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): February 27, 2024

MannKind Corporation

(Exact name of Registrant as Specified in Its Charter)

Delaware	**000-50865**	**13-3607736**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
1 Casper Street Danbury, Connecticut		**06810**
(Address of Principal Executive Offices)		**(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 February 27, 2024, 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 February 27, 2024
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: February 27, 2024

By: /s/ David Thomson, Ph.D., J.D.
David Thomson, Ph.D., J.D.
Corporate Vice President, General Counsel and Secretary

mannkind

EXHIBIT 99.1

MANNKIND CORPORATION REPORTS 2023 FOURTH QUARTER AND FULL YEAR FINANCIAL RESULTS: PROVIDES CLINICAL DEVELOPMENT UPDATE

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

- *2023 Total revenues of $199M; +99% vs. 2022*
- *4Q 2023 Total revenues of $58M; +62% vs. 2022*
- *4Q 2023 Net income of $1M; Non-GAAP net income of $7M*
- *$302M of cash and cash equivalents and investments at December 31, 2023*

DANBURY, Conn. and WESTLAKE VILLAGE, Calif. February 27, 2024 (Globe Newswire) **— MannKind Corporation (Nasdaq: MNKD)** today reported financial results for the quarter and full year ended December 31, 2023.

“We doubled our total revenues to nearly $200 million in 2023 and ended the year with a robust fourth quarter total revenue of $58 million,” said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. "With our strong year-end cash position of over $300 million, we are well positioned to capitalize on upcoming data read-outs for Afrezza and move MNKD-101 (clofazimine inhalation suspension) into phase 3 and MNKD-201 (nintedanib DPI) into phase 1 in the first half of 2024."

Fourth Quarter 2023 Results

Revenue Highlights

	Three Months Ended December 31,			
	2023	2022	$ Change	% Change
	(Dollars in thousands)			
Net revenue – Afrezza	$ 15,487	$ 12,006	$ 3,481	29 %
Net revenue – V-Go	4,708	5,434	$ (726)	(13 %)
Revenue – collaborations and services	17,249	9,544	$ 7,705	81 %
Royalties – collaborations	21,028	9,075	$ 11,953	132 %
Total revenues	$ 58,472	$ 36,059	$ 22,413	62 %

Afrezza® net revenue for the fourth quarter of 2023 increased $3.5 million, or 29%, compared to the same period in 2022 as a result of higher product demand and higher price (including a decrease in gross-to-net adjustments as a percentage of gross sales). V-Go® net revenue for the fourth quarter of 2023 decreased $0.7 million, or 13%, 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). Collaborations and services revenue increased $7.7 million, or 81%, compared to the same period in 2022 primarily attributable to an increase in manufacturing Tyvaso DPI for United Therapeutics ("UT"). Royalties related to Tyvaso DPI for the fourth quarter of 2023 increased $12.0 million, or 132%, primarily as a result of increased patient demand.

Commercial product gross margin in the fourth quarter of 2023 was 70% compared to 77% for the same period in 2022. The decrease in gross margin was primarily attributable to an increase in cost of goods sold for Afrezza due to the timing of the capitalization of costs to inventory and lower net revenue for V-Go.

Cost of revenue – collaborations and services was $12.0 million for the fourth quarter of 2023 and remained consistent with the same period in 2022. Higher manufacturing volumes resulted in efficiencies which contributed to a lower effective cost per unit.

Research and development ("R&D") expenses for the fourth quarter of 2023 were $9.2 million compared to $7.2 million for the same period in 2022. The $2.1 million increase was primarily attributed to increased development activities for INHALE-3 which commenced in the second quarter of 2023, INHALE-1 and other research and development activities, partially offset by a decrease in development activities for MNKD-101 due to the completion of a toxicology study in 2022.

Selling expenses were $11.0 million in the fourth quarter of 2023 compared to $11.6 million for the same period in 2022. The $0.6 million decrease was primarily due to lower promotional activities.

General and administrative expenses for the fourth quarter of 2023 were $9.5 million compared to $10.5 million for the same period in 2022. The $1.0 million decrease was primarily attributable to a decrease in personnel and consulting costs.

