and subsequent periodic reports on Form 10-Q. 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		Year	
	Ended December 31,		Ended December 31,	
	2024	2023	2024	2023
(In thousands except per share data)				
Revenues:				
Commercial product sales	\$ 23,057	\$ 20,195	\$ 82,329	\$ 74,029
Collaborations and services	26,710	17,249	100,840	52,954
Royalties	27,009	21,028	102,335	71,979
Total revenues	<u>76,776</u>	<u>58,472</u>	<u>285,504</u>	<u>198,962</u>
Expenses:				
Cost of goods sold	4,808	6,114	17,429	20,863
Cost of revenue – collaborations and services	14,796	11,953	59,173	41,908
Research and development	11,138	9,236	45,893	31,283
Selling, general and administrative	23,972	20,535	94,329	94,314
(Gain) loss on foreign currency transaction	<u>(4,433)</u>	<u>2,776</u>	<u>(3,907)</u>	<u>1,916</u>

Total expenses	50,281	50,614	212,917	190,284
Income (loss) from operations	26,495	7,858	72,587	8,678
Other income (expense):				
Interest income, net	2,825	1,725	12,615	6,154
Interest expense on liability for sale of future royalties	(3,452)	(185)	(16,172)	(185)
Interest expense on financing liability	(2,467)	(2,493)	(9,828)	(9,825)
Interest expense	(1,562)	(2,677)	(11,981)	(15,151)
Gain on bargain purchase	—	—	5,259	—
Other income (expense)	—	(164)	32	122
Loss on settlement of debt	(13,394)	—	(20,444)	—
Loss on available-for-sale securities	—	(1,102)	(1,550)	(170)
Total other expense	(18,050)	(4,896)	(42,069)	(19,055)
Income (loss) before income tax expense	8,445	2,962	30,518	(10,377)
Income tax expense	1,023	1,561	2,930	1,561
Net income (loss)	\$ 7,422	\$ 1,401	\$ 27,588	\$ (11,938)
Net income (loss) per share – basic	\$ 0.03	\$ 0.01	\$ 0.10	\$ (0.04)
Weighted average shares used to compute net income (loss)				
per share – basic	279,191	269,648	274,415	267,014
Net income (loss) per share – diluted	\$ 0.03	\$ 0.00	\$ 0.10	\$ (0.04)
Weighted average shares used to compute net income (loss)				
per share – diluted ⁽¹⁾	290,631	323,880	283,844	267,014

(1) Diluted weighted average shares ("DWAS") differs from basic weighted average shares due to the weighted average number of shares that would be outstanding upon exercise or vesting of outstanding share-based payments to employees and conversion of convertible notes. For the year ended December 31, 2024, DWAS included 9,429 shares issuable upon exercise or vesting of outstanding share-based payments. 6,967 shares issuable upon conversion of our senior convertible notes were excluded as their effect would be antidilutive.

MANNKIND CORPORATION AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS

	December 31, 2024	December 31, 2023
	(In thousands except share and per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 46,339	\$ 238,480
Short-term investments	150,917	56,619
Accounts receivable, net	11,804	14,901
Inventory	27,886	28,545
Prepaid expenses and other current assets	31,360	34,848
Total current assets	268,306	373,393
Restricted cash	737	—
Long-term investments	5,482	7,155
Property and equipment, net	85,365	84,220
Goodwill	1,931	1,931
Other intangible assets	5,265	1,073
Other assets	26,757	7,426
Total assets	\$ 393,843	\$ 475,198
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 6,792	\$ 9,580

Sold portion of royalty revenue (1)	(2,701)	(0.01)	(2,103)	(0.01)	(10,234)	(0.04)	(2,103)	(0.01)
Interest expense on liability for sale of future royalties	3,452	0.01	185	—	16,172	0.06	185	—
Stock compensation	5,818	0.02	3,786	0.01	21,358	0.08	17,649	0.07
(Gain) loss on foreign currency transaction	(4,433)	(0.02)	2,776	0.01	(3,907)	(0.01)	1,916	0.01
Gain on bargain purchase	—	—	—	—	(5,259)	(0.02)	—	—
Loss on settlement of debt	13,394	0.05	—	—	20,444	0.07	—	—
Loss on available-for-sale securities	—	—	1,102	—	1,550	0.01	170	—
Non-GAAP adjusted net income (loss)	<u>\$ 22,952</u>	<u>\$ 0.08</u>	<u>\$ 7,147</u>	<u>\$ 0.02</u>	<u>\$ 67,712</u>	<u>\$ 0.25</u>	<u>\$ 5,879</u>	<u>\$ 0.03</u>
Weighted average shares used to compute net income (loss) per share – basic	279,191		269,648		274,415		267,014	

(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.

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Source: MannKind