



MannKind Corporation Reports 2023 Third Quarter Financial Results

November 7, 2023 9:00 PM EST

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

- 3Q 2023 Total revenues of \$51M; +56% vs. 3Q 2022
- 3Q YTD 2023 Total revenues of \$140M; +121% vs. 3Q YTD 2022
- 3Q 2023 Net income of \$2M; Non-GAAP net income of \$4M
- 3Q 2023 Tyvaso DPI royalties of \$20M; +225% vs. 3Q 2022
- 3Q 2023 Endocrine BU net revenues of \$18M; Afrezza net revenues +24% vs. 3Q 2022

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., Nov. 07, 2023 (GLOBE NEWSWIRE) -- MannKind Corporation (Nasdaq: MNKD) today reported financial results for the quarter ended September 30, 2023.

"We had another strong quarter of revenue growth with total revenues exceeding \$51 million," said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. "With the continued success of Tyvaso DPI[®], we believe we will continue to have the ability to execute our commercial operating plan and fund our pipeline development efforts."

Third Quarter 2023 Results

Revenue Highlights

	Three Months Ended September 30,			
	2023	2022	\$ Change	% Change
	(Dollars in thousands)			
Net revenue – Afrezza	\$ 13,476	\$ 10,831	\$ 2,645	24 %
Net revenue – V-Go	4,451	5,428	\$ (977)	(18 %)
Revenue – collaborations and services	13,108	10,346	\$ 2,762	27 %
Royalties – collaborations	20,218	6,220	\$ 13,998	225 %
Total revenues	\$ 51,253	\$ 32,825	\$ 18,428	56 %

Afrezza[®] net revenue for the third quarter of 2023 increased \$2.6 million, or 24%, compared to the same period in 2022 as a result of higher product demand and higher price. V-Go[®] net revenue for the third quarter of 2023 decreased \$1.0 million, or 18%, compared to the same period in 2022 as a result of lower product demand and an increase in rebates (as a percentage of gross sales). The increase in collaborations and services revenue was primarily attributable to an increase in the sale of semi-finished Tyvaso DPI to UT. Royalties related to Tyvaso DPI for the third quarter of 2023 increased \$14.0 million, or 225%, primarily as a result of an increase in patient demand.

Commercial product gross margin in the third quarter of 2023 was 78% compared to 69% for the same period in 2022, primarily attributable to an increase in Afrezza net revenue and a decrease in cost of goods sold.

Cost of revenue – collaborations and services for the third quarter of 2023 was \$10.3 million compared to \$12.4 million for the same period in 2022, a decrease of \$2.2 million, or 18%, due to an increase in manufacturing activities resulting in more costs being capitalized into inventory, and an increase in labor costs associated with the expansion of our manufacturing capacity for Tyvaso DPI, which were capitalized and subsequently reimbursed by UT.

Research and development ("R&D") expenses for the third quarter of 2023 were \$10.0 million compared to \$4.1 million for the same period in 2022. The \$5.9 million increase was primarily attributed to development activities for MNKD-101 (inhaled clofazimine), an Afrezza post-marketing clinical study (INHALE-3) which commenced in the second quarter of 2023, increased headcount, and increased costs associated with other pipeline products.

Selling expenses was \$13.4 million in the third quarter of 2023 and remained consistent with the same period in 2022 at \$13.5 million.

General and administrative expenses for the third quarter of 2023 were \$10.5 million compared to \$9.1 million for the same period in 2022. The \$1.4 million increase was primarily attributable to an increase in personnel costs, including stock-based compensation and headcount.

Interest income was \$1.6 million for the third quarter of 2023 compared to \$0.7 million for the same period in 2022. The increase was primarily due to higher yields on our marketable securities and money market funds.

Interest expense on notes was \$2.8 million and interest expense on financing liability (related to the sale-leaseback of our Danbury manufacturing facility) was \$2.5 million for the third quarter of 2023 and remained consistent with the same period in 2022.

