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 9, 2021

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)

30930 Russell Ranch Road, Suite 300, Westlake Village, California 91362

(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 November 9, 2021, MannKind Corporation issued a press release announcing its financial results for the quarter ended September 30, 2021, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 2.02 and the attached exhibit are being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01. Financial Statements and Exhibits.

Exhibit 99.1. Press release dated November 9, 2021

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: November 9, 2021

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

MANNKIND CORPORATION REPORTS 2021 THIRD QUARTER FINANCIAL RESULTS

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

- *3Q 2021 Total Revenues of $22.2 million; +45% vs. 3Q 2020*
- *3Q 2021 Afrezza Net Revenue of $9.8 million; +34% vs. 3Q 2020*
- *$181.1 million of Cash, Cash Equivalents and Investments at September 30, 2021*
- *Sale-Leaseback of Danbury manufacturing facility closed November 8, 2021*

WESTLAKE VILLAGE, Calif., November 9, 2021 (Globe Newswire**) -- MannKind Corporation (Nasdaq: MNKD)** today reported financial results for the quarter and nine months ended September 30, 2021.

“The MannKind team continues to stay focused and execute our corporate objectives of preparing for the commercial launch of Tyvaso DPI, moving our pipeline forward and growing Afrezza,” said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. “The recently completed animal toxicology studies of inhaled clofazimine support our timeline of moving this unique chemical entity into Phase 1 clinical trials by year-end.”

Third Quarter 2021 Results

Total revenues were $22.2 million for the third quarter of 2021, an increase of $6.9 million or 45% from the same period in 2020, reflecting Afrezza net revenue of $9.8 million and collaboration and services revenue of $12.5 million. Afrezza net revenue increased $2.5 million, or 34%, compared to $7.3 million in the third quarter of 2020 as a result of higher prescription demand and price, including lower gross-to-net deductions. Collaboration and services revenue for the third quarter of 2021 increased $4.4 million, or 54%, compared to the third quarter of 2020 primarily due to additional development work associated with our collaboration with United Therapeutics (“UT”).

Afrezza gross profit for the third quarter of 2021 was $5.9 million compared to $3.7 million in the same period of 2020, a 61% increase that was driven primarily by an increase in Afrezza net revenue. Gross margin in the third quarter of 2021 was 61% compared to 51% for the same period in 2020, reflecting the favorable impact of increased revenue.

Research and development (“R&D”) expenses for the third quarter of 2021 were $3.7 million compared to $1.5 million for the third quarter of 2020. This increase of $2.2 million, or 146%, was attributable to research activities on our product pipeline and to the initiation of the Afrezza pediatrics clinical study (INHALE-1).

Selling, general and administrative (“SG&A”) expenses for the third quarter of 2021 were $17.2 million compared to $13.9 million for the third quarter of 2020, an increase of $3.3 million, or 24%. The increase was primarily attributable to promotional expenses and patient support services of $2.0 million as well as personnel-related expenses of $2.6 million, which was driven by increased stock-based compensation and additional headcount to support Afrezza growth. The spending in SG&A in the third quarter of 2021 was partially offset by a reduction for the promotional cost for Thyquidity that was recognized as cost of revenue — collaboration and services in 2021.

For the third quarter of 2021, the gain on foreign currency translation for insulin purchase commitments denominated in Euros was $2.1 million compared to a loss of $3.9 million for the third quarter of 2020. The fluctuation was due to the change in the U.S. dollar to Euro foreign currency exchange rate.

Interest expense on debt for the third quarter of 2021 was $2.8 million compared to $2.4 million for the third quarter of 2020. This increase of $0.4 million was the result of interest on the $230.0 million 2.5% senior convertible notes issued in the first quarter of 2021, partially offset by a decrease in interest due to the repayment of $35.1 million of outstanding principal under the Mann Group non-convertible promissory note and the repayment of $10.0 million outstanding principal under the MidCap credit facility in the second quarter of 2021. In addition, we reduced the interest rates on the outstanding principal balances under the MidCap credit facility and the Mann Group convertible note through amendments to the respective agreements in the second quarter of 2021.

Gain on extinguishment of debt, a non-cash item, for the three months ended September 30, 2021 was $4.9 million as a result of the Small Business Association's (the "SBA") forgiveness of our PPP loan in July 2021.

The net loss for the third quarter of 2021 was $4.4 million, or $0.02 per share, compared to $11.3 million in the third quarter of 2020, or $0.05 per share. The decreased net loss of $6.8 million was primarily due to an increase in Afrezza net revenues and revenues from collaboration and services, as well as a non-cash gain on the extinguishment of the PPP loan, partially offset by an increase in the cost of revenue from collaboration and services and of SG&A expenses. Non-GAAP net loss, adjusted to exclude the PPP loan debt extinguishment was $9.4 million, or $0.04 per share, for the three months ended September 30, 2021 compared to $11.3 million, or $0.05 per share, for the prior year period.

