MannKind Corporation Reports 2024 Third Quarter Financial Results and Provides Business Update

November 7, 2024 9:02 PM EST

Conference Call to Begin Today at 4:30 p.m. (ET)

- *3Q 2024 Total revenues of $70M; +37% vs. 3Q 2023*
- *YTD 2024 Total revenues of $209M; +49% vs. YTD 2023*
- *YTD 2024 Net income of $20 million; Non-GAAP net income of $45 million*
- *Orphan lung disease studies proceeding as planned*
  - *MNKD-101 Phase 3 clinical trial expands globally*
  - *MNKD-201 Phase 1 successfully completed; Plan to meet with FDA in 1H 2025*

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., Nov. 07, 2024 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)** today reported financial results for the quarter ended September 30, 2024.

“Our business demonstrated double-digit revenue growth compared to last year, led by Tyvaso DPI revenues,” said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. “The third quarter has also been marked by strong progress in our clinical development programs, with enrollment underway in the Phase 3 trial of MNKD-101 to study its effect in NTM lung disease and successful completion of a Phase 1 trial of MNKD-201 for IPF. We also recently announced positive topline results from the Afrezza INHALE-3 post-marketing study and expect to announce topline data from the Phase-3 INHALE-1 pediatric study by year-end.”

Third Quarter 2024 Results

Revenue Highlights

	Three Months Ended September 30,			
	2024	2023	$ Change	% Change
	(Dollars in thousands)			
Royalties – collaboration	$ 27,083	$ 20,218	$ 6,865	34 %
Revenue – collaborations and services	23,268	13,108	$ 10,160	78 %
Net revenue – Afrezza	15,035	13,476	$ 1,559	12 %
Net revenue – V-Go	4,693	4,451	$ 242	5 %
Total revenues	$ 70,079	$ 51,253	$ 18,826	37 %

In the third quarter of 2024, compared to the same period in 2023:

- royalties for Tyvaso DPI® increased $6.9 million, or 34%, due to increased sales by United Therapeutics ("UT");
- collaborations and services revenue increased $10.2 million, or 78%, primarily attributable to an increase in manufacturing activities for Tyvaso DPI;
- Afrezza® net revenue increased $1.6 million, or 12%, as a result of higher demand and improved gross-to-net adjustments; and
- V-Go® net revenue increased $0.2 million, or 5%, as a result of improved gross-to-net adjustments and increased price, partially offset by lower product demand.

Commercial product gross margin in the third quarter of 2024 was 84% compared to 78% for the same period in 2023. The increase in gross margin was primarily attributable to an increase in Afrezza net revenue.

Cost of revenue – collaborations and services for the third quarter of 2024 was $14.8 million compared to $10.3 million for the same period in 2023. The $4.5 million increase was primarily attributable to increased manufacturing volume for Tyvaso DPI.

Research and development ("R&D") expenses for the third quarter of 2024 were $12.9 million compared to $10.0 million for the same period in 2023. The $2.9 million increase was primarily attributed to increased costs for a Phase 3 clinical study of MNKD-101, a Phase 1 clinical study of a dry-powder formulation of MNKD-201, and personnel costs due to increased headcount following a transaction with Pulmatrix, Inc.

Selling expenses were $13.1 million for the third quarter of 2024 compared to $13.4 million for the same period in 2023. The $0.3 million decrease was primarily due to reduced personnel costs related to a sales force restructuring completed during the first quarter of 2024, partially offset by an increase

in promotional activities.

General and administrative expenses were $10.8 million for the third quarter of 2024 compared to $10.5 million for the same period in 2023. The $0.3 million increase was primarily attributable to increases in personnel costs partially offset by reduced consulting fees.

Interest income, net, was $3.2 million for the third quarter of 2024 compared to $1.6 million for the same period in 2023. The $1.6 million increase was primarily due to an increase in the underlying investments from the proceeds of the sale of 1% of our Tyvaso DPI royalties in December 2023 and higher yields on our securities portfolio.

Interest expense on liability for sale of future royalties was $4.1 million for the third quarter of 2024 and was attributable to imputed interest and amortization of debt issuance costs on the liability recorded in connection with the sale of 1% of our Tyvaso DPI royalties in December 2023.

Interest expense on financing liability related to the sale-leaseback of our Danbury manufacturing facility was $2.5 million for the third quarter of 2024 and remained consistent with the same period in 2023.

Interest expense was $1.8 million for the third quarter of 2024 compared to $2.8 million for the same period in 2023. The decrease of $1.0 million was primarily due to repayment of the MidCap credit facility and Mann Group convertible note in April 2024.

