



MannKind Corporation Reports 2024 Second Quarter Financial Results: Provides Clinical Development Update

August 7, 2024 12:00 PM EDT

Conference Call to Begin Today at 9:00 a.m. (ET)

- 2Q 2024 Total revenues of \$72M; +49% vs. 2Q 2023
- YTD 2024 Total revenues of \$139M; +55% vs. YTD 2023
- YTD 2024 Net income of \$9 million; Non-GAAP net income of \$29 million
- Advances two orphan lung programs to human studies
 - MNKD-101 Phase 3 clinical trial activities initiated
 - MNKD-201 Phase 1 clinical trial on schedule to read out 4Q 2024

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

"We achieved our ninth consecutive quarter of revenue growth and are approaching an annual revenue run rate of over \$275 million based on the first half of 2024," said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. "We are excited about our future as we move our orphan lung programs into Phase 1 and Phase 3 studies and look forward to the additional Afrezza data read-outs later this year. We believe our diversification strategy of allocating capital towards our pipeline, in-line growth and debt reduction sets us up to deliver sustainable short and long-term value for our shareholders."

Second Quarter 2024 Results

Revenue Highlights

	Three Months Ended June 30,			
	2024	2023	\$ Change	% Change
	(Dollars in thousands)			
Royalties – collaboration	\$ 25,592	\$ 19,055	\$ 6,537	34 %
Revenue – collaborations and services	26,014	11,211	\$ 14,803	132 %
Net revenue – Afrezza	16,289	13,527	\$ 2,762	20 %
Net revenue – V-Go	4,491	4,818	\$ (327)	(7 %)
Total revenues	\$ 72,386	\$ 48,611	\$ 23,775	49 %

Second quarter royalties for Tyvaso DPI[®] increased \$6.5 million, or 34%, over the same period in prior year due to increased sales by United Therapeutics ("UT"). Collaborations and services revenue increased \$14.8 million, or 132%, compared to the same period in 2023 primarily attributable to an increase in manufacturing activities for Tyvaso DPI. Afrezza[®] net revenue for the second quarter of 2024 increased \$2.8 million, or 20%, compared to the same period in 2023 primarily as a result of price (including a decrease in gross-to-net adjustments) and higher demand. V-Go[®] net revenue for the second quarter of 2024 decreased \$0.3 million, or 7%, compared to the same period in 2023 as a result of lower product demand partially offset by increased price.

Commercial product gross margin in the second quarter of 2024 was 73% compared to 72% 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 second quarter of 2024 was \$14.8 million compared to \$9.0 million for the same period in 2023. The \$5.8 million increase was primarily attributable to increased manufacturing volume and related production activities for Tyvaso DPI. Higher manufacturing volumes resulted in efficiencies, which contributed to a lower effective cost per unit.

Research and development ("R&D") expenses for the second quarter of 2024 were \$11.8 million compared to \$6.5 million for the same period in 2023. The \$5.4 million increase was primarily attributed to increased costs for development activities for clofazimine inhaled suspension (MNKD-101), an Afrezza pediatric clinical study (INHALE-1), and initiation of a Phase 1 clinical study of a dry-powder formulation of nintedanib (MNKD-201) for treatment of pulmonary fibrotic diseases, partially offset by lower costs for an Afrezza post-marketing clinical study (INHALE-3).

Selling expenses were \$11.5 million for the second quarter of 2024 compared to \$14.0 million for the same period in 2023. The \$2.5 million decrease was primarily due to reduced personnel related to a sales force restructuring completed during the first quarter of 2024.

General and administrative expenses were \$12.6 million for the second quarter of 2024 compared to \$11.9 million for the same period in 2023. The \$0.7 million increase was primarily attributable to increases in estimated returns associated with sales of V-Go that pre-date our acquisition of the product and personnel costs.

Interest income, net, was \$3.2 million for the second quarter of 2024 compared to \$1.5 million for the same period in 2023. The \$1.6 million increase was primarily due to higher yields on our securities portfolio and an increase in the underlying investments from the proceeds of 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 \$2.4 million for the second quarter of

2024 and remained consistent with the same period in 2023.