Nine Months September 30, 2021

Total revenues were $62.9 million for the nine months ended September 30, 2021, an increase of $16.2 million or 35% from the same period in 2020, reflecting Afrezza net revenue of $27.8 million and collaboration and services revenue of $35.1 million. Afrezza net revenue increased 25% compared to $22.3 million for the nine months ended September 30, 2020, as a result of higher prescription demand, the negative effects of the COVID-19 pandemic in the prior year period, a more favorable mix of Afrezza cartridges, and price including lower gross-to-net deductions. Collaboration and services revenue for the nine months ended September 30, 2021 increased $10.7 million, or 44%, compared to the nine months ended September 30, 2020, primarily due to additional development work associated with our collaboration with UT.

Afrezza gross profit for the nine months ended September 30, 2021 was $15.3 million compared to $10.8 million in the same period of 2020, a 41% increase that was driven primarily by an increase in Afrezza net revenue. Cost of goods sold increased $1.1 million compared to the same period in 2020, primarily due to a $2.0 million fee for an amendment of our insulin supply agreement and a $1.1 million decrease in manufacturing activities which resulted in a lower amount of costs capitalized to inventory, partially offset by $0.9 million of costs associated with lower manufacturing cost per unit and the termination of the free goods program in December 2020. Gross margin for the nine months ended September 30, 2021 was 55% compared to 49% for the same period in 2020. On a non-GAAP basis, which excludes the $2.0 million insulin supply amendment fee, gross margin was 62% for the nine months ended September 30, 2021 compared to 49% for the same period in 2020, reflecting the favorable impact of increased revenue.

R&D expenses for the nine months ended September 30, 2021 were $8.4 million compared to $4.7 million for the nine months ended September 30, 2020. This increase of $3.7 million, or 79%, was attributable to costs incurred for research activities on the product pipeline and to the initiation of the INHALE-1 study as well as personnel costs associated with additional headcount.

SG&A expenses for the nine months ended September 30, 2021 were $54.7 million compared to $41.9 million for the nine months ended September 30, 2020, an increase of $12.8 million, or 30%. The increase was primarily attributable to promotional expenses and patient support services of $5.8 million and personnel-related expenses of $8.5 million, which reflected increased stock-based compensation, additional headcount to support Afrezza growth and our voluntary reduction in compensation expense in response to the COVID-19 pandemic in the prior year. The spend in selling expenses was partially offset by a reduction related to the co-promotional cost for Thyquidity, which was recognized as cost of revenue – collaborations and services.

An impairment of $1.9 million was recognized for the nine months ended September 30, 2020 for a commitment asset related to the future funding commitments of the MidCap credit facility.

For the nine months ended September 30, 2021, the gain on foreign currency translation for insulin purchase commitments denominated in Euros was $5.0 million compared to a $4.0 million loss for the nine months ended September 30, 2020. The fluctuation was due to the change in the U.S. dollar to Euro foreign currency exchange rate.

Interest expense on debt for the nine months ended September 30, 2021 was $12.4 million compared to $7.1 million for the nine months ended September 30, 2020. This increase of $5.3 million was the result of a $3.7 million milestone obligation achieved in the first quarter of 2021 and interest on the $230.0 million 2.5% senior convertible notes issued in the first quarter of 2021, partially offset by a decrease in interest due to the repayment of $35.1 million of outstanding principal under the Mann Group non-convertible promissory note and the repayment of $10.0 million outstanding principal under the MidCap credit facility in the second quarter of 2021. In addition, we reduced the interest rates on the outstanding principal balances under the MidCap credit facility and the Mann Group convertible note through amendments to the respective agreements in the second quarter of 2021.

Non-cash net loss on extinguishment of debt of $17.2 million for the nine months ended September 30, 2021 consisted of a $22.1 million loss on extinguishment of debt for the amendment to the Mann Group convertible note, which did not result in a change in our financial position, partially offset by a $4.9 million gain on extinguishment of debt as a result of the SBA’s forgiveness of our PPP loan in July 2021.

The net loss for the nine months ended September 30, 2021 was $52.9 million, or $0.21 per share, compared to a $30.8 million net loss in the nine months ended September 30, 2020, or $0.14 per share. The increased net loss of $22.0 million was primarily due to the non-cash loss on extinguishment of the Mann Group convertible note of $22.1 million net of a non-cash gain on extinguishment of the PPP loan of $4.9 million, as well as an increase in SG&A expenses, cost of revenue – collaboration and services, partially offset by an increase in Afrezza net revenues and revenues from collaboration and services. Non-GAAP net loss as adjusted for the $17.2 million net loss on extinguishment of debt and the $2.0 million Amphastar amendment fee was $33.7 million, or $0.14 per share, for the nine months ended September 30, 2021 compared to $30.8 million, or $0.14 per share, for the same period in the prior year.

Cash, cash equivalents, and investments at September 30, 2021 were $181.1 million compared to $67.0 million at December 31, 2020. The increase in cash, cash equivalents and investments was primarily due to the issuance of $230.0 million of 2.5 % senior convertible notes in the first quarter of 2021.

Non-GAAP Measures

To supplement our unaudited condensed consolidated financial statements presented under U.S. generally accepted accounting principles (GAAP), we are presenting certain 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 unaudited condensed 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 its 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 tables reconcile our gross margin financial measure to a non-GAAP presentation as adjusted for the nