



MannKind Corporation Reports 2023 Second Quarter Financial Results

August 7, 2023 8:00 PM EDT

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

- 2Q 2023 Total revenues of \$49M; +157% vs. 2Q 2022
- 2Q 2023 Tyvaso DPI royalties of \$19M; +63% vs. 1Q 2023
- 2Q 2023 Endocrine Business Unit net revenues of \$18M; Afrezza net revenues +27% vs. 2Q 2022
- 2Q 2023 Income from operations of \$2M; Non-GAAP income from operations of \$8M

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

"We are excited to report positive income from operations in the second quarter driven by growing patient demand for Tyvaso DPI[®] and Afrezza as well as manufacturing revenues from Tyvaso DPI," said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. "In addition, we have optimized our commercial operations supporting Afrezza[®] and V-Go[®], which is expected to get our Endocrine Business Unit to profitability starting in 2024."

Second Quarter 2023 Results

Revenue Highlights

	Three Months Ended June 30,			
	2023	2022	\$ Change	% Change
	(Dollars in thousands)			
Net revenue – Afrezza	\$ 13,527	\$ 10,649	\$ 2,878	27 %
Net revenue – V-Go	4,818	2,073	\$ 2,745	*
Revenue – collaborations and services	11,211	5,868	\$ 5,343	91 %
Royalties – collaborations	19,055	304	\$ 18,751	*
Total revenues	\$ 48,611	\$ 18,894	\$ 29,717	157 %

* Not meaningful

Afrezza net revenue for the second quarter of 2023 increased \$2.9 million, or 27%, compared to the same period in 2022 as a result of higher product demand and price. V-Go was acquired in the second quarter of 2022 and achieved \$22.0 million in cumulative net revenues one year post-acquisition, which was at the high end of our forecasted range. The increase in collaborations and services revenue was primarily attributable to revenues associated with the commercial supply agreement (the "CSA") with United Therapeutics ("UT"). In the second quarter of 2022, revenue associated with the CSA was deferred until we began commercial manufacturing and subsequently selling Tyvaso DPI in June 2022. Royalties related to Tyvaso DPI, launched in late second quarter of 2022 by UT, were \$19.0 million in the second quarter of 2023 and continued to grow based on strong patient demand.

Commercial product gross margin in the second quarter of 2023 was 72% compared to 64% for the same period in 2022, primarily attributable to an increase in Afrezza net revenue, which has a higher gross margin than V-Go.

Cost of revenue – collaborations and services for the second quarter of 2023 was \$9.0 million compared to \$8.3 million for the same period in 2022, an increase of \$0.7 million, due to an increase in manufacturing activities for Tyvaso DPI.

Research and development ("R&D") expenses for the second quarter of 2023 were \$6.5 million compared to \$4.9 million for the same period in 2022. The \$1.6 million increase was primarily attributed to development activities for MNKD-101 (inhaled clofazimine) and an Afrezza post-marketing clinical study (INHALE-3), which commenced in the second quarter of 2023.

Selling expenses for the second quarter of 2023 were \$14.0 million compared to \$15.9 million for the same period in 2022. The \$1.9 million decrease was primarily attributable 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 after the acquisition of V-Go in the second quarter of 2022.

General and administrative expenses for the second quarter of 2023 were \$11.9 million compared to \$10.2 million for the same period in 2022. The \$1.8 million increase was primarily attributable to higher stock-based compensation and increased headcount.

Interest income was \$1.5 million for the second quarter of 2023 compared to \$0.5 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 financing liability was \$2.4 million for the second quarter of 2023 and remained consistent with the same period in 2022.

Interest expense was \$6.9 million in the second quarter of 2023 compared to \$6.6 million for the same period in 2022, which remained consistent due to fixed interest rates on notes and consistent recognition of interest expense related to the achievement of Afrezza milestones.

Gain on available-for-sale securities for the second quarter of 2023 was \$0.9 million as a result of the change in the fair value of the investment that

related to credit risk.