Gain on bargain purchase of $5.3 million for the third quarter of 2024 was the result of the excess of the fair value of net assets acquired over the fair value of the consideration paid in the Pulmatrix transaction.

Nine Months September 30, 2024

Revenue Highlights

	Nine Months Ended September 30,			
	2024	2023	$ Change	% Change
	(Dollars in thousands)			
Royalties – collaboration	$ 75,326	$ 50,951	$ 24,375	48 %
Revenue – collaborations and services	74,130	35,705	$ 38,425	108 %
Net revenue – Afrezza	45,762	39,427	$ 6,335	16 %
Net revenue – V-Go	13,510	14,407	$ (897)	(6 %)
Total revenues	$ 208,728	$ 140,490	$ 68,238	49 %

For the nine months ended September 30, 2024, compared to the same period in 2023:

- royalties related to Tyvaso DPI increased $24.4 million, or 48%, due to increased sales by UT;
- collaborations and services revenue increased $38.4 million, or 108%, primarily attributable to an increase in manufacturing activities for Tyvaso DPI;
- Afrezza net revenue for the nine months ended September 30, 2024 increased $6.3 million, or 16%, primarily as a result of higher demand and price and improved gross-to-net adjustments; and
- V-Go net revenue for the nine months ended September 30, 2024 decreased $0.9 million, or 6%, as a result of lower product demand, partially offset by improved gross-to-net adjustments and increased price.

Commercial product gross margin in the nine months ended September 30, 2024 was 79% compared to 73% for the same period in 2023. The increase in gross margin was primarily attributable to an increase in Afrezza net revenue.

Cost of revenue – collaborations and services for the nine months ended September 30, 2024 was $44.4 million compared to $30.0 million for the same period in 2023. The $14.4 million increase was primarily attributable to increased manufacturing volume for product sold to UT.

R&D expenses for the nine months ended September 30, 2024 were $34.8 million compared to $22.0 million for the same period in 2023. The $12.8 million increase was primarily attributed to increased expenditures for development activities and a Phase 3 clinical study of MNKD-101, a Phase 1 study of MNKD-201, and personnel costs due to increased headcount as a result of the Pulmatrix transaction.

Selling expenses were $36.2 million in the nine months ended September 30, 2024 compared to $40.8 million for the same period in 2023. The $4.6 million decrease was primarily due to reduced personnel costs related to a sales force restructuring completed during the first quarter of 2024.

General and administrative expenses for the nine months ended September 30, 2024 were $34.2 million compared to $33.0 million for the same period in 2023. The $1.2 million increase was primarily attributable to a loss of $1.4 million related to estimated returns associated with sales of V-Go that pre-date our acquisition of the product and increases in personnel costs, partially offset by reduced consulting fees.

Interest income, net, was $9.8 million for the nine months ended September 30, 2024 compared to $4.4 million for the same period in 2023. The $5.4 million increase was primarily due to an increase in the underlying investments from the proceeds of the sale of 1% of our Tyvaso DPI royalties in December 2023 and higher yields on our securities portfolio.

Interest expense on liability for sale of future royalties was $12.7 million for the nine months ended September 30, 2024 and was attributable to imputed interest and amortization of debt issuance costs on the liability recorded in connection with the sale of 1% of our Tyvaso DPI royalties in December 2023.

Interest expense on financing liability related to the sale-leaseback of our Danbury manufacturing facility was $7.4 million for the nine months ended September 30, 2024 and remained consistent with the same period in 2023.

Interest expense was $10.4 million for the nine months ended September 30, 2024 compared to $12.5 million for the same period in 2023. The decrease of $2.1 million was primarily due to repayment of the MidCap credit facility and Mann Group convertible note in April 2024.

Gain on bargain purchase of $5.3 million for the nine months ended September 30, 2024 was the result of the excess of the fair value of net assets acquired over the fair value of the consideration paid in the Pulmatrix transaction.

Loss on available-for-sale securities for the nine months ended September 30, 2024 was $1.6 million resulting from the modification of the Thirona note terms. Gain on available-for-sale securities for the same period in 2023 was $0.9 million as a result of the change in fair value of the Thirona investment.

Loss on extinguishment of debt of $7.1 million for the nine months ended September 30, 2024 was incurred in connection with the prepayment of the MidCap credit facility and the Mann Group convertible note in April 2024.

Cash, cash equivalents and investments as of September 30, 2024 were $268.4 million.

