MannKind Corporation Reports Second Quarter 2025 Financial Results And Provides Business Update

August 6, 2025 11:05 AM EDT

Conference call today at 9:00 am ET

- *2Q 2025 revenues of $76.5M, +6% v. 2Q 2024*
- *YTD 2025 revenues of $154.9M, +12% v. YTD 2024*
- *Advanced pipeline:*
  - *Submitted sBLA for Afrezza® in pediatric population*
  - *MNKD-101: NTM global Phase 3 trial (ICoN-1) enrollment ahead of schedule*
  - *MNKD-201: Plan to initiate Phase 2 clinical trial for IPF by YE 2025*

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., Aug. 06, 2025 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)** today reported financial results for the second quarter 2025 and provided a business update.

"The submission of our supplemental Biologics License Application (sBLA) for Afrezza in pediatric patients is a meaningful milestone for MannKind and people living with diabetes," said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. "In our orphan lung pipeline, we're encouraged by the robust enrollment progress in the ICoN-1 trial of inhaled clofazimine for NTM lung disease, and we are excited to advance nintedanib DPI into Phase 2 for IPF."

2Q 2025 Business Update and Upcoming Milestones

Afrezza INHALE-1 Pediatric Phase 3 clinical trial

- Submitted an sBLA for Afrezza® (insulin human) Inhalation Powder in the pediatric population with a review acceptance decision expected in early 4Q 2025
  - The filing is based on data from the INHALE-1 study of Afrezza in children and adolescents (aged 4-17 years)
- Topline results from the full pediatric study including the safety extension have been submitted for presentation at a medical meeting in 2H 2025

Inhaled Clofazimine (MNKD-101) Phase 3 global clinical trial (ICoN-1)

- Enrollment ahead of schedule; expect to achieve interim enrollment target of 100 patients in early 4Q 2025

Nintedanib DPI (MNKD-201)

- Expect to initiate Phase 2 clinical trial for IPF by YE 2025

Endocrine Business Unit

- Presented data from recent pediatric and adult studies of Afrezza affirming positive outcomes utilizing inhaled insulin at the American Diabetes Association's 85th Scientific Sessions in June
- Application submitted to FDA to update labeling regarding initial Afrezza conversion dose; decision expected 4Q 2025
- Afrezza performance 2Q 2025 compared to 2Q 2024: $18.3 million v. $16.3 million, a 13% increase

Corporate and Financial

- Cash, cash equivalents and investments as of June 30, 2025 totaled $201.2 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

Second Quarter 2025 Financial Results

Revenues

	Three Months Ended June 30,			
	2025	2024	$ Change	% Change
Revenues	(Dollars in thousands)			
Royalties	$ 31,228	$ 25,592	$ 5,636	22 %
Collaborations and services	22,845	26,014	$ (3,169)	(12 %)
Afrezza	18,329	16,289	$ 2,040	13 %
V-Go	4,125	4,491	$ (366)	(8 %)
Total revenues	$ 76,527	$ 72,386	$ 4,141	6 %

Total revenues increased $4.1 million, or 6% in the second quarter of 2025 compared to the same period in the prior year. Revenue increases were driven by royalties earned on increased net sales of Tyvaso DPI® and higher commercial product revenue for Afrezza, mainly due to higher demand and price and a lower rate of sales deductions. The overall increase in revenue was partially offset by a decrease in collaboration and services revenue due to the net impact of one-time items. There was also a decrease in net revenue for V-Go® due to lower demand, offset by decreased sales deductions due to lower rebates on certain commercial contracts.

Operating Expenses and Other Financial Highlights

- Research and development expenses increased by $1.9 million, or 16%, for the three months ended June 30, 2025 compared to the same period in the prior year. The increase was primarily attributable to continued patient enrollment in the ICoN-1 study for MNKD-101, clinical production scale up for MNKD-201, and personnel costs primarily due to additional headcount as a result of the Pulmatrix transaction completed in the third quarter of 2024, which bolstered research capabilities and capacity. These increases were partially offset by the completion of the Company's Afrezza post-marketing clinical study (INHALE-3) and Phase 1 MNKD-201 studies in 2024, as well as lower costs as the Company closed out its Afrezza pediatric clinical study (INHALE-1).

- Selling, general and administrative expenses increased by $7.5 million, or 31%, for the three months ended June 30, 2025 compared to the same period in the prior year. The increase was primarily driven by higher headcount and personnel-related costs, including deploying a medical science liaison team, and higher Afrezza promotional costs.