Interest income was $1.7 million for the fourth quarter of 2023 compared to $1.0 million for the same period in 2022. The $0.8 million increase was primarily due to higher yields on our marketable securities and money market funds.

Interest expense on notes was $2.5 million and interest expense on financing liability (related to the sale-leaseback of our Danbury manufacturing facility) was $2.7 million for the fourth quarter of 2023 and remained consistent with the same period in 2022.

Loss on available-for-sale securities for the fourth quarter of 2023 was $1.1 million as a result of the change in fair value of the investment which related to credit risk.

Year Ended December 31, 2023

Revenue Highlights

	Year Ended December 31,			
	2023	2022	$ Change	% Change
	(Dollars in thousands)			
Net revenue – Afrezza	$ 54,914	$ 43,316	$ 11,598	27%
Net revenue – V-Go	19,115	12,931	$ 6,184	48%
Revenue – collaborations and services	52,954	27,924	$ 25,030	90%
Royalties – collaborations	71,979	15,599	$ 56,380	*
Total revenues	$ 198,962	$ 99,770	$ 99,192	99%

* Not meaningful

Afrezza net revenue for the year ended December 31, 2023 increased $11.6 million, or 27%, compared to the same period in 2022 primarily as a result of higher product demand and price (including a decrease in gross-to-net adjustments as a percentage of gross sales). V-Go net revenue for the year ended December 31, 2023 increased $6.2 million, compared to the same period in 2022. The increase reflects a full year of sales in 2023 compared to seven months in 2022 after V-Go was acquired in May of that year. Net revenue from collaborations and services for the year ended December 31, 2023 increased $25.0 million, or 90%, primarily as a result of an increase in manufacturing Tyvaso DPI for UT and the deferral of manufacturing revenue 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 $72.0 million for the year ended December 31, 2023, reflecting a full year of sales and increasing patient demand over the period.

Commercial product gross margin was 72% for the year ended December 31, 2023 and remained consistent with the same period in 2022.

Cost of revenue – collaborations and services for the year ended December 31, 2023 was $41.9 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. Higher manufacturing volumes resulted in efficiencies which contributed to a lower effective cost per unit.

R&D expenses for the year ended December 31, 2023 were $31.3 million compared to $19.7 million for the same period in 2022. The $11.6 million increase was primarily attributed to increases in development activities for MNKD-101, costs for INHALE-3, which commenced in the second quarter of 2023, costs for INHALE-1 and other research and development activities.

Selling expenses for the year ended December 31, 2023 were $51.8 million compared to $53.8 million for the same period in 2022. The $2.0 million decrease was primarily due to the termination of an Afrezza pilot promotional effort with a contract sales force targeting primary care physicians, which ended in the third quarter of 2022, partially offset by increased personnel and promotional activities related to the acquisition of V-Go in the second quarter of 2022.

General and administrative expenses for the year ended December 31, 2023 were $42.5 million compared to $37.7 million for the same period in 2022. The $4.8 million increase was primarily attributable to increased personnel and consulting costs, including stock-based compensation and headcount.

Interest income was $6.2 million for the year ended December 31, 2023 compared to $2.5 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 notes and milestone rights was $15.2 million and interest expense on financing liability was $9.8 million for the year ended December 31, 2023 and remained consistent with the same period in 2022.

Loss on available-for-sale securities for the year ended December 31, 2023 was $0.2 million as a result of the change in the fair value of the investment which related to credit risk.

Cash, cash equivalents and investments as of December 31, 2023 were $302.3 million.