Non-GAAP Measures

To supplement our condensed consolidated financial statements presented under U.S. generally accepted accounting principles ("GAAP"), we are presenting non-GAAP net income (loss) and non-GAAP net income (loss) per share - diluted, which are non-GAAP financial measures. We are providing these non-GAAP financial measures to disclose additional information to facilitate the comparison of past and present operations, and they are among the indicators management uses as a basis for evaluating our financial performance. 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 in the future 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 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 report 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 (loss) and net income (loss) per share ("EPS") for diluted weighted average shares as reported in our condensed consolidated statements of operations to a non-GAAP presentation.

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2024		2023		2024		2023	
	Net Income	Basic EPS	Net Income	Basic EPS	Net Income	Basic EPS	Net Loss	Basic EPS
	(In thousands except per share data)							
GAAP reported net income (loss)	$ 11,550	$ 0.04	$ 1,721	$ 0.01	$ 20,166	$ 0.07	$ (13,339)	$ (0.05)
Non-GAAP adjustments:								
Sold portion of royalty revenue[1]	(2,708)	(0.01)	—	—	(7,533)	(0.03)	—	—
Interest expense on liability for sale of future royalties	4,089	0.02	—	—	12,720	0.04	—	—
Stock compensation	5,227	0.02	4,601	0.02	15,540	0.06	13,836	0.05
Loss (gain) on foreign currency transaction	2,454	0.01	(2,065)	(0.01)	526	—	(860)	—
Gain on bargain purchase	(5,259)	(0.02)	—	—	(5,259)	(0.02)	—	—
Loss on extinguishment of debt	—	—	—	—	7,050	0.03	—	—
Loss (gain) on available-for-sale securities	—	—	—	—	1,550	0.01	(932)	—
Non-GAAP adjusted net income (loss)	$ 15,353	$ 0.06	$ 4,257	$ 0.02	$ 44,760	$ 0.16	$ (1,295)	$ (0.00)
Weighted average shares used to compute net income (loss) per share – basic	274,998		268,732		272,811		266,126	

(1) Represents the non-cash portion of the 1% royalty on net sales of Tyvaso DPI earned during the periods presented which is remitted to the royalty purchaser and recognized as royalties – collaboration in our consolidated statements of operations. Our revenues from royalties – collaboration during 3Q 2024 and the nine months ended September 30, 2024 totaled $27.1 million and $75.3 million, respectively, of which $2.7 million and $7.5 million, respectively, were attributed to the royalty purchaser.

Clinical Development Update and Anticipated Milestones

Afrezza INHALE-3 (T1D, Afrezza vs. standard of care multiple daily injections or pumps) Phase 4 clinical trial

- Top-level 30-week results demonstrated that switching to or remaining on Afrezza allowed nearly twice as many people to get to the A1C (<7%) goal during the extension period
- Additional data to be presented at Advanced Technologies and Treatments for Diabetes (ATTD) and other conferences in 1H 2025

Afrezza INHALE-1 Pediatric Phase 3 clinical trial

- Primary endpoint analysis results expected in 4Q 2024
- Six-month data with safety extension expected in 1H 2025
- FDA submission for label expansion planned in 2025

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

- Trial cleared to proceed in four countries (U.S., Japan, South Korea and Australia) with a fifth (Taiwan) expected in 4Q 2024
- First patient randomized in the US in 3Q
- Approximately 230 participants to be randomized at 100+ sites for a minimum of 180 evaluable participants

MNKD-201 (nintedanib DPI) Phase 1 clinical trial

- Trial successfully completed, primary objective met demonstrating positive safety results and was well-tolerated in healthy volunteers
- Participants did not experience adverse events typically reported with oral nintedanib
- Preclinical chronic toxicology did not show any adverse findings
- FDA End-of-Phase 1 meeting expected in 1H 2025

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 the expected timing of patient enrollment and global expansion in a clinical study of MNKD-101; the expected timing for data read-outs from clinical studies of Afrezza; timing for an end-of-Phase 1 meeting with the FDA for MNKD-201; and the timing of a planned FDA submission for Afrezza. 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; 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, 2023, filed with the SEC on February 27, 2024, 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.

