

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 09, 2023

MannKind Corporation

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

000-50865
(Commission File Number)

13-3607736
(IRS Employer
Identification No.)

1 Casper Street
Danbury, Connecticut
(Address of Principal Executive Offices)

06810
(Zip Code)

Registrant's Telephone Number, Including Area Code: (818) 661-5000

N/A

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.01 per share	MNKD	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

On May 9, 2023, MannKind Corporation issued a press release, a copy of which is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

Exhibit 99.1 [Press release dated May 9, 2023](#)

Exhibit 104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MannKind Corporation

Date: May 9, 2023

By: /s/ David Thomson, Ph.D., J.D.

David Thomson, Ph.D., J.D.

Corporate Vice President, General Counsel and Secretary

**MANNKIND CORPORATION REPORTS
2023 FIRST QUARTER FINANCIAL RESULTS**

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

- 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

DANBURY, Conn. and WESTLAKE VILLAGE, Calif. May 9, 2023 (Globe Newswire) — **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	<u>\$ 40,626</u>	<u>\$ 11,992</u>	\$ 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.

###

MannKind Contact:

Rose Alinaya, Investor Relations

(818) 661-5000

IR@mannkindcorp.com

MANKIND CORPORATION AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended March 31,	
	2023	2022
(In thousands except per share data)		
Revenues:		
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)
Shares used to compute net loss per share – basic and diluted	263,969	251,887

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

	March 31,	
	2023	2022
(In thousands except share and per share data)		
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 85,869	\$ 69,767
Short-term investments	80,273	101,079
Accounts receivable, net	19,714	16,801
Inventory	21,998	21,772
Prepaid expenses and other current assets	15,445	25,477
Total current assets	223,299	234,896
Property and equipment, net	54,837	45,126
Goodwill	1,998	2,428
Other intangible asset	1,133	1,153
Long-term investments	492	1,961
Other assets	16,378	9,718
Total assets	\$ 298,137	\$ 295,282
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 13,889	\$ 11,052
Accrued expenses and other current liabilities	32,995	35,553
Financing liability – current	9,626	9,565
Midcap credit facility – current	11,667	—
Deferred revenue – current	2,316	1,733
Recognized loss on purchase commitments – current	11,360	9,393
Total current liabilities	81,853	67,296
Mann Group convertible note	8,829	8,829
Accrued interest – Mann Group convertible note	54	55
Financing liability – long term	94,441	94,512
Midcap credit facility	27,704	39,264
Senior convertible notes	225,761	225,397
Recognized loss on purchase commitments – long term	59,829	62,916
Operating lease liability	4,879	5,343
Deferred revenue – long term	45,659	37,684
Milestone liabilities	4,524	4,524
Deposits from customer	—	—
Total liabilities	553,533	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	2,643	2,638
Additional paid-in capital	2,969,225	2,964,293
Accumulated deficit	(3,227,264)	(3,217,469)
Total stockholders' deficit	(255,396)	(250,538)
Total liabilities and stockholders' deficit	\$ 298,137	\$ 295,282