Non-GAAP Measures

To supplement our 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 - basic, 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 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 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 table reconciles our financial measure for income (loss) from operations, net income (loss) and net income (loss) per share ("EPS") for basic and diluted weighted average shares as reported in our consolidated statement of operations to a non-GAAP presentation as adjusted for select non-cash items: 1% royalty on net revenues for Tyvaso DPI ("Sold portion of royalty revenue") and interest expense on the related liability, stock-based compensation expense, gain on foreign currency transaction and gain on available-for-sale securities for the periods presented (in thousands, except per share amounts):

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
	(In thousands except per share data)			
GAAP income (loss) from operations	$ 7,858	$ (12,790)	$ 8,678	$ (64,110)
Select non-cash adjustments:				
Sold portion of royalty revenue [1]	(2,103)	—	(2,103)	—
Stock compensation	3,786	2,597	17,649	13,447
Loss (gain) on foreign currency transaction	2,776	3,474	1,916	(4,811)
Non-GAAP income (loss) from operations	$ 12,317	$ (6,719)	$ 26,140	$ (55,474)
GAAP net income (loss)	$ 1,401	$ (17,947)	$ (11,938)	$ (87,400)
Select non-cash adjustments:				
Sold portion of royalty revenue [1]	(2,103)	—	(2,103)	—
Stock compensation	3,786	2,597	17,649	13,447
Loss (gain) on foreign currency transaction	2,776	3,474	1,916	(4,811)
Interest expense on liability for sale of future royalties	185	—	185	—
Loss on available-for-sale securities	1,102	932	170	932
Non-GAAP net income (loss)	$ 7,147	$ (10,944)	$ 5,879	$ (77,832)
GAAP net income (loss) per share - basic	$ 0.01	$ (0.07)	$ (0.04)	$ (0.34)
Select non-cash adjustments:				
Sold portion of royalty revenue	(0.01)	0.00	(0.01)	0.00
Stock compensation	0.01	0.01	0.07	0.05
Loss (gain) on foreign currency transaction	0.01	0.01	0.01	(0.02)
Interest expense on liability for sale of future royalties	0.00	0.00	0.00	0.00
Loss on available-for-sale securities	0.00	0.00	0.00	0.00
Non-GAAP net income (loss) per share - basic	$ 0.02	$ (0.05)	$ 0.03	$ (0.31)
Weighted average shares - basic	269,648	263,378	267,014	257,092

(1) Represents the non-cash portion of the 1% royalty on net sales of Tyvaso DPI earned during 4Q 2023 which is remitted to the royalty purchaser and recognized as royalties from collaborations in our consolidated statements of operations. Our revenues from royalties from collaborations during 4Q 2023 totaled $21.0 million, of which $2.1 million will be remitted to the royalty purchaser.

Clinical Development Update

Afrezza INHALE-1 (pediatric phase 3 clinical trial)

- Enrollment completed in February 2024
- Upcoming expected data read-outs:
  - Primary endpoint analysis in 4Q 2024
  - Full results in 1H 2025
  - FDA submission for label expansion expected in 2025

Afrezza INHALE-3 (T1DM, Afrezza vs. standard of care including AID pumps; phase 4 clinical trial)

- Enrollment completed ahead of schedule in 4Q 2023
- Upcoming expected data read-outs:
  - First meal dosing – ATTD oral presentation in March 2024
  - 17-week top-line data/primary endpoints to be presented at ADA in June 2024
  - Additional data to be presented at ADCES August conference

MNKD-101 (clofazimine inhalation suspension)

- Phase 3 development program aligned with the FDA – IND expected to be filed in 1Q 2024
- Co-primary endpoints of sputum conversion and patient-reported outcomes
- Up to 100 global sites, first patient expected to enroll in 2Q 2024

MNKD-201 (nintedanib DPI)

- Phase 1 development program in healthy volunteers, expected to dose first patient in 2Q 2024
- Results expected in late 2024

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 commencement of clinical studies of MNKD-101 and MNKD-201, FDA submissions and the data read-outs from clinical studies of Afrezza and MNKD-201. 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 developing product candidates, 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, 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.

