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 5, 2022

MannKind Corporation

(Exact Name of Registrant as Specified in Charter)

Delaware	**000-50865**	**13-3607736**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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. ☐

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

Item 2.02. Results of Operations and Financial Condition.

On May 5, 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 May 5, 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

Date: May 5, 2022

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

MANNKIND CORPORATION REPORTS 2022 FIRST QUARTER FINANCIAL RESULTS

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

- *1Q 2022 Afrezza Net Revenue of $9.8 million; +21% vs. 1Q 2021*
- *1Q 2022 Afrezza Gross Margin 77%; Gross Profit +99% vs 1Q 2021*
- *$233.0 million of Cash, Cash Equivalents, and Investments at March 31, 2022*
- *Tyvaso DPI PDUFA date May 2022*

DANBURY, Conn. and WESTLAKE VILLAGE, Calif. May 5, 2022 (Globe Newswire) **— MannKind Corporation (Nasdaq: MNKD)** today reported financial results for the quarter ended March 31, 2022.

“As we approach the FDA action date for Tyvaso DPI, our company is focused on supporting United Therapeutics in their planned commercial launch,” said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. “Our endocrine business unit execution has resulted in Afrezza net revenue growth of 21% vs. the first quarter 2021 and we continue to add sites and patients into our Afrezza pediatric trial, INHALE-1.”

Total revenues were $12.0 million for the first quarter of 2022, reflecting Afrezza net revenue of $9.8 million and collaborations and services revenue of $2.2 million. Afrezza net revenue increased 21% compared to $8.1 million in the first quarter of 2021 as a result of wholesaler inventory ordering patterns for the first quarter of 2021, which was adversely impacted as wholesalers decreased inventory levels, plus price, which included more favorable gross-to-net deductions. Collaborations and services revenue decreased $7.2 million compared to the first quarter of 2021 primarily due to the completion of the R&D Services associated with our collaboration with United Therapeutics (“UT”). In August 2021, we entered into a commercial supply agreement (“CSA”) with UT. Revenue associated with the CSA is deferred as of March 31, 2022 and will be recognized over the period when commercial product is sold to UT. The deferred revenue balance associated with the CSA increased by $7.1 million in the first quarter to $25.7 million as of March 31, 2022.

Afrezza gross profit for the first quarter of 2022 was $7.5 million compared to $3.8 million in the same period of 2021, an increase of $3.8 million, or 99%, which was driven by an increase in Afrezza sales and a decrease in cost of goods sold. The Afrezza cost of goods sold decreased by $2.0 million, or 47%, compared to the same period in 2021, primarily as a result of the absorption of manufacturing-related costs due to the manufacturing of a second product. Afrezza gross margin in the first quarter of 2022 was 77% compared to 47% for the same period in 2021.

Cost of revenue – collaborations and services increased by $5.4 million in the first quarter of 2022 compared to the same period in 2021 primarily due to an increase in costs of manufacturing activities in preparation for supplying commercial product to UT.

Research and development expenses for the first quarter of 2022 were $3.5 million compared to $2.4 million for the first quarter of 2021. This $1.1 million increase was mainly related to costs incurred for research and development activities for our product pipeline, including a phase 1 clinical trial for inhaled clofazimine.

Selling, general and administrative expenses for the first quarter of 2022 were $20.7 million compared to $17.4 million for the first quarter of 2021. This $3.3 million increase was primarily attributable to an enhanced primary care physician-focused promotional campaign that began in the fourth quarter of 2021, Afrezza territory restructuring costs, as well as promotional and patient support services expenses to support Afrezza sales growth.

For the first quarter of 2022, the gain on foreign currency translation (for insulin purchase commitments denominated in Euros) was $2.0 million compared to $3.8 million for the first quarter of 2021. The fluctuation was due to a change in the U.S. dollar to Euro foreign currency exchange rate.

Interest expense on financing liability was $2.4 million for the first quarter of 2022 and represented interest incurred on the sale lease-back transaction for our manufacturing facility in Danbury, CT.

Interest expense on debt for the first quarter of 2022 was $2.7 million compared to $6.5 million for the first quarter of 2021. This decrease of $3.7 million was primarily due to a milestone payment obligation that was achieved during the first quarter of 2021, partially offset by an increase in interest expense related to our senior convertible notes.

The net loss for the first quarter of 2022 was $26.0 million, or $0.10 per share, compared to $12.9 million in the first quarter of 2021, or $0.05 per share. The $13.1 million increase in the net loss was primarily due to a decrease in revenues from collaboration and services and an increase in the cost of revenue for collaborations and services. Revenue associated with the CSA is deferred as of March 31, 2022 and will be recognized over the period when commercial product is sold to UT. The increase in cost of revenue for collaborations and services was primarily due to an increase in costs of manufacturing activities in preparation for supplying commercial product to UT.

