

CORRECTION -- MannKind Corporation Reports 2023 First Quarter Financial Results

May 10, 2023 12:21 AM EDT

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

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., May 09, 2023 (GLOBE NEWSWIRE) -- In a release issued under the same headline earlier today by MannKind Corporation (Nasdaq: MKND), please note in the second table, titled "CONDENSED CONSOLIDATED BALANCE SHEETS", the right column header was incorrectly labeled as "March 31, 2022", when it should be labeled "December 31, 2022". The corrected release follows:

- 1Q 2023 Total Revenues of \$41 million; +239% vs. 1Q 2022
- 1Q 2023 Revenues associated with Tyvaso DPI of \$23 million
- 1Q 2023 Loss from operations decreased 72% vs. 1Q 2022 to \$6 million
- \$167 million of Cash, Cash Equivalents and Investments at March 31, 2023

MannKind Corporation (Nasdaq: MNKD) today reported financial results for the quarter ended March 31, 2023.

"Demand for Tyvaso DPI [®] has been very strong, which resulted in \$23 million in revenues in the first quarter of 2023," said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. "I'm excited about our inhaled platform and orphan lung pipeline as we get ready to launch our Phase 2/3 inhaled clofazimine trial for patients in the second half of 2023."

Revenue Highlights

	Three Months Ended March 31,						
		2023		2022		\$ Change	% Change
		(Dollars in thousands)					
Net revenue – Afrezza	\$	12,423	\$	9,826	\$	2,597	26 %
Net revenue – V-Go		5,139		_	\$	5,139	*
Revenue – collaborations and services		11,386		2,166	\$	9,220	426 %
Royalties – collaborations		11,678		_	\$	11,678	*
Total revenues	\$	40,626	\$	11,992	\$	28,634	239 %

^{*} Not meaningful

Afrezza[®] net revenue for the first quarter of 2023 increased compared to the same period in 2022 as a result of higher product demand, higher price (including a more favorable gross-to-net adjustment) and a more favorable cartridge mix. V-Go[®] was acquired in the second quarter of 2022. The increase in collaborations and services revenue reflected that the commercial manufacturing of Tyvaso DPI had not yet commenced in the prior period. Royalties related to Tyvaso DPI, launched in the second quarter of 2022 by United Therapeutics ("UT"), continued to grow based on strong patient demand.

Commercial product gross margin in the first quarter of 2023 was 69% compared to 77% for the same period in 2022 primarily related to the addition of V-Go in the second quarter of 2022 which had a lower gross margin than Afrezza.

Cost of revenue – collaborations and services for the first quarter of 2023 was \$10.7 million compared to \$8.7 million for the same period in 2022, an increase of \$2.0 million, due to an increase in manufacturing activities for Tyvaso DPI.

Research and development expenses for the first quarter of 2023 were \$5.6 million compared to \$3.5 million for the same period in 2022. The \$2.1 million increase was primarily attributed to costs incurred to develop our product pipeline, including MNKD-101 (inhaled clofazimine) and the Afrezza pediatrics clinical study (INHALE-1).

Selling expenses for the first quarter of 2023 were \$13.3 million compared to \$12.7 million for the same period in 2022. The \$0.6 million increase was primarily due to V-Go promotional efforts and increased headcount after the acquisition in the second quarter of 2022 as well as an increase in Afrezza promotional activities, partially offset by the termination of an Afrezza pilot promotional effort targeting primary care physicians which ended in the third quarter of 2022.

General and administrative expenses for the first quarter of 2023 were \$10.5 million compared to \$7.9 million for the same period in 2022. The \$2.6 million increase was primarily attributable to higher stock-based compensation, increased headcount, and higher professional fees.

Interest expense on financing liability was \$2.4 million for the first quarter of 2023 and remained consistent with the same period in 2022.

Interest expense on notes was \$2.8 million in the first quarter of 2023 and remained consistent with the same period in 2022 due to fixed interest rates and no changes in debt balances.

Cash, cash equivalents and investments as of March 31, 2023 were \$166.6 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 pipeline advancement, including the planned launch of MannKind's inhaled clofazimine trial for patients in the second half of 2023. 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 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 March 31, 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 March 31,					
	2023			2022		
	(In thousands except per share data)					
Revenues:	•	47.500	•	0.000		
Net revenue – commercial product sales	\$	17,562	\$	9,826		
Revenue – collaborations and services		11,386		2,166		
Royalties – collaborations		11,678				
Total revenues		40,626		11,992		
Expenses:						
Cost of goods sold		5,530		2,284		
Cost of revenue – collaborations and services		10,683		8,714		
Research and development		5,605		3,536		
Selling		13,310		12,728		
General and administrative		10,542		7,969		
Loss (gain) on foreign currency transaction		954		(1,983)		
Total expenses		46,624		33,248		
Loss from operations		(5,998)		(21,256)		
Other (expense) income:						
Interest income, net		1,302		377		
Interest expense on financing liability		(2,424)		(2,371)		
Interest expense on notes		(2,786)		(2,748)		
Other income		111				
Total other expense		(3,797)		(4,742)		
Loss before income tax expense		(9,795)		(25,998)		
Benefit from income taxes		_		_		
Net loss	\$	(9,795)	\$	(25,998)		
Net loss per share – basic and diluted	\$	(0.04)	\$	(0.10)		

MANNKIND CORPORATION AND SUBSIDIARY CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31,	D	December 31, 2022 except share and are data)	
	2023			
	(In thousand	s exce		
ASSETS				
Current assets:				
Cash and cash equivalents	\$ 85,86	9 \$	69,767	
Short-term investments	80,27	3	101,079	
Accounts receivable, net	19,71	4	16,801	
Inventory	21,99	8	21,772	
Prepaid expenses and other current assets	15,44	5	25,477	
Total current assets	223,29	9	234,896	
Property and equipment, net	54,83	7	45,126	
Goodwill	1,99	8	2,428	
Other intangible asset	1,13	3	1,153	
Long-term investments	49		1,961	
Other assets	16,37	8	9,718	
Total assets	\$ 298,13		295,282	
LIABILITIES AND STOCKHOLDERS' DEFICIT				
Current liabilities:				
Accounts payable	\$ 13,88	9 \$	11,052	
Accrued expenses and other current liabilities	32,99		35,553	
Financing liability – current	9,62		9,565	
Midcap credit facility – current	11,66			
Deferred revenue – current	2,31		1,733	
Recognized loss on purchase commitments – current	11,36		9,393	
Total current liabilities	81,85		67,296	
Mann Group convertible note	8,82		8,829	
Accrued interest – Mann Group convertible note	•	4	55	
·			94,512	
Financing liability – long term	94,44			
Midcap credit facility	27,70		39,264	
Senior convertible notes	225,76		225,397	
Recognized loss on purchase commitments – long term	59,82		62,916	
Operating lease liability	4,87		5,343	
Deferred revenue – long term	45,65		37,684	
Milestone liabilities	4,52	4	4,524	
Deposits from customer		- -		
Total liabilities	553,53	<u>3</u>	545,820	
Stockholders' deficit:				
Undesignated preferred stock, \$0.01 par value – 10,000,000 shares authorized; no shares issued or outstanding as of March 31, 2023 and December 31, 2022		_	_	
Common stock, \$0.01 par value – 400,000,000 shares authorized, 264,278,760 and 263,793,305 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	2.64	.3	2,638	
Additional paid-in capital	2,04 2,969,22		2,964,293	
Accumulated deficit				
	(3,227,26		(3,217,469)	
Total stockholders' deficit	(255,39		(250,538)	
Total liabilities and stockholders' deficit	\$ 298,13	7 \$	295,282	



Source: MannKind