MANNKIND CORPORATION AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023

	(In thousands except per share data)			
Revenues:				
Net revenue – commercial product sales	$ 19,728	$ 17,927	$ 59,272	$ 53,834
Revenue – collaborations and services	23,268	13,108	74,130	35,705
Royalties – collaboration	27,083	20,218	75,326	50,951
Total revenues	70,079	51,253	208,728	140,490
Expenses:				
Cost of goods sold	3,197	3,995	12,621	14,749
Cost of revenue – collaborations and services	14,826	10,259	44,377	29,955
Research and development	12,926	9,989	34,755	22,047
Selling	13,093	13,440	36,189	40,752
General and administrative	10,823	10,538	34,168	33,027
Loss (gain) on foreign currency transaction	2,454	(2,065)	526	(860)
Total expenses	57,319	46,156	162,636	139,670
Income from operations	12,760	5,097	46,092	820
Other income (expense):				
Interest income, net	3,179	1,580	9,790	4,429
Interest expense on liability for sale of future royalties	(4,089)	—	(12,720)	—
Interest expense on financing liability	(2,470)	(2,459)	(7,361)	(7,332)
Interest expense	(1,801)	(2,815)	(10,419)	(12,474)
Gain on bargain purchase	5,259	—	5,259	—
Other income	32	318	32	286
Loss on extinguishment of debt	—	—	(7,050)	—
(Loss) gain on available-for-sale securities	—	—	(1,550)	932
Total other expense	110	(3,376)	(24,019)	(14,159)
Income (loss) before income tax expense	12,870	1,721	22,073	(13,339)
Income tax expense	1,320	—	1,907	—
Net income (loss)	$ 11,550	$ 1,721	$ 20,166	$ (13,339)
Net income (loss) per share – basic	$ 0.04	$ 0.01	$ 0.07	$ (0.05)
Weighted average shares used to compute net income (loss) per share – basic	274,998	268,732	272,811	266,126
Net income (loss) per share – diluted	$ 0.04	$ 0.01	$ 0.07	$ (0.05)
Weighted average shares used to compute net income (loss) per share – diluted	284,693 (1)	323,770 (1)	281,407 (1)	266,126

(1) Diluted weighted average shares ("DWAS") differs from basic 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 three and nine months ended September 30, 2024 DWAS included and 9,695 and 8,596, respectively, shares of outstanding share-based payments. 44,120 shares issuable upon conversion of our Senior convertible notes were excluded as their effect would be antidilutive. For the three months ended September 30, 2023 DWAS included 7,548 shares of outstanding share-based payments, 44,120 shares issuable upon conversion of our Senior convertible notes, and 3,370 shares issuable upon conversion of our Mann Group convertible note.

MANNKIND CORPORATION AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2024	December 31, 2023
	(In thousands except share and per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 62,373	$ 238,480
Short-term investments	189,215	56,619
Accounts receivable, net	18,184	14,901
Inventory	26,663	28,545
Prepaid expenses and other current assets	31,229	34,848
Total current assets	327,664	373,393
Restricted cash	735	—
Long-term investments	16,796	7,155
Property and equipment, net	85,339	84,220
Goodwill	1,931	1,931
Other intangible assets	5,313	1,073
Other assets	26,422	7,426
Total assets	$ 464,200	$ 475,198
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		

Accounts payable	$ 6,444	$ 9,580
Accrued expenses and other current liabilities	37,386	42,036
Liability for sale of future royalties – current	11,755	9,756
Financing liability – current	9,998	9,809
Deferred revenue – current	6,518	9,085
Recognized loss on purchase commitments – current	—	3,859
Midcap credit facility – current	—	20,000
Total current liabilities	72,101	104,125
Senior convertible notes	227,941	226,851
Liability for sale of future royalties – long term	137,140	136,054
Financing liability – long term	94,005	94,319
Deferred revenue – long term	65,150	69,794
Recognized loss on purchase commitments – long term	62,638	60,942
Operating lease liability	12,167	3,925
Milestone liabilities	2,813	3,452
Financing lease liability	171	—
Midcap credit facility – long term	—	13,019
Mann Group convertible note	—	8,829
Accrued interest – Mann Group convertible note	—	56
Total liabilities	674,126	721,366
Stockholders' deficit:		
Undesignated preferred stock, $0.01 par value – 10,000,000 shares authorized; no shares issued or outstanding as of September 30, 2024 or December 31, 2023	—	—
Common stock, $0.01 par value – 800,000,000 shares authorized; 275,775,038 and 270,034,495 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	2,753	2,700
Additional paid-in capital	2,995,974	2,980,539
Accumulated other comprehensive income	588	—
Accumulated deficit	(3,209,241)	(3,229,407)
Total stockholders' deficit	(209,926)	(246,168)
Total liabilities and stockholders' deficit	$ 464,200	$ 475,198

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Source: MannKind