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 Corporation

MannKind Corporation (Nasdaq: MNKD) focuses on the development and commercialization of inhaled therapeutic products for patients with endocrine and orphan lung diseases. MannKind is currently commercializing Afrezza® (insulin human) Inhalation Powder, the Company’s first FDA-approved product and the only inhaled ultra rapid-acting mealtime insulin in the United States, where it is available by prescription from pharmacies nationwide. Afrezza is also available by prescription in Brazil, where it is commercialized by the Company’s partner, Biomm SA. MannKind was established in 1991, and is located in Danbury, Conn., and Westlake Village, Calif. The Company also employs field sales and medical representatives across the U.S. Please visit mannkindcorp.com to learn more.

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 expected PDUFA date for Tyvaso DPI and our ability to support United Therapeutics in its planned commercial launch of Tyvaso DPI. 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: the FDA may not complete its review of the NDA for Tyvaso DPI on the timeframe expected for various reasons, including due to disruptions that may be caused by personnel shortages, citizen petitions and the COVID-19 pandemic; the FDA may determine not to approve Tyvaso DPI; and if we fail as an effective manufacturing organization, we may be unable to support commercialization of Tyvaso DPI, if approved. These and other are 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, 2021, filed with the SEC on February 24, 2022, and in its Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, 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 an investigational combination product that is not approved for any use in any country. The Tyvaso DPI tradename is pending final FDA review. TYVASO DPI is a trademark of United Therapeutics Corporation.

AFREZZA is a registered trademark of MannKind Corporation.

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MannKind Contact:
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MANNKIND CORPORATION AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	March 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 67,243	$ 124,184
Short-term investments	95,203	79,932
Accounts receivable, net	9,823	4,739
Inventory	8,044	7,152
Prepaid expenses and other current assets	3,952	3,482
Total current assets	184,265	219,489
Property and equipment, net	41,453	36,612
Long-term investments	70,542	56,619
Other assets	12,058	8,441
Total assets	$ 308,318	$ 321,161
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 8,702	$ 6,956
Accrued expenses and other current liabilities	27,131	27,419
Financing liability — current	9,410	6,977
Deferred revenue — current	1,307	827
Recognized loss on purchase commitments — current	6,944	6,170
Total current liabilities	53,494	48,349
Senior convertible notes	224,307	223,944
Midcap credit facility	38,939	38,833
Promissory notes	18,425	18,425
Accrued interest — promissory notes	520	404
Financing liability — long term	93,463	93,525
Recognized loss on purchase commitments — long term	72,400	76,659
Operating lease liability	826	1,040
Deferred revenue — long term	26,116	19,543
Milestone rights liability	4,838	4,838
Deposits from customer	7,054	4,950
Total liabilities	540,382	530,510
Stockholders' deficit:		
Undesignated preferred stock, $0.01 par value — 10,000,000 shares authorized; no shares issued or outstanding as of March 31, 2022 and December 31, 2021	—	—
Common stock, $0.01 par value - 400,000,000 shares authorized, 252,413,434 and 251,477,562 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	2,524	2,515
Additional paid-in capital	2,922,555	2,918,205
Accumulated other comprehensive loss	(1,076)	—
Accumulated deficit	(3,156,067)	(3,130,069)
Total stockholders' deficit	(232,064)	(209,349)
Total liabilities and stockholders' deficit	$ 308,318	$ 321,161

MANNKIND CORPORATION AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	Three Months Ended March 31,	
	2022	2021
Revenues:		
Net revenue — commercial product sales	$ 9,826	$ 8,099
Revenue — collaborations and services	2,166	9,337
Total revenues	11,992	17,436
Expenses:		
Cost of goods sold	2,284	4,315
Cost of revenue — collaborations and services	8,714	3,295
Research and development	3,536	2,442
Selling, general and administrative	20,697	17,413
Gain on foreign currency translation	(1,983)	(3,838)
Total expenses	33,248	23,627
Loss from operations	(21,256)	(6,191)
Other (expense) income:		
Interest income, net	377	3
Interest expense on financing liability	(2,371)	—
Interest expense on notes	(2,748)	(6,452)
Other expense	—	(276)
Total other expense	(4,742)	(6,725)
Loss before provision for income taxes	(25,998)	(12,916)
Provision for income taxes	—	—
Net loss	$ (25,998)	$ (12,916)
Net loss per share - basic and diluted	$ (0.10)	$ (0.05)
Shares used to compute net loss per share - basic and diluted	251,887	246,631