- Loss on foreign currency transaction was $5.4 million for the three months ended June 30, 2025, compared to a gain of $0.5 million for the same period in the prior year. This was due to fluctuations in U.S. dollar to Euro exchange rates. Under the Company's Insulin Supply Agreement with Amphastar, payment obligations for future purchases are denominated in Euros. The Company records the foreign currency transaction impact of the U.S. dollar to Euro exchange rate associated with the future purchase commitments.

- For the second quarter of 2025, the Company reported net income of $0.7 million, or $0.00 earnings per share – basic, compared to net loss of $2.0 million, or $0.01 loss per share – basic, for the same period in 2024, an increase in net income of $2.7 million.

- For the second quarter of 2025, the Company reported non-GAAP net income of $13.9 million, or $0.05 earnings per share – basic, compared to non-GAAP net income of $14.3 million, or $0.05 earnings per share – basic, for the same period in 2024, a decrease in net income of $0.4 million, or 3%. 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.

Six Months Ended June 30, 2025

Revenues

	Six Months Ended June 30,			
	2025	2024	$ Change	% Change
Revenues	(Dollars in thousands)			
Royalties	$ 61,233	$ 48,243	$ 12,990	27 %
Collaborations and services	52,221	50,862	$ 1,359	3 %
Afrezza	33,216	30,727	$ 2,489	8 %
V-Go	8,211	8,817	$ (606)	(7 %)
Total revenues	$ 154,881	$ 138,649	$ 16,232	12 %

Total revenues increased $16.2 million, or 12%, for the six months ended June 30, 2025 compared to the same period in the prior year. Revenue increases were driven by royalties earned on increased net sales of Tyvaso DPI® and higher revenue from collaborations and services due to increased product sold to United Therapeutics Corporation. Commercial product revenue increased for Afrezza, mainly due to higher demand and price, partially offset by a decrease in net revenue for V-Go® due to lower demand, offset by decreased sales deductions due to lower rebates on certain commercial contracts.

Operating Expenses and Other Financial Highlights

- Research and development expenses increased by $2.9 million, or 13%, for the six months ended June 30, 2025 compared to the same period in the prior year. The increase was primarily attributable to continued patient enrollment in ICoN-1 study, clinical production scale up for MNKD-201, and personnel costs primarily due to additional headcount as a result of the Pulmatrix transaction completed in the third quarter of 2024, which bolstered research capabilities and capacity. These increases were partially offset by the completion of the INHALE-3 study, the Phase 1 and toxicology studies for MNKD-201 in 2024 as well as lower costs for INHALE-1 as the study was closed out in the second quarter of 2025.

- Selling, general and administrative expenses increased by $10.2 million, or 22%, for the six months ended June 30, 2025 compared to the same period in the prior year. The increase was largely attributable to higher headcount and personnel-related expenses as well as deploying a medical science liaison team, and Afrezza promotional costs. These increases were partially offset by $1.4 million charge recorded in the prior year period for estimated returns associated with sales of V-Go that pre-dated the Company's acquisition of the product.

- Loss on foreign currency transactions was $7.9 million for the six months ended June 30, 2025, compared to a gain of $1.9 million for the same period in the prior year, due to fluctuations in U.S. dollar to Euro exchange rates related to the future purchase commitments.

- For the six months ended June 30, 2025, The Company reported net income of $13.8 million, or $0.05 earnings per share – basic, compared to net income of $8.6 million, or $0.03 earnings per share – basic, for the same period in 2024, an increase in net income of $5.2 million.

- For the six months ended June 30, 2025, the Company reported non-GAAP net income of $35.5 million, or $0.12 earnings per share – basic, compared to non-GAAP net income of $29.4 million, or $0.11 earnings per share – basic, for the same period in 2024, an increase in net income of $6.1 million, or 21%. 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 patient enrolment timelines for MNKD-101, the initiation of a Phase 2 study of MNKD-201, the expected timing for trial results and regulatory events related to Afrezza, and potential tariff exposure. 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, 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; manufacturing risks; and other risks detailed in MannKind’s filings with the Securities and Exchange Commission (“SEC”), including under the “Risk Factors” heading of its most recently filed Quarterly Report 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 Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
	(In thousands except per share data)			
Revenues:				
Commercial product sales	$ 22,454	$ 20,780	$ 41,427	$ 39,544
Collaborations and services	22,845	26,014	52,221	50,862
Royalties	31,228	25,592	61,233	48,243
Total revenues	76,527	72,386	154,881	138,649
Expenses:				
Cost of goods sold – commercial	4,607	5,605	8,375	9,424
Cost of revenue – collaborations and services	15,961	14,772	29,709	29,551
Research and development	13,675	11,816	24,697	21,829
Selling, general and administrative	31,622	24,112	56,636	46,441
Loss (gain) on foreign currency transaction	5,363	(529)	7,872	(1,928)
Total expenses	71,228	55,776	127,289	105,317
Income from operations	5,299	16,610	27,592	33,332
Other income (expense):				
Interest income, net	1,832	3,177	3,788	6,611
Interest expense	(285)	(6,051)	(4,930)	(8,618)
Interest expense on liability for sale of future royalties	(3,473)	(4,383)	(7,050)	(8,631)
Interest expense on financing liability	(2,433)	(2,444)	(4,843)	(4,891)
Loss on settlement of debt	—	(7,050)	—	(7,050)
Loss on available-for-sale securities	—	(1,550)	—	(1,550)
Total other expense	(4,359)	(18,301)	(13,035)	(24,129)
Income (loss) before income tax expense	940	(1,691)	14,557	9,203
Income tax expense	272	323	731	587
Net income (loss)	$ 668	$ (2,014)	$ 13,826	$ 8,616
Net income (loss) per share – basic	$ 0.00	$ (0.01)	$ 0.05	$ 0.03
Weighted average shares used to compute net income (loss) per share – basic	304,954	273,056	304,222	271,706
Net income (loss) per share – diluted	$ 0.00	$ (0.01)	$ 0.04	$ 0.03
Weighted average shares used to compute net income (loss) per share – diluted	311,484	273,056	312,381	279,358