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MANNKIND CORPORATION AND SUBSIDIARY
CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
	(In thousands except per share data)			
Revenues:				
Net revenue – commercial product sales	$ 20,195	$ 17,440	$ 74,029	$ 56,247
Revenue – collaborations and services	17,249	9,544	52,954	27,924
Royalties – collaborations	21,028	9,075	71,979	15,599
Total revenues	58,472	36,059	198,962	99,770
Expenses:				
Cost of goods sold	6,114	4,081	20,863	16,003
Cost of revenue – collaborations and services	11,953	12,043	41,908	41,494
Research and development	9,236	7,156	31,283	19,721
Selling	11,024	11,616	51,776	53,753
General and administrative	9,511	10,479	42,538	37,720
Loss (gain) on foreign currency transaction	2,776	3,474	1,916	(4,811)
Total expenses	50,614	48,849	190,284	163,880
Income (loss) from operations	7,858	(12,790)	8,678	(64,110)
Other income (expense):				
Interest income, net	1,725	957	6,154	2,513
Interest expense on financing liability	(2,493)	(2,478)	(9,825)	(9,758)
Interest expense	(2,677)	(2,809)	(15,151)	(15,011)
Interest expense on liability for sale of future royalties	(185)	—	(185)	—
Loss on available-for-sale securities	(1,102)	(932)	(170)	(932)
Other income (expense)	(164)	105	122	(102)
Total other expense	(4,896)	(5,157)	(19,055)	(23,290)
Income (loss) before income tax expense	2,962	(17,947)	(10,377)	(87,400)
Income tax expense	(1,561)	—	(1,561)	—
Net income (loss)	$ 1,401	$ (17,947)	$ (11,938)	$ (87,400)
Net income (loss) per share – basic	$ 0.01	$ (0.07)	$ (0.04)	$ (0.34)
Weighted average shares used to compute net income (loss) per share – basic	269,648	263,378	267,014	257,092
Net income (loss) per share – diluted	$ 0.00	$ (0.07)	$ (0.04)	$ (0.34)
Weighted average shares used to compute net income (loss) per share – diluted	323,880	(1) 263,378	267,014	257,092

(1) Diluted weighted average shares differs from basic due to the weighted average number of shares that would be outstanding upon conversion of our Senior convertible notes (44,120 shares) and Mann Group convertible note (3,370 shares), and exercise or vesting of outstanding share-based payments to employees (6,742 shares). These adjustments to weighted average shares are only applied to periods with net income.

MANNKIND CORPORATION AND SUBSIDIARY
CONSOLIDATED BALANCE SHEETS

	December 31, 2023	December 31, 2022
	(In thousands except share and per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 238,480	$ 69,767
Short-term investments	56,619	101,079
Accounts receivable, net	14,901	16,801
Inventory	28,545	21,772
Prepaid expenses and other current assets	34,848	25,477
Total current assets	373,393	234,896
Property and equipment, net	84,220	45,126
Goodwill	1,931	2,428
Other intangible asset	1,073	1,153
Long-term investments	7,155	1,961
Other assets	7,426	9,718
Total assets	$ 475,198	$ 295,282
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 9,580	$ 11,052
Accrued expenses and other current liabilities	42,036	35,553
Financing liability – current	9,809	9,565
Midcap credit facility – current	20,000	—
Liability for sale of future royalties – current	9,756	—
Deferred revenue – current	9,085	1,733
Recognized loss on purchase commitments – current	3,859	9,393
Total current liabilities	104,125	67,296
Mann Group convertible note	8,829	8,829
Accrued interest – Mann Group convertible note	56	55
Financing liability – long term	94,319	94,512
Midcap credit facility – long term	13,019	39,264
Senior convertible notes	226,851	225,397
Liability for sale of future royalties – long term	136,054	—
Recognized loss on purchase commitments – long term	60,942	62,916
Operating lease liability	3,925	5,343
Deferred revenue – long term	69,794	37,684
Milestone liabilities	3,452	4,524
Total liabilities	721,366	545,820
Stockholders' deficit:		
Undesignated preferred stock, $0.01 par value – 10,000,000 shares authorized; no shares issued or outstanding as of December 31, 2023 and 2022	—	—
Common stock, $0.01 par value – 800,000,000 and 400,000,000 shares authorized as of December 31, 2023 and 2022, respectively, and 270,034,495 and 263,793,305 shares issued and outstanding as of December 31, 2023 and 2022, respectively	2,700	2,638
Additional paid-in capital	2,980,539	2,964,293
Accumulated other comprehensive income	—	—
Accumulated deficit	(3,229,407)	(3,217,469)
Total stockholders' deficit	(246,168)	(250,538)
Total liabilities and stockholders' deficit	$ 475,198	$ 295,282