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

May 8, 2024 8:18 PM EDT

Conference Call to Begin Today at 5:00 p.m. (ET)

- *1Q 2024 Total revenues of $66M; +63% vs. 1Q 2023*
- *1Q 2024 Net income of $11M; Non-GAAP net income of $15M*
- *$304M of cash and cash equivalents and investments at March 31, 2024*
- *In early April, repaid Midcap senior-secured debt and Mann Group convertible debt totaling approximately $37M*
- *FDA Fast Track designation and IND clearance received for MNKD-101*

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., May 08, 2024 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)** today reported financial results for the quarter ended March 31, 2024.

"We achieved our eighth consecutive quarter of revenue growth putting us on a run rate of over $250 million in revenue for 2024," said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. "In the last week, we received Fast Track designation and clearance of the IND for MNKD-101 which may allow us to bring this innovative product to patients more quickly."

Revenue Highlights

	Three Months Ended March 31,			
	2024	2023	$ Change	% Change
	(Dollars in thousands)			
Royalties – collaborations	$ 22,651	$ 11,678	$ 10,973	94 %
Revenue – collaborations and services	24,848	11,386	$ 13,462	118 %
Net revenue – Afrezza	14,438	12,423	$ 2,015	16 %
Net revenue – V-Go	4,326	5,139	$ (813)	(16 %)
Total revenues	$ 66,263	$ 40,626	$ 25,637	63 %

Royalties related to Tyvaso DPI for the first quarter of 2024 increased $11.0 million, or 94%, due to increased patient demand. Collaborations and services revenue increased $13.5 million, or 118%, compared to the same period in 2023 primarily attributable to an increase in manufacturing Tyvaso DPI for United Therapeutics ("UT"). Afrezza® net revenue for the first quarter of 2024 increased $2.0 million, or 16%, compared to the same period in 2023 as a result of higher price (including a decrease in gross-to-net adjustments). V-Go® net revenue for the first quarter of 2024 decreased $0.8 million, or 16%, compared to the same period in 2023 as a result of lower product demand.

Commercial product gross margin in the first quarter of 2024 was 80% compared to 69% 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 quarter of 2024 was $14.8 million compared to $10.7 million for the same period in 2023. The $4.1 million increase was primarily attributable to increased manufacturing volume and related production activities. Higher manufacturing volumes resulted in efficiencies which contributed to a lower effective cost per unit.

Research and development ("R&D") expenses for the first quarter of 2024 were $10.0 million compared to $5.6 million for the same period in 2023. The $4.4 million increase was primarily attributed to increased development activities for clofazimine inhaled suspension (MNKD-101), costs for an Afrezza post-marketing clinical study (INHALE-3) which commenced in the second quarter of 2023 and personnel expenses due to increased headcount.

Selling expenses were $11.6 million in the first quarter of 2024 compared to $13.3 million for the same period in 2023. The $1.7 million decrease was primarily due to reduced personnel and travel expenses related to sales force restructuring activities completed during the quarter.

General and administrative expenses for the first quarter of 2024 were $10.7 million compared to $10.5 million for the same period in 2023. The $0.2 million increase was primarily attributable to a loss of $1.2 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 $3.4 million for the first quarter of 2024 compared to $1.3 million for the same period in 2023. The $2.1 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 notes was $2.6 million and interest expense on financing liability (related to the sale-leaseback of our Danbury manufacturing facility) was $2.4 million for the first quarter of 2024 and remained consistent with the same period in 2023.

Interest expense on liability for sale of future royalties was $4.2 million for the first quarter of 2024 due to imputed interest and amortization of debt issuance costs on the liability recorded in connection with the sale of a portion of our future royalties in December 2023.

Cash, cash equivalents and investments as of March 31, 2024 were $304.5 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 measure 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 as adjusted for select non-cash items: 1% royalty on net revenues for Tyvaso DPI ("sold portion of royalty revenue") and interest expense on the related liability, stock-based compensation expense and (gain) loss on foreign currency transaction for the periods presented:

	Three Months Ended March 31,			
	2024		2023	
	Net Income	Diluted EPS	Net Loss	Diluted EPS
	(In thousands except per share data)			
GAAP reported	$ 10,630	$ 0.04	$ (9,795)	$ (0.04)
Select non-cash adjustments:				
Sold portion of royalty revenue [1]	(2,265)	(0.01)	—	—
Interest expense on liability for sale of future royalties	4,248	0.01	—	—
Stock compensation	3,885	0.01	3,655	0.01
(Gain) loss on foreign currency transaction	(1,399)	—	954	0.01
Non-GAAP adjusted	$ 15,099	$ 0.05	$ (5,186)	$ (0.02)
Weighted average shares used to compute net income (loss) per share – diluted	324,733		263,969	

(1) Represents the non-cash portion of the 1% royalty on net sales of Tyvaso DPI earned during 1Q 2024 which is remitted to the royalty purchaser and recognized as royalties from collaborations in our consolidated statements of operations. Our revenues from royalties from collaborations during 1Q 2024 totaled $22.7 million, of which $2.3 million will be remitted to the royalty purchaser.