Nine Months September 30, 2023

Revenue Highlights

	Nine Months Ended September 30,			% Change
	2023	2022	\$ Change	

Net revenue — Afrezza	\$ 39,427	\$ 31,306	\$ 8,121	26 %
Net revenue — V-Go	14,407	7,501	\$ 6,906	92 %
Revenue — collaborations and services	35,705	18,380	\$ 17,325	94 %
Royalties — collaborations	<u>50,951</u>	<u>6,524</u>	\$ 44,427	*
Total revenues	\$ 140,490	\$ 63,711	\$ 76,779	121 %

* Not meaningful

Afrezza net revenue for the nine months ended September 30, 2023 increased \$8.1 million, or 26%, compared to the same period in 2022 primarily as a result of higher product demand and price. V-Go net revenue for the nine months ended September 30, 2023 increased \$6.9 million, compared to the same period in 2022. The increase was a result of nine months of sales in 2023 compared to four months in the prior year as V-Go was acquired in May 2022. Net revenue from collaborations and services for the nine months ended September 30, 2023 increased \$17.3 million as a result of manufacturing revenue being deferred in the prior year period until we began commercial manufacturing in May 2022. Royalties related to Tyvaso DPI, launched in the late second quarter of 2022 by UT, reached \$51.0 million in the nine months ended September 30, 2023 due to an increase in patient demand.

Commercial product gross margin in the nine months ended September 30, 2023 was 73% compared to 69% for the same period in 2022, primarily attributable to an increase in Afrezza sales and a decrease in cost of goods sold.

Cost of revenue – collaborations and services for the nine months ended September 30, 2023 was \$30.0 million and remained consistent with the same period in 2022 as manufacturing activities shifted from preproduction efforts in the first five months of 2022 to full commercial production of Tyvaso DPI thereafter.

R&D expenses for the nine months ended September 30, 2023 were \$22.0 million compared to \$12.6 million for the same period in 2022. The \$9.5 million increase was primarily attributed to development activities for MNKD-101, an Afrezza post-marketing clinical study (INHALE-3) which commenced in the second quarter of 2023, increased headcount, and increased costs associated with other pipeline products.

Selling expenses for the nine months ended September 30, 2023 were \$40.8 million compared to \$42.1 million for the same period in 2022. The \$1.4 million decrease was primarily due to the termination of an Afrezza pilot promotional effort targeting primary care physicians, which ended in the third quarter of 2022, partially offset by increased headcount and promotional activities after the acquisition of V-Go in the second quarter of 2022.

General and administrative expenses for the nine months ended September 30, 2023 were \$33.0 million compared to \$27.2 million for the same period in 2022. The \$5.8 million increase was primarily attributable to personnel costs, including stock-based compensation and headcount.

Interest income was \$4.4 million for the nine months ended September 30, 2023 compared to \$1.6 million for the same period in 2022. The increase was primarily due to higher yields on our marketable securities and money market funds.

Interest expense on notes and milestone rights was \$12.5 million and interest expense on financing liability was \$7.3 million for the nine months ended September 30, 2023 and remained consistent with the same period in 2022.

Gain on available-for-sale securities for the nine months ended September 30, 2023 was \$0.9 million as a result of the change in the fair value of the investment that related to credit risk.

Cash, cash equivalents and investments as of September 30, 2023 were \$144.3 million.

Non-GAAP Measures

To supplement our unaudited condensed consolidated financial statements presented under U.S. generally accepted accounting principles (GAAP), we are presenting non-GAAP income (loss) from operations, non-GAAP net income (loss) and non-GAAP net income (loss) per share, 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 unaudited 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 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 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 tables reconcile our financial measure for income (loss) from operations, net income (loss) and earnings (loss) per share ("EPS") for basic and diluted weighted average shares as reported in our condensed consolidated statement of operations to a non-GAAP presentation as adjusted for the non-cash stock-based compensation expense, non-cash gain on foreign currency transaction and non-cash gain on available-for-sale securities for the periods presented:

	Three Months		Nine Months	
	Ended September 30, 2023	2022	Ended September 30, 2023	2022
	(In thousands except per share data)			
GAAP income (loss) from operations	\$ 5,097	\$ (9,610)	\$ 820	\$ (51,320)
Increase (decrease) for excluded non-cash items:				
Stock compensation	4,601	3,622	13,836	10,850
Gain on foreign currency transaction	(2,065)	(1,799)	(860)	(8,285)
Non-GAAP income (loss) from operations	<u>\$ 7,633</u>	<u>\$ (7,787)</u>	<u>\$ 13,796</u>	<u>\$ (48,755)</u>

GAAP net income (loss)	\$	1,721	\$	(14,432)	\$	(13,339)	\$	(69,453)
Increase (decrease) for excluded non-cash items:								
Stock compensation		4,601		3,622		13,836		10,850
Gain on foreign currency transaction		(2,065)		(1,799)		(860)		(8,285)
Gain on available-for-sale securities		—		—		(932)		—
Non-GAAP net income (loss)	\$	<u>4,257</u>	\$	<u>(12,609)</u>	\$	<u>(1,295)</u>	\$	<u>(66,888)</u>
GAAP net income (loss) per share - basic	\$	0.01	\$	(0.06)	\$	(0.05)	\$	(0.27)
Increase (decrease) for excluded non-cash items:								
Stock compensation		0.02		0.01		0.05		0.04
Gain on foreign currency transaction		(0.01)		(0.01)		0.00		(0.03)
Gain on available-for-sale securities		0.00		0.00		0.00		0.00
Non-GAAP net income (loss) per share - basic	\$	<u>0.02</u>	\$	<u>(0.06)</u>	\$	<u>(0.00)</u>	\$	<u>(0.26)</u>
GAAP net income (loss) per share - diluted	\$	0.01	\$	(0.06)	\$	(0.05)	\$	(0.27)
Increase (decrease) for excluded non-cash items:								
Stock compensation		0.01		0.01		0.05		0.04
Gain on foreign currency transaction		(0.01)		(0.01)		0.00		(0.03)
Gain on available-for-sale securities		0.00		0.00		0.00		0.00
Non-GAAP net income (loss) per share - diluted	\$	<u>0.01</u>	\$	<u>(0.06)</u>	\$	<u>(0.00)</u>	\$	<u>(0.26)</u>
Weighted average shares - basic		268,732		259,300		266,126		254,974
Weighted average shares - diluted		323,770		259,300		266,126		254,974

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 inhaled therapeutic products for patients 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, pulmonary arterial hypertension (PAH) and nontuberculous mycobacterial (NTM) lung disease. 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.

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](#), [Twitter](#) 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 continued success of Tyvaso DPI, the execution of our commercial operating plan and the potential for our revenue from the sales of Tyvaso DPI to fund our pipeline. 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 product commercialization, risks associated with developing product candidates, risks associated with MannKind's ability to manage its existing cash resources or raise additional cash resources, 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, 2022, filed with the SEC on February 23, 2023, and under the “Risk Factors” heading of its Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, 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.

Tyvaso DPI is a trademark of United Therapeutics Corporation.

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

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MANNKIND CORPORATION AND SUBSIDIARY CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

Three Months Ended September 30,		Nine Months Ended September 30,	
2023	2022	2023	2022
(In thousands except per share data)			