Interest expense was \$6.1 million for the second quarter of 2024 compared to \$6.9 million for the same period in 2023. The decrease of \$0.8 million was primarily due to repayment of the MidCap credit facility and Mann Group convertible note in April 2024.

Interest expense on liability for sale of future royalties was \$4.4 million for the second 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.

Loss on available-for-sale securities for the second quarter of 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 relating to credit risk.

Loss on extinguishment of debt of \$7.1 million for the second quarter of 2024 was incurred in connection with the prepayment of the MidCap credit facility and Mann Group convertible note in April 2024.

First Half of 2024

Revenue Highlights

	Six Months Ended June 30,			
	2024	2023	\$ Change	% Change
	(Dollars in thousands)			
Royalties – collaboration	\$ 48,243	\$ 30,733	\$ 17,510	57 %
Revenue – collaborations and services	50,862	22,597	\$ 28,265	125 %
Net revenue – Afrezza	30,727	25,951	\$ 4,776	18 %
Net revenue – V-Go	8,817	9,956	\$ (1,139)	(11 %)
Total revenues	\$ 138,649	\$ 89,237	\$ 49,412	55 %

Royalties related to Tyvaso DPI for the first half of 2024 increased \$17.5 million, or 57%, due to increased sales by UT. Collaborations and services revenue increased \$28.3 million, or 125%, compared to the same period in 2023 primarily attributable to an increase in manufacturing activities for Tyvaso DPI. Afrezza net revenue for the first half of 2024 increased \$4.8 million, or 18%, compared to the same period in 2023 primarily as a result of price (including a decrease in gross-to-net adjustments) and higher demand. V-Go net revenue for the first half of 2024 decreased \$1.1 million, or 11%, compared to the same period in 2023 as a result of lower product demand partially offset by increased price.

Commercial product gross margin in the first half of 2024 was 76% compared to 70% 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 first half of 2024 was \$29.6 million compared to \$19.7 million for the same period in 2023. The \$9.9 million increase was primarily attributable to increased manufacturing volume and related production activities for product sold to UT.

R&D expenses for the first half of 2024 were \$21.8 million compared to \$12.1 million for the same period in 2023. The \$9.8 million increase was primarily attributed to increased costs for development activities for MNKD-101, the INHALE-1 study, an Afrezza post-marketing clinical study (INHALE-3) which commenced in the second quarter of 2023, personnel expenses due to increased headcount, and initiation of a Phase 1 study of MNKD-201 for treatment of pulmonary fibrotic diseases.

Selling expenses were \$23.1 million in the first half of 2024 compared to \$27.3 million for the same period in 2023. The \$4.2 million decrease was primarily due to reduced personnel and travel expenses related to a sales force restructuring completed during the first quarter of 2024.

General and administrative expenses for the first half of 2024 were \$23.3 million compared to \$22.5 million for the same period in 2023. The \$0.9 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, partially offset by reduced personnel costs.

Interest income, net, was \$6.6 million for the first half of 2024 compared to \$2.8 million for the same period in 2023. The \$3.8 million increase was primarily due to higher yields on our securities portfolio and an increase in the underlying investments from the proceeds of 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 \$4.9 million for the first half of 2024 and remained consistent with the same period in 2023.

Interest expense was \$8.6 million for the first half of 2024 compared to \$9.7 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.

Interest expense on liability for sale of future royalties was \$8.6 million for the first half 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.

Loss on available-for-sale securities for the first half of 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 relating to credit risk.

