



MannKind Corporation Reports 2022 Fourth Quarter and Full Year Financial Results

02/23/23

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

- 2022 Total Revenues of \$100 million; +32% vs. 2021
- 2022 Royalties from Tyvaso DPI of \$16 million; 4Q 2022 of \$9 million
- 4Q 2022 Commercial Products Net Revenue of \$17 million; +54% vs. 4Q 2021
- \$173 million of Cash and Cash Equivalents and Investments at December 31, 2022

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., Feb. 23, 2023 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)** today reported financial results for the fourth quarter and full year ended December 31, 2022.

“For 2022, we recognized almost \$100 million in total revenues – an incredible triumph for our entire organization,” said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. “With our revenues growing nicely, we are focusing on our product pipeline where our INHALE-1 Phase 3 trial for Afrezza in pediatrics reached 50% enrollment at December 31, 2022 and our inhaled clofazimine will move into an adaptive Phase 2/3 study in the second half of 2023.”

Fourth Quarter 2022 Results

Revenue Highlights

	For the Three Months Ended December 31,			
	2022	2021	\$ Change	% Change
Net revenue — Afrezza	\$ 12,006	\$ 11,340	\$ 666	6 %
Net revenue — V-Go	5,434	—	\$ 5,434	*
Revenue — collaborations and services	9,544	1,175	\$ 8,369	712 %
Royalties — collaborations	9,075	—	\$ 9,075	*
Total revenues	\$ 36,059	\$ 12,515	\$ 23,544	188 %

* Not meaningful

The increase in Afrezza[®] net revenue was mainly a result of higher demand. V-Go was acquired in the second quarter of 2022. The increase in collaborations and services revenue reflected the fact that the manufacture of Tyvaso[®] DPI for commercial sale had not yet commenced in the previous period. Royalties from United Therapeutics (“UT”) for Tyvaso DPI continued to grow based on strong patient demand.

Afrezza gross margin in the fourth quarter of 2022 was 92% compared to 62% for the same period in 2021, mainly due to a decrease in cost of goods sold driven by lower inventory write offs, lower cost of production per unit and a higher amount of manufacturing activity in 2022 (which absorbed more cost to inventory). V-Go[®] gross margin was 42% for the fourth quarter of 2022.

Cost of revenue – collaborations and services for the fourth quarter of 2022 was \$12.0 million compared to \$7.1 million for the same period in 2021, an increase of \$4.9 million, primarily due to an increase in manufacturing activities associated with the production of Tyvaso DPI.

Research and development (“R&D”) expenses for the fourth quarter of 2022 were \$7.2 million compared to \$3.9 million for the same period in 2021. This \$3.3 million increase was primarily attributed to costs incurred to develop our product pipeline, including the Afrezza pediatrics clinical study (INHALE-1) and MNKD-101 (inhaled clofazimine).

Selling expenses for the fourth quarter of 2022 were \$11.6 million compared to \$13.5 million for the same period in 2021. This \$1.9 million decrease was primarily attributable to the net impact of lower personnel-related costs associated with the first quarter of 2022 Afrezza sales force restructuring, and a pilot promotional effort aimed at primary care physicians that began in the fourth quarter of 2021 and ended in the third quarter of 2022, partially offset by V-Go promotional efforts.

General and administrative (“G&A”) expenses for the fourth quarter of 2022 were \$10.5 million compared to \$9.2 million for the same period in 2021. This \$1.3 million increase was primarily attributable to higher stock-based compensation and increased headcount.

Interest expense on financing liability was \$2.5 million for the fourth quarter of 2022 and represented interest incurred on the sale

lease-back transaction for our manufacturing facility in Danbury, CT, which was entered into in the fourth quarter of 2021.

Interest expense on notes was flat in the fourth quarter of 2022 compared to the same period in 2021 due to fixed interest rates and no changes in debt balances.

Year Ended December 31, 2022

Revenue Highlights

	For the Year Ended December 31,			
	2022	2021	\$ Change	% Change
Net revenue — Afrezza	\$ 43,316	\$ 39,168	\$ 4,148	11 %
Net revenue — V-Go	12,931	—	\$ 12,931	*
Revenue — collaborations and services	27,924	36,274	\$ (8,350)	(23 %)
Royalties — collaborations	15,599	—	\$ 15,599	*
Total revenues	\$ 99,770	\$ 75,442	\$ 24,328	32 %

* Not meaningful

Afrezza net revenue increased year-over-year primarily due to higher price (including a more favorable gross-to-net adjustment), higher product demand, and a more favorable cartridge mix. Collaborations and services revenue decreased, primarily due to the completion of the R&D services associated with our collaboration with UT, which was partially offset by revenues associated with the manufacturing of Tyvaso DPI. As of December 31, 2022, \$37.9 million of manufacturing revenue associated with Tyvaso DPI remains deferred and will be recognized as commercial product is sold to UT.

Afrezza gross margin for 2022 was 80% compared to 57% for the same period in 2021, driven primarily by a decrease in excess manufacturing capacity costs (as Tyvaso DPI was in commercial production in 2022), a decrease in inventory write offs and an amendment fee associated with our Insulin Supply Agreement in 2021. V-Go gross margin was 43% for 2022.

Cost of revenue – collaborations and services for 2022 was \$41.5 million compared to \$22.0 million for the same period in 2021, an increase of \$19.5 million, primarily due to an increase in manufacturing activities for the production of Tyvaso DPI.

R&D expenses for 2022 were \$19.7 million compared to \$12.3 million for the prior year. This \$7.4 million increase was primarily attributable to costs incurred to develop our product pipeline, including INHALE-1 and MNKD-101.

Selling expenses for 2022 were \$53.8 million compared to \$45.5 million for the prior year. This \$8.3 million increase was primarily attributable to the primary care pilot program, elimination of the Thyquidity co-promotion (which permitted some expenses associated with the sales force to be recognized as cost of revenue for collaborations and services in the same period of 2021), V-Go promotional efforts after the acquisition in the second quarter of 2022, and partially offset by the net favorable impact of personnel-related costs associated with the Afrezza sales force restructuring in 2022.

G&A expenses for 2022 were \$37.7 million compared to \$31.9 million for the prior year. This \$5.8 million increase was primarily attributable to higher stock-based compensation, increased headcount, and higher professional fees.

Interest expense on the financing liability was \$9.8 million for 2022 and represented interest incurred on the sale lease-back transaction for our manufacturing facility in Danbury, CT.

Interest expense on notes was flat for 2022 compared to 2021 due to fixed interest rates and no changes in debt balances.

Cash and cash equivalents and investments as of December 31, 2022 were \$172.8 million.

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 MannKind's revenue growth and pipeline advancement, including the planned adaptive Phase 2/3 study. 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 these 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, as filed with the SEC on November 8, 2022, and under the "Risk Factors" heading of its Annual Report on Form 10-K for the year ended December 31, 2022, being filed with the SEC on February 23, 2023. 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 CONSOLIDATED BALANCE SHEETS

	December 31,	
	2022	2021
	(In thousands except share and per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 69,767	\$ 124,184
Short-term investments	101,079	79,932
Accounts receivable, net	16,801	4,739
Inventory	21,772	7,152
Prepaid expenses and other current assets	25,477	3,482
Total current assets	234,896	219,489
Property and equipment, net	45,126	36,612
Goodwill	2,428	—
Other intangible asset	1,153	—
Long-term investments	1,961	56,619
Other assets	9,718	8,441
Total assets	\$ 295,282	\$ 321,161
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 11,052	\$ 6,956
Accrued expenses and other current liabilities	35,553	27,419
Financing liability — current	9,565	6,977
Deferred revenue — current	1,733	827
Recognized loss on purchase commitments — current	9,393	6,170

Total current liabilities	67,296	48,349
Promissory notes	8,829	18,425
Accrued interest — promissory notes	55	404
Financing liability — long term	94,512	93,525
Midcap credit facility	39,264	38,833
Senior convertible notes	225,397	223,944
Recognized loss on purchase commitments — long term	62,916	76,659
Operating lease liability	5,343	1,040
Deferred revenue — long term	37,684	19,543
Milestone liabilities	4,524	4,838
Deposits from customer	—	4,950
Total liabilities	<u>545,820</u>	<u>530,510</u>
Stockholders' deficit:		
Undesignated preferred stock, \$0.01 par value — 10,000,000 shares authorized; no shares issued or outstanding at December 31, 2022 and 2021	—	—
Common stock, \$0.01 par value — 400,000,000 shares authorized, 263,793,305 and 251,477,562 shares issued and outstanding at December 31, 2022 and 2021, respectively	2,638	2,515
Additional paid-in capital	2,964,293	2,918,205
Accumulated deficit	<u>(3,217,469)</u>	<u>(3,130,069)</u>
Total stockholders' deficit	<u>(250,538)</u>	<u>(209,349)</u>
Total liabilities and stockholders' deficit	<u>\$ 295,282</u>	<u>\$ 321,161</u>

**MANKIND CORPORATION AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS**

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
	(In thousands except per share data)			
Revenues:				
Net revenue — commercial product sales	\$ 17,440	\$ 11,340	\$ 56,247	\$ 39,168
Revenue — collaborations and services	9,544	1,175	27,924	36,274
Royalties — collaborations	9,075	—	15,599	—
Total revenues	<u>36,059</u>	<u>12,515</u>	<u>99,770</u>	<u>75,442</u>
Expenses:				
Cost of goods sold	4,081	4,295	16,003	16,833
Cost of revenue — collaborations and services	12,043	7,139	41,494	22,024
Research and development	7,156	3,886	19,721	12,312
Selling	11,616	13,536	53,753	45,528
General and administrative	10,479	9,191	37,720	31,889
Asset impairment	—	—	—	106
Loss (gain) on foreign currency translation	3,474	(1,564)	(4,811)	(6,567)
Loss on purchase commitments	—	—	—	339
Total expenses	<u>48,849</u>	<u>36,483</u>	<u>163,880</u>	<u>122,464</u>
Loss from operations	<u>(12,790)</u>	<u>(23,968)</u>	<u>(64,110)</u>	<u>(47,022)</u>
Other (expense) income:				
Interest income, net	957	48	2,513	112
Interest expense on financing liability	(2,478)	(1,373)	(9,758)	(1,373)
Interest expense on notes	(2,809)	(2,769)	(15,011)	(15,204)
Loss on available-for-sale securities	(932)	—	(932)	—
Loss on extinguishment of debt	—	—	—	(17,200)
Other income (expense)	105	1	(102)	(239)
Total other expense	<u>(5,157)</u>	<u>(4,093)</u>	<u>(23,290)</u>	<u>(33,904)</u>

Loss before income tax expense	(17,947)	(28,061)	(87,400)	(80,926)
Provision for income taxes	—	—	—	—
Net loss	<u>\$ (17,947)</u>	<u>\$ (28,061)</u>	<u>\$ (87,400)</u>	<u>\$ (80,926)</u>
Net loss per share — basic and diluted	<u>\$ (0.07)</u>	<u>\$ (0.11)</u>	<u>\$ (0.34)</u>	<u>\$ (0.32)</u>
Shares used to compute net loss per share — basic and diluted	263,378	251,083	257,092	249,244

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Source: MannKind