Clinical Development Update

Afrezza INHALE-1 (pediatric phase 3 clinical trial)

- Patient enrollment and randomization completed in 1Q 2024
- 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

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

- Last participant completed randomized treatment phase in 1Q 2024
- First meal dosing presented at ATTD conference in March 2024
- Upcoming expected data read-outs:
  - Randomized treatment phase top-line data/primary endpoints to be presented at ADA conference in June 2024
  - Additional data to be presented at ADCES August conference

MNKD-101 (clofazimine inhalation suspension)

- Fast Track designation received from the FDA

- FDA clearance of Investigational New Drug Application ("IND")
- Co-primary endpoints of sputum conversion and patient-reported outcomes
- Up to 120 global sites, first patient expected to enroll in 2Q 2024

MNKD-201 (nintedanib DPI)

- FDA clearance to proceed to Phase 1 clinical trial
- Phase 1 development program in healthy volunteers, expected to dose first patient in 2Q 2024
- Results expected in late 2024

Conference Call

MannKind will host a conference call and presentation webcast to discuss these results today at 5:00 p.m. Eastern Time. Those interested in listening to the conference call live via the Internet may do so by visiting the Company's website at mannkindcorp.com under Events & Presentations. A replay will be available on MannKind's website for 14 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 dosing in clinical studies of MNKD-101 and MNKD-201; the potential for expedited review of a regulatory submission for MNKD-101 and the potential to bring MNKD-101 to patients more quickly; 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, as updated by the "Risk Factors" in its Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2024, 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.

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MANNKIND CORPORATION AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended March 31,	
	2024	2023
	(In thousands except per share data)	
Revenues:		
Net revenue – commercial product sales	$ 18,764	$ 17,562
Revenue – collaborations and services	24,848	11,386
Royalties – collaborations	22,651	11,678
Total revenues	66,263	40,626
Expenses:		
Cost of goods sold	3,819	5,530
Cost of revenue – collaborations and services	14,779	10,683
Research and development	10,013	5,605
Selling	11,601	13,310

General and administrative	10,728		10,542
(Gain) loss on foreign currency transaction	(1,399)		954
Total expenses	49,541		46,624
Income (loss) from operations	16,722		(5,998)
Other income (expense):			
Interest income, net	3,434		1,302
Interest expense on financing liability	(2,447)		(2,424)
Interest expense	(2,567)		(2,786)
Interest expense on liability for sale of future royalties	(4,248)		—
Other income	—		111
Total other expense	(5,828)		(3,797)
Income (loss) before income tax expense	10,894		(9,795)
Income tax expense	264		—
Net income (loss)	$ 10,630		$ (9,795)
Net income (loss) per share – basic	$ 0.04		$ (0.04)
Weighted average shares used to compute net income (loss) per share – basic	270,356		263,969
Net income (loss) per share – diluted	$ 0.04	(1)	$ (0.04)
Weighted average shares used to compute net income (loss) per share – diluted	324,733	(2)	263,969

(1) The calculation of diluted EPS includes an add back of interest expense to net income which represents interest that would not be recognized if the conversion of our Senior convertible notes and Mann Group convertible note were converted to shares of our common stock. The related interest expense for 1Q 2024 was $1,856 and resulted in adjusted net income of $12,486. These adjustments are only applied to periods with net income.

(2) Diluted weighted average shares differs from basic due to the weighted average number of shares that would be outstanding upon conversion of our Senior convertible notes (44,120 shares) and Mann Group convertible note (3,370 shares), and exercise or vesting of outstanding share-based payments to employees (6,887 shares). These adjustments to weighted average shares are only applied to periods with net income.

MANNKIND CORPORATION AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2024	December 31, 2023
	(In thousands except share and per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 193,272	$ 238,480
Short-term investments	107,457	56,619
Accounts receivable, net	19,912	14,901
Inventory	26,442	28,545
Prepaid expenses and other current assets	36,019	34,848
Total current assets	383,102	373,393
Property and equipment, net	83,620	84,220
Goodwill	1,931	1,931
Other intangible asset	1,053	1,073
Long-term investments	3,726	7,155
Other assets	7,447	7,426
Total assets	$ 480,879	$ 475,198
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 7,149	$ 9,580
Accrued expenses and other current liabilities	42,291	42,036
Financing liability – current	9,872	9,809
Midcap credit facility – current	20,000	—
Liability for sale of future royalties – current	10,537	9,756
Deferred revenue – current	7,601	9,085
Recognized loss on purchase commitments – current	2,446	3,859
Total current liabilities	99,896	104,125
Mann Group convertible note	8,829	8,829
Accrued interest – Mann Group convertible note	55	56
Financing liability – long term	94,207	94,319
Midcap credit facility – long term	8,105	13,019
Senior convertible notes	227,214	226,851
Liability for sale of future royalties – long term	137,418	136,054
Recognized loss on purchase commitments – long term	60,287	60,942

Operating lease liability	3,645	3,925
Deferred revenue – long term	67,741	69,794
Milestone liabilities	3,452	3,452
Total liabilities	710,849	721,366
Stockholders' deficit:		
Undesignated preferred stock, $0.01 par value – 10,000,000 shares authorized; no shares issued or outstanding as of March 31, 2024 or December 31, 2023	—	—
Common stock, $0.01 par value – 800,000,000 shares authorized; 270,801,781 and 270,034,495 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	2,703	2,700
Additional paid-in capital	2,986,104	2,980,539
Accumulated deficit	(3,218,777)	(3,229,407)
Total stockholders' deficit	(229,970)	(246,168)
Total liabilities and stockholders' deficit	$ 480,879	$ 475,198

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Source: MannKind