Loss on extinguishment of debt of \$7.1 million for the first half of 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, restricted cash and investments as of June 30, 2024 were \$261.9 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 June 30,				Six Months Ended June 30,			
	2024		2023		2024		2023	
	Net Income (Loss)	Basic EPS	Net Loss	Basic EPS	Net Income	Basic EPS	Net Loss	Basic EPS
(In thousands except per share data)								
GAAP reported net income (loss)	\$ (2,014)	\$ (0.01)	\$ (5,265)	\$ (0.02)	\$ 8,616	\$ 0.03	\$ (15,060)	\$ (0.06)
Non-GAAP adjustments:								
Sold portion of royalty revenue ⁽¹⁾	(2,559)	(0.01)	—	—	(4,824)	(0.02)	—	—
Interest expense on liability for sale of future royalties	4,383	0.02	—	—	8,631	0.03	—	—
Stock compensation	6,428	0.02	5,580	0.02	10,313	0.04	9,235	0.04
(Gain) loss on foreign currency transaction	(529)	—	251	—	(1,928)	(0.01)	1,205	—
Loss (gain) on available-for-sale securities	1,550	0.01	(932)	—	1,550	0.01	(932)	—
Loss on extinguishment of debt	7,050	0.02	—	—	7,050	0.03	—	—
Non-GAAP adjusted net income (loss)	\$ 14,309	\$ 0.05	\$ (366)	\$ —	\$ 29,408	\$ 0.11	\$ (5,552)	\$ (0.02)
Weighted average shares used to compute net income (loss) per share – basic	273,056	\$ 0.05	265,626	\$ (0.00)	271,706	\$ 0.11	264,802	\$ (0.02)

(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 2Q 2024 and the first half of 2024 totaled \$25.6 million and \$48.2 million, respectively, of which \$2.6 million and \$4.8 million, respectively, were attributed to the royalty purchaser.

Clinical Development Update

Afrezza INHALE-3 (T1DM, Afrezza vs. standard of care; phase 4 clinical trial)

- First meal dosing data published online in *Diabetes Care* in July 2024
- Randomized treatment phase top-line data/primary endpoints presented at American Diabetes Association conference in June 2024
 - Inhaled insulin improved the ability to achieve target A1c (<7%) by 76% over the standard of care (30% of Afrezza participants vs. 17% on standard of care)
 - 24% of Afrezza vs. 13% on standard of care met time-in-range > 70% with no increased hypoglycemia by continuous glucose monitoring
 - Over 50% of subjects at the end of the study expressed interest in continuing Afrezza
 - Met 17-week primary endpoint; full 30-week data expected to read out later this year
- Additional data to be presented at Association of Diabetes Care and Education Specialists conference in August 2024

Afrezza INHALE-1 (pediatric phase 3 clinical trial)

- Upcoming expected data read-outs and planned U.S. Food and Drug Administration ("FDA") submission:
 - Primary endpoint analysis in 4Q 2024
 - Full results in 1H 2025
 - FDA submission for label expansion in 2025

MNKD-101 (clofazimine inhalation suspension)

- Phase 3 clinical trial activities initiated and site activation commenced in 2Q 2024
- Co-primary endpoints of sputum conversion and patient-reported outcomes
- Up to 120 global sites with 180 patients expected to be evaluated

MNKD-201 (nintedanib DPI)

- Phase 1 trial in healthy volunteers underway with first participant dosed in 2Q 2024
- Chronic toxicology and Phase 1 results expected in 4Q 2024

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 at <https://investors.mannkindcorp.com/events-and-presentations>. A replay will also be available in the same location within 24 hours following the call and be 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 annual revenue run rate; MannKind's ability to deliver sustainable short and long-term value for its shareholders; the expected timing of patient enrollment and dosing in clinical studies of MNKD-101; expected timing for data read-outs for clinical studies of MNKD-201 and Afrezza; and the timing of planned FDA submissions 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 manufacturing and supply; risks associated with developing product candidates; risks and uncertainties related to unforeseen delays that may impact the timing of progressing 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.

Tyvaso DPI is a trademark of United Therapeutics Corporation.

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

MANNKIND CORPORATION AND SUBSIDIARY CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(In thousands except per share data)			
Revenues:				
Net revenue – commercial product sales	\$ 20,780	\$ 18,345	\$ 39,544	\$ 35,907
Revenue – collaborations and services	26,014	11,211	50,862	22,597
Royalties – collaboration	25,592	19,055	48,243	30,733
Total revenues	<u>72,386</u>	<u>48,611</u>	<u>138,649</u>	<u>89,237</u>
Expenses:				
Cost of goods sold	5,605	5,224	9,424	10,754
Cost of revenue – collaborations and services	14,772	9,013	29,551	19,696
Research and development	11,816	6,453	21,829	12,058
Selling	11,495	14,002	23,096	27,312
General and administrative	12,617	11,947	23,345	22,489
(Gain) loss on foreign currency transaction	(529)	251	(1,928)	1,205

