# 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): November 8, 2022

## **MannKind Corporation**

(Exact Name of Registrant as Specified in Charter)

Delaware

(State or Other Jurisdiction of Incorporation)

000-50865 (Commission File Number) **13-3607736** (I.R.S. Employer Identification Number)

1 Casper Street, Danbury, Connecticut 06810

(Address of Principal Executive Offices) (Zip Code)

(818) 661-5000

(Registrant's telephone number, including area code)

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). 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.  $\Box$ 

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

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

## Item 2.02. Results of Operations and Financial Condition.

On November 8, 2022, 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 November 8, 2022

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**

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

David Thomson, Ph.D., J.D. Corporate Vice President, General Counsel and Secretary

Date: November 8, 2022

# mannkind

## MANNKIND CORPORATION REPORTS 2022 THIRD QUARTER FINANCIAL RESULTS

## Conference Call to Begin Today at 9:00 a.m. (ET)

- 3Q 2022 Total Revenues of \$32.8 million; +48% vs. 3Q 2021
- 3Q 2022 Royalties from Tyvaso DPI of \$6.2 million
- 3Q 2022 Commercial Products Net Revenue of \$16.3 million; +67% vs. 3Q 2021

## DANBURY, Conn. and WESTLAKE VILLAGE, Calif. November 8, 2022 (Globe Newswire) — MannKind Corporation (Needers MNKD) to day reported financial results for the third quarter and nine months and ad Sentember 20, 2022

(Nasdaq: MNKD) today reported financial results for the third quarter and nine months ended September 30, 2022.

"In the third quarter, we grew total revenues by 48% over 2021 as our collaboration with United Therapeutics had its first full quarter during which we recognized both manufacturing revenue and royalties associated with the launch of Tyvaso DPI," said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. "In addition, our Endocrine Business Unit grew revenues 67% over 2021 as we integrated the V-Go acquisition and continued to grow Afrezza demand."

## **Third Quarter 2022 Results**

Total revenues were \$32.8 million for the third quarter of 2022, reflecting Afrezza® net revenue of \$10.8 million, V-Go® net revenue of \$5.4 million, collaborations and services revenue of \$10.3 million, and royalties of \$6.2 million. Afrezza net revenue increased 11% compared to \$9.8 million in the third quarter of 2021 as a result of price (including a more favorable gross-to-net adjustment) and higher patient demand, partially offset by wholesaler inventory ordering patterns which resulted in lower inventory levels for the third quarter of 2022. Collaborations and services revenue decreased \$2.1 million compared to the third quarter of 2021 primarily due to the completion of the research and development ("R&D") services associated with our collaboration with United Therapeutics ("UT"), which was mostly offset by manufacturing revenue from sales of Tyvaso DPI® to UT following the launch of Tyvaso DPI in June 2022.

Afrezza gross profit for the third quarter of 2022 was \$8.7 million compared to \$5.9 million in the same period of 2021, an increase of \$2.8 million, or 47%, which was driven by an increase in Afrezza sales and a decrease in cost of goods sold. Afrezza's cost of goods sold decreased by \$1.7 million, or 45%, compared to the same period in 2021, primarily due to a \$2.0 million decrease in excess capacity costs. Afrezza gross margin in the third quarter of 2022 was 81% compared to 61% for the same period in 2021. V-Go gross profit for the third quarter of 2022 was \$2.5 million with a gross margin of 46%.

Cost of revenue – collaborations and services in the third quarter of 2022 was \$12.4 million compared to \$6.1 million for the same period in 2021, an increase of \$6.4 million, primarily due to an increase in manufacturing activities for the production of Tyvaso DPI.

R&D expenses for the third quarter of 2022 were \$4.1 million compared to \$3.6 million for the third quarter of 2021. This \$0.5 million increase was mainly related to personnel costs for headcount hired in the second half of 2021, partially offset by a decrease in the Afrezza pediatrics clinical study (INHALE-1) due to study startup costs incurred in the third quarter of 2021.

Selling, general and administrative ("SG&A") expenses for the third quarter of 2022 were \$22.6 million compared to \$17.2 million for the third quarter of 2021. This \$5.4 million increase was primarily attributable to V-Go promotional efforts, the elimination of a co-promotion collaboration (which permitted some expenses associated with the sales force to be recognized as cost of revenue for collaborations and services in the third quarter of 2021), higher stock-based compensation, the net impact of personnel-related costs due to Afrezza sales force restructuring and increased professional fees.