MANNKIND CORPORATION AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	June 30, 2025	December 31, 2024
	(In thousands except share and per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 57,006	$ 46,339
Short-term investments	121,979	150,917
Accounts receivable, net	27,142	11,804
Inventory	28,491	27,886
Prepaid expenses and other current assets	44,409	31,360
Total current assets	279,027	268,306
Restricted cash	741	737
Long-term investments	22,240	5,482
Property and equipment, net	82,965	85,365
Goodwill	1,931	1,931
Other intangible assets	5,169	5,265
Other assets	19,624	26,757
Total assets	$ 411,697	$ 393,843
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 10,257	$ 6,792
Accrued expenses and other current liabilities	30,915	40,293
Senior convertible notes – current	36,166	—
Liability for sale of future royalties – current	13,344	12,283
Financing liability – current	10,190	10,062
Deferred revenue – current	10,954	12,407
Total current liabilities	111,826	81,837
Liability for sale of future royalties – long term	137,230	137,362
Financing liability – long term	93,476	93,877
Deferred revenue – long term	45,472	51,160
Recognized loss on purchase commitments – long term	66,076	58,204
Operating lease liability	10,656	11,645
Milestone liabilities	2,003	2,523
Senior convertible notes	—	36,051
Total liabilities	466,739	472,659
Commitments and contingencies		
Stockholders' deficit:		
Undesignated preferred stock, $0.01 par value – 10,000,000 shares authorized; no shares issued or outstanding as of June 30, 2025 or December 31, 2024	—	—
Common stock, $0.01 par value – 800,000,000 shares authorized; 306,332,133 and 302,959,782 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	3,063	3,029
Additional paid-in capital	3,128,631	3,118,865
Accumulated other comprehensive income	1,257	1,109
Accumulated deficit	(3,187,993)	(3,201,819)
Total stockholders' deficit	(55,042)	(78,816)
Total liabilities and stockholders' deficit	$ 411,697	$ 393,843

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 press release 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 June 30,				Six Months Ended June 30,			
	2025		2024		2025		2024	
	Net Income	Basic EPS	Net Income	Basic EPS	Net Income	Basic EPS	Net Income	Basic EPS
	(In thousands except per share data)							
GAAP reported net income	$ 668	$ —	$ (2,014)	$ (0.01)	$ 13,826	$ 0.05	$ 8,616	$ 0.03
Non-GAAP adjustments:								
Sold portion of royalty revenue [1]	(3,123)	(0.01)	(2,559)	(0.01)	(6,123)	(0.02)	(4,824)	(0.02)
Interest expense on liability for sale of future royalties	3,473	0.01	4,383	0.02	7,050	0.02	8,631	0.03
Stock compensation	7,520	0.03	6,428	0.02	12,905	0.04	10,313	0.04
Loss (gain) on foreign currency transaction	5,363	0.02	(529)	—	7,872	0.03	(1,928)	(0.01)
Loss on settlement of debt	—	—	7,050	0.02	—	—	7,050	0.03
Loss on available-for-sale securities	—	—	1,550	0.01	—	—	1,550	0.01
Non-GAAP adjusted net income	$ 13,901	$ 0.05	$ 14,309	$ 0.05	$ 35,530	$ 0.12	$ 29,408	$ 0.11
Weighted average shares used to compute net income per share – basic	304,954		273,056		304,222		271,706	

(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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