First half of 2023

Revenue Highlights

	Six Months Ended June 30,			
	2023	2022	\$ Change	% Change
Net revenue — Afrezza	\$ 25,951	\$ 20,475	\$ 5,476	27 %
Net revenue — V-Go	9,956	2,073	\$ 7,883	*
Revenue — collaborations and services	22,597	8,034	\$ 14,563	181 %
Royalties — collaborations	30,733	304	\$ 30,429	*
Total revenues	\$ 89,237	\$ 30,886	\$ 58,351	189 %

* Not meaningful

Afrezza net revenue for the first half of 2023 increased \$5.5 million, or 27%, compared to the same period in 2022 primarily as a result of higher product demand and price. V-Go was acquired in the second quarter of 2022 and achieved \$22.0 million in net revenues one year post-acquisition, which was at the high end of our forecasted range. The increase in collaborations and services revenue was primarily attributable to the deferral of revenue associated with the CSA until we began commercial manufacturing and subsequently selling Tyvaso DPI in June 2022. Royalties related to Tyvaso DPI, launched in the late second quarter of 2022 by UT, reached \$30.7 million in the first half of 2023 based on strong patient demand.

Commercial product gross margin in the first half of 2023 was 70%, which was consistent with the same period in 2022.

Cost of revenue – collaborations and services for the first half of 2023 was \$19.7 million compared to \$17.0 million for the same period in 2022, an increase of \$2.7 million, due to an increase in manufacturing activities for Tyvaso DPI.

R&D expenses for the first half of 2023 were \$12.1 million compared to \$8.4 million for the same period in 2022. The \$3.6 million increase was primarily attributed to development activities for MNKD-101 and INHALE-3.

Selling expenses for the first half of 2023 were \$27.3 million compared to \$28.6 million for the same period in 2022. The \$1.3 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 expenses after the acquisition of V-Go in the second quarter of 2022.

General and administrative expenses for the first half of 2023 were \$22.5 million compared to \$18.1 million for the same period in 2022. The \$4.3 million increase was primarily attributable to higher stock-based compensation and increased headcount.

Interest income was \$2.8 million for the six months ended June 30, 2023 compared to \$0.9 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 financing liability was \$4.9 million for the first half of 2023 and remained consistent with the same period in 2022.

Interest expense on notes was \$9.7 million in the first half of 2023 compared to \$9.4 million for the same period in 2022, which remained consistent due to fixed interest rates on notes and consistent recognition of interest expense related to the achievement of Afrezza milestones.

Gain on available-for-sale securities for the first half of 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 June 30, 2023 were \$146.6 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 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 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 and non-cash gain (loss) on foreign currency transactions for the periods presented:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(In thousands except per share data)			
GAAP Income (loss) from operations	\$ 1,721	\$ (20,454)	\$ (4,277)	\$ (41,710)
Increase (decrease) for excluded non-cash items:				

Stock compensation	5,580	4,422	9,235	7,228
Loss (gain) on foreign currency transaction	251	(4,503)	1,205	(6,486)
Non-GAAP income (loss) from operations	\$ 7,552	\$ (20,535)	\$ 6,163	\$ (40,968)
GAAP net loss	\$ (5,265)	\$ (29,023)	\$ (15,060)	\$ (55,021)
Increase (decrease) for excluded non-cash items:				
Stock compensation	5,580	4,422	9,235	7,228
Loss (gain) on foreign currency transaction	251	(4,503)	1,205	(6,486)
Gain on available-for-sale securities	(932)	—	(932)	—
Non-GAAP net loss	\$ (366)	\$ (29,104)	\$ (5,552)	\$ (54,279)
GAAP net loss per share - basic and diluted	\$ (0.02)	\$ (0.11)	\$ (0.06)	\$ (0.22)
Increase (decrease) for excluded non-cash items:				
Stock compensation	0.02	0.02	0.03	0.03
Loss (gain) on foreign currency transaction	0.00	(0.02)	0.00	(0.03)
Gain on available-for-sale securities	0.00	0.00	0.00	0.00
Non-GAAP net loss per share - basic and diluted	\$ 0.00	\$ (0.11)	\$ (0.03)	\$ (0.22)
Weighted average shares - basic and diluted	265,626	253,644	264,802	252,775

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 optimization of our commercial operations for Afrezza and V-Go and the potential for our Endocrine Business Unit to reach profitability starting in 2024. 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 June 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(In thousands except per share data)			
Revenues:				
Net revenue – commercial product sales	\$ 18,345	\$ 12,722	\$ 35,907	\$ 22,548
Revenue – collaborations and services	11,211	5,868	22,597	8,034