For the third quarter of 2022, the gain on foreign currency translation (for insulin purchase commitments denominated in Euros) was \$1.8 million compared to \$2.1 million for the third quarter of 2021. The fluctuation was due to a change in the U.S. dollar to Euro foreign currency exchange rate.

Interest income, consisting of interest on investments net of amortization, increased \$0.6 million for the third quarter of 2022 to \$0.7 million primarily due to higher yields on our marketable securities and money market funds.

Interest expense on the financing liability was \$2.5 million for the third quarter of 2022, representing interest incurred on the November 2021 sale and lease-back of our manufacturing facility in Danbury, CT.

The net loss for the third quarter of 2022 was \$14.4 million, or \$0.06 per share, compared to \$4.4 million in the third quarter of 2021, or \$0.02 per share. The \$10.0 million increase in net loss was primarily due to an increase in selling, general and administrative expense, interest on the financing liability, and the \$4.9 million gain on extinguishment of debt in the third quarter of 2021.

## Nine Months September 30, 2022

Total revenues were \$63.7 million for the nine months ended September 30, 2022, reflecting Afrezza net revenue of \$31.3 million, V-Go net revenue of \$7.5 million, collaborations and services revenue of \$18.4 million and royalties of \$6.5 million. Afrezza net revenue increased 13% compared to \$27.8 million in the nine months ended September 30, 2021 as a result of price (including a more favorable gross-to-net adjustment) higher product demand and a more favorable cartridge mix. Collaborations and services revenue for the nine months ended September 30, 2022 decreased \$16.7 million compared to the same period in the prior year, primarily due to the completion of the R&D services associated with our collaboration with UT, which was partially offset by revenues associated with Tyvaso DPI of \$15.8 million. As of September 30, 2022, \$32.2 million of revenue associated with UT remains deferred and will be recognized as commercial product is sold to UT.

Afrezza gross profit for the nine months ended September 30, 2022 was \$23.6 million, compared to \$15.3 million in the same period of 2021, an increase of \$8.3 million, or 54%, which was driven by an increase in Afrezza sales and a decrease in cost of goods sold. Afrezza's cost of goods sold for the nine months ended September 30, 2022 decreased by \$4.8 million, or 38%, compared to the same period in 2021, primarily due to a \$3.8 million decrease in excess capacity costs and a \$2.0 million fee incurred for the amendment of the Insulin Supply Agreement in the prior year period. Afrezza gross margin for the nine months ended September 30, 2022 was \$3.3 million with a gross margin of 44%.

Cost of revenue – collaborations and services for the nine months ended September 30, 2022 was \$29.5 million compared to \$14.9 million for the same period in 2021, an increase of \$14.6 million, primarily due to an increase in manufacturing activities for the production of Tyvaso DPI.

R&D expenses for the nine months ended September 30, 2022 were \$12.6 million compared to \$8.4 million for the same period in 2021. This \$4.2 million increase was primarily attributable to personnel costs for headcount hired in the second half of 2021, development activities on our product pipeline, and the Afrezza pediatrics clinical study (INHALE-1).

SG&A expenses for the nine months ended September 30, 2022 were \$69.4 million compared to \$54.7 million for the same period in 2021. This \$14.7 million increase was primarily attributable to a pilot promotional effort aimed at primary care physicians that began in Q4 2021, elimination of a co-promotion collaboration (which permitted some expenses associated with the sales force to be recognized as cost of revenue from collaborations and services in the same period of 2021), promotional expenses to support V-Go, higher stock-based compensation and increased professional and consulting fees.

For the nine months ended September 30, 2022, the gain on foreign currency translation (for insulin purchase commitments denominated in Euros) was \$8.3 million compared to \$5.0 million for the same period of 2021. The fluctuation was due to a change in the U.S. dollar to Euro foreign currency exchange rate.

Interest income, consisting of interest on investments net of amortization, increased \$1.5 million for the nine months ended September 30, 2022 to \$1.6 million primarily due to higher yields on our marketable securities and money market funds.

Interest expense on the financing liability was \$7.3 million for the nine months ended September 30, 2022, representing interest incurred on the November 2021 sale and lease-back of our manufacturing facility in Danbury, CT.

The net loss for the nine months ended September 30, 2022 was \$69.5 million, or \$0.27 per share, compared to \$52.9 million in the same period of 2021, or \$0.21 per share. The \$16.6 million increase in the net loss was primarily due to higher cost of revenue for collaborations and services due to increased manufacturing activities for Tyvaso DPI, higher selling, general and administrative expenses, interest on the financing liability and increased research and development expenses, offset by a \$17.2 million loss on the extinguishment of debt in 2021.

As of September 30, 2022, cash and cash equivalents and investments were \$177.8 million.