Revenues:								
Net revenue – commercial product sales	\$	17,927	\$	16,259	\$	53,834	\$	38,807
Revenue – collaborations and services		13,108		10,346		35,705		18,380
Royalties – collaborations		20,218		6,220		50,951		6,524
Total revenues		<u>51,253</u>		<u>32,825</u>		<u>140,490</u>		<u>63,711</u>
Expenses:								
Cost of goods sold		3,995		5,021		14,749		11,922
Cost of revenue – collaborations and services		10,259		12,439		29,955		29,451
Research and development		9,989		4,136		22,047		12,565
Selling		13,440		13,541		40,752		42,137
General and administrative		10,538		9,097		33,027		27,241
Gain on foreign currency transaction		(2,065)		(1,799)		(860)		(8,285)
Total expenses		<u>46,156</u>		<u>42,435</u>		<u>139,670</u>		<u>115,031</u>
Income (loss) from operations		<u>5,097</u>		<u>(9,610)</u>		<u>820</u>		<u>(51,320)</u>
Other income (expense):								
Interest income, net		1,580		663		4,429		1,556
Interest expense on financing liability		(2,459)		(2,466)		(7,332)		(7,280)
Interest expense		(2,815)		(2,812)		(12,474)		(12,202)
Gain on available-for-sale securities		—		—		932		—
Other income (expense)		318		(207)		286		(207)
Total other expense		<u>(3,376)</u>		<u>(4,822)</u>		<u>(14,159)</u>		<u>(18,133)</u>
Income (loss) before income tax expense		1,721		(14,432)		(13,339)		(69,453)
Benefit from income taxes		—		—		—		—
Net income (loss)	\$	<u>1,721</u>	\$	<u>(14,432)</u>	\$	<u>(13,339)</u>	\$	<u>(69,453)</u>
Net income (loss) per share – basic	\$	<u>0.01</u>	\$	<u>(0.06)</u>	\$	<u>(0.05)</u>	\$	<u>(0.27)</u>
Weighted average shares used to compute net income (loss) per share – basic		<u>268,732</u>		<u>259,300</u>		<u>266,126</u>		<u>254,974</u>
Net income (loss) per share – diluted	\$	<u>0.01</u>	\$	<u>(0.06)</u>	\$	<u>(0.05)</u>	\$	<u>(0.27)</u>
Weighted average shares used to compute net income (loss) per share – diluted		323,770		259,300		266,126		254,974

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

	September 30, 2023	December 31, 2022
	(In thousands except share and per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 83,016	\$ 69,767
Short-term investments	58,000	101,079
Accounts receivable, net	21,822	16,801
Inventory	27,117	21,772
Prepaid expenses and other current assets	<u>35,620</u>	<u>25,477</u>
Total current assets	225,575	234,896
Property and equipment, net	80,411	45,126
Goodwill	1,931	2,428
Other intangible asset	1,093	1,153
Long-term investments	3,271	1,961
Other assets	8,047	9,718
Total assets	<u>\$ 320,328</u>	<u>\$ 295,282</u>

LIABILITIES AND STOCKHOLDERS' DEFICIT

Current liabilities:		
Accounts payable	\$ 16,754	\$ 11,052
Accrued expenses and other current liabilities	32,098	35,553
Financing liability – current	9,747	9,565
Midcap credit facility – current	20,000	—
Deferred revenue – current	3,670	1,733
Recognized loss on purchase commitments – current	<u>14,105</u>	<u>9,393</u>
Total current liabilities	96,374	67,296
Mann Group convertible note	8,829	8,829
Accrued interest – Mann Group convertible note	57	55
Financing liability – long term	94,375	94,512
Midcap credit facility – long term	17,921	39,264

Senior convertible notes	226,487	225,397
Recognized loss on purchase commitments – long term	50,534	62,916
Operating lease liability	4,289	5,343
Deferred revenue – long term	69,469	37,684
Milestone liabilities	3,772	4,524
Total liabilities	<u>572,107</u>	<u>545,820</u>
Stockholders' deficit:		
Undesignated preferred stock, \$0.01 par value – 10,000,000 shares authorized; no shares issued or outstanding as of September 30, 2023 and December 31, 2022	—	—
Common stock, \$0.01 par value – 800,000,000 and 400,000,000 shares authorized as of September 30, 2023 and December 31, 2022, respectively, and 269,543,539 and 263,793,305 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	2,695	2,638
Additional paid-in capital	2,975,891	2,964,293
Accumulated other comprehensive income	443	—
Accumulated deficit	<u>(3,230,808)</u>	<u>(3,217,469)</u>
Total stockholders' deficit	<u>(251,779)</u>	<u>(250,538)</u>
Total liabilities and stockholders' deficit	\$ 320,328	\$ 295,282

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Source: MannKind