Royalties – collaborations	19,055	304	30,733	304
Total revenues	<u>48,611</u>	<u>18,894</u>	<u>89,237</u>	<u>30,886</u>
Expenses:				
Cost of goods sold	5,224	4,617	10,754	6,901
Cost of revenue – collaborations and services	9,013	8,298	19,696	17,012
Research and development	6,453	4,893	12,058	8,429
Selling	14,002	15,868	27,312	28,596
General and administrative	11,947	10,175	22,489	18,144
Loss (gain) on foreign currency transaction	251	(4,503)	1,205	(6,486)
Total expenses	<u>46,890</u>	<u>39,348</u>	<u>93,514</u>	<u>72,596</u>
Income (loss) from operations	<u>1,721</u>	<u>(20,454)</u>	<u>(4,277)</u>	<u>(41,710)</u>
Other income (expense):				
Interest income, net	1,547	516	2,849	893
Interest expense on financing liability	(2,449)	(2,443)	(4,873)	(4,814)
Interest expense	(6,873)	(6,642)	(9,659)	(9,390)
Gain on available-for-sale securities	932	—	932	—
Other expense	(143)	—	(32)	—
Total other expense	<u>(6,986)</u>	<u>(8,569)</u>	<u>(10,783)</u>	<u>(13,311)</u>
Loss before income tax expense	<u>(5,265)</u>	<u>(29,023)</u>	<u>(15,060)</u>	<u>(55,021)</u>
Benefit from income taxes	—	—	—	—
Net loss	<u>\$ (5,265)</u>	<u>\$ (29,023)</u>	<u>\$ (15,060)</u>	<u>\$ (55,021)</u>
Net loss per share – basic and diluted	<u>\$ (0.02)</u>	<u>\$ (0.11)</u>	<u>\$ (0.06)</u>	<u>\$ (0.22)</u>
Weighted average shares used to compute net loss per share – basic and diluted	265,626	253,644	264,802	252,775

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

	<u>June 30, 2023</u>	<u>December 31, 2022</u>
	(In thousands except share and per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 86,184	\$ 69,767
Short-term investments	58,163	101,079
Accounts receivable, net	27,789	16,801
Inventory	25,290	21,772
Prepaid expenses and other current assets	<u>32,807</u>	<u>25,477</u>
Total current assets	230,233	234,896
Property and equipment, net	69,510	45,126
Goodwill	1,931	2,428
Other intangible asset	1,113	1,153
Long-term investments	2,282	1,961
Other assets	<u>8,353</u>	<u>9,718</u>
Total assets	<u>\$ 313,422</u>	<u>\$ 295,282</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 17,127	\$ 11,052
Accrued expenses and other current liabilities	36,833	35,553
Financing liability – current	9,686	9,565
Midcap credit facility – current	16,667	—
Deferred revenue – current	3,489	1,733
Recognized loss on purchase commitments – current	<u>13,164</u>	<u>9,393</u>
Total current liabilities	96,966	67,296
Mann Group convertible note	8,829	8,829
Accrued interest – Mann Group convertible note	55	55
Financing liability – long term	94,395	94,512
Midcap credit facility – long term	22,811	39,264
Senior convertible notes	226,124	225,397
Recognized loss on purchase commitments – long term	56,063	62,916
Operating lease liability	4,646	5,343
Deferred revenue – long term	60,248	37,684
Milestone liabilities	<u>3,772</u>	<u>4,524</u>
Total liabilities	<u>573,909</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 June 30, 2023 and December 31, 2022	—	—
Common stock, \$0.01 par value – 800,000,000 and 400,000,000 shares authorized as of June 30, 2023 and December 31, 2022, respectively, and 268,235,145 and 263,793,305 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	2,682	2,638
Additional paid-in capital	2,968,917	2,964,293
Accumulated other comprehensive income	443	—
Accumulated deficit	<u>(3,232,529)</u>	<u>(3,217,469)</u>
Total stockholders' deficit	<u>(260,487)</u>	<u>(250,538)</u>
Total liabilities and stockholders' deficit	\$ 313,422	\$ 295,282

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Source: MannKind