Total expenses	55,776	46,890	105,317	93,514
Income (loss) from operations	16,610	1,721	33,332	(4,277)
Other income (expense):				
Interest income, net	3,177	1,547	6,611	2,849
Interest expense on financing liability	(2,444)	(2,449)	(4,891)	(4,873)
Interest expense	(6,051)	(6,873)	(8,618)	(9,659)
Interest expense on liability for sale of future royalties	(4,383)	—	(8,631)	—
(Loss) gain on available-for-sale securities	(1,550)	932	(1,550)	932
Loss on extinguishment of debt	(7,050)	—	(7,050)	—
Other expense	—	(143)	—	(32)
Total other expense	(18,301)	(6,986)	(24,129)	(10,783)
Income (loss) before income tax expense	(1,691)	(5,265)	9,203	(15,060)
Income tax expense	323	—	587	—
Net income (loss)	\$ (2,014)	\$ (5,265)	\$ 8,616	\$ (15,060)
Net income (loss) per share – basic	\$ (0.01)	\$ (0.02)	\$ 0.03	\$ (0.06)
Weighted average shares used to compute net income (loss) per share – basic	273,056	265,626	271,706	264,802
Net income (loss) per share – diluted	\$ (0.01)	\$ (0.02)	\$ 0.03	\$ (0.06)
Weighted average shares used to compute net income (loss) per share – diluted	273,056	265,626	279,358 ⁽¹⁾	264,802

(1) Diluted weighted average shares ("DWAS") differs from basic due to the weighted average number of shares that would be outstanding upon conversion of convertible notes and exercise or vesting of outstanding share-based payments to employees. For the six months ended June 30, 2024, DWAS included 7,652 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.

**MANKIND CORPORATION AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS**

	<u>June 30, 2024</u>	<u>December 31, 2023</u>
	(In thousands except share and per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 96,643	\$ 238,480
Short-term investments	151,118	56,619
Accounts receivable, net	23,346	14,901
Inventory	24,753	28,545
Prepaid expenses and other current assets	30,080	34,848
Total current assets	325,940	373,393
Restricted cash	732	—
Long-term investments	13,398	7,155
Property and equipment, net	85,144	84,220
Goodwill	1,931	1,931
Other intangible asset	1,033	1,073
Other assets	15,658	7,426
Total assets	\$ 443,836	\$ 475,198
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 9,556	\$ 9,580
Accrued expenses and other current liabilities	40,952	42,036
Liability for sale of future royalties – current	12,149	9,756
Financing liability – current	9,935	9,809
Deferred revenue – current	7,420	9,085
Recognized loss on purchase commitments – current	—	3,859
Midcap credit facility – current	—	20,000
Total current liabilities	80,012	104,125
Senior convertible notes	227,577	226,851
Liability for sale of future royalties – long term	135,365	136,054
Financing liability – long term	94,094	94,319
Deferred revenue – long term	66,116	69,794
Recognized loss on purchase commitments – long term	60,183	60,942
Operating lease liability	3,272	3,925
Financing lease liability	184	—
Milestone liabilities	2,813	3,452

Mann Group convertible note	—	8,829
Accrued interest – Mann Group convertible note	—	56
Midcap credit facility – long term	—	13,019
Total liabilities	<u>669,616</u>	<u>721,366</u>
Stockholders' deficit:		
Undesignated preferred stock, \$0.01 par value – 10,000,000 shares authorized; no shares issued or outstanding as of June 30, 2024 or December 31, 2023	—	—
Common stock, \$0.01 par value – 800,000,000 shares authorized; 274,467,247 and 270,034,495 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	2,740	2,700
Additional paid-in capital	2,992,271	2,980,539
Accumulated deficit	<u>(3,220,791)</u>	<u>(3,229,407)</u>
Total stockholders' deficit	<u>(225,780)</u>	<u>(246,168)</u>
Total liabilities and stockholders' deficit	\$ 443,836	\$ 475,198

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mannkind

Source: MannKind