## **Conference Call**

MannKind will host a conference call and presentation webcast to discuss these results today at 9:00 a.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 <u>mannkindcorp.com</u> under <u>Events &</u> <u>Presentations</u>. 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 innovative therapeutic products and devices to address serious unmet medical needs for those living with endocrine and orphan lung diseases.

We are committed to using our formulation capabilities and device engineering provess 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.

TYVASO DPI is a registered 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 BALANCE SHEETS (In thousands, except share and per share data)

	Sept	September 30, 2022		
ASSETS				
Current assets:	•			
Cash and cash equivalents	\$	54,308	\$	124,184
Short-term investments		110,738		79,932
Accounts receivable, net		23,493		4,739
Inventory		18,273		7,152
Prepaid expenses and other current assets		11,569		3,482
Total current assets		218,381		219,489
Property and equipment, net		41,182		36,612
Goodwill		3,067		_
Other intangible asset		1,169		
Long-term investments		12,728		56,619
Other assets		17,310		8,441
Total assets	\$	293,837	\$	321,161
Current liabilities:				
Accounts payable	\$	9,871	\$	6,956
Accrued expenses and other current liabilities	ψ	30,350	Φ	27,419
Financing liability — current		9,525		6,977
Deferred revenue — current		1,786		827
Recognized loss on purchase commitments — current		8,065		6,170
Total current liabilities		59,597		48,349
Senior convertible notes		225,034		223,944
Midcap credit facility		39,155		38,833
Mann Group convertible note		8,829		18,425
Accrued interest — promissory note		56		404
Financing liability — long term		94,484		93,525
Recognized loss on purchase commitments — long term		62,173		76,659
Operating lease liability		5,666		1,040
Deferred revenue — long term		31,996		19,543
Milestone liabilities		4,524		4,838
Deposits from customer		4,524		4,858
Total liabilities		531,514		530,510
Stockholders' deficit:		551,514		550,510
Undesignated preferred stock, \$0.01 par value — 10,000,000 shares authorized;				
no shares issued or outstanding as of September 30, 2022 and December 31, 2021				
Common stock, \$0.01 par value - 400,000,000 shares authorized,				
263,156,165 and 251,477,562 shares issued and outstanding		2 (22		0.514
at September 30, 2022 and December 31, 2021, respectively		2,632		2,515
Additional paid-in capital		2,960,419		2,918,205
Accumulated other comprehensive loss		(1,206)		(2.122.25
Accumulated deficit		(3,199,522)		(3,130,069
Total stockholders' deficit		(237,677)	*	(209,349
Total liabilities and stockholders' deficit	\$	293,837	\$	321,161

## MANNKIND CORPORATION AND SUBSIDIARY CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

## (In thousands, except per share data)

	Three Months Ended September 30,			Nine Months Ended September 30,				
		2022		2021		2022		2021
Revenues:								
Net revenue — commercial product sales	\$	16,259	\$	9,753	\$	38,807	\$	27,828
Revenue — collaborations and services		10,346		12,458		18,380		35,099
Royalties — collaborations		6,220		_		6,524		
Total revenues		32,825		22,211		63,711		62,927
Expenses:								
Cost of goods sold		5,021		3,812		11,922		12,538
Cost of revenue — collaborations and services		12,439		6,075		29,451		14,885
Research and development		4,136		3,655		12,565		8,426
Selling, general and administrative		22,638		17,221		69,378		54,690
Gain on foreign currency translation		(1,799)		(2,068)		(8,285)		(5,003)
Loss on purchase commitments		—						339
Total expenses		42,435		28,801		115,031		85,981
Loss from operations		(9,610)		(6,590)		(51,320)		(23,054)
Other (expense) income:					_			
Interest income, net		663		36		1,556		64
Interest expense on financing liability		(2,466)		_		(7,280)		_
Interest expense on notes		(2,812)		(2,803)		(12,202)		(12,435)
Gain (loss) on extinguishment of debt, net				4,930				(17,200)
Other (expense) income		(207)		1		(207)		(240)
Total other expense		(4,822)		2,164	_	(18,133)		(29,811)
Loss before provision for income taxes		(14,432)		(4,426)		(69,453)		(52,865)
Provision for income taxes		_		_		_		—
Net loss	\$	(14,432)	\$	(4,426)	\$	(69,453)	\$	(52,865)
Net loss per share - basic and diluted	\$	(0.06)	\$	(0.02)	\$	(0.27)	\$	(0.21)
Shares used to compute net loss per share - basic and diluted		259,300		249,910		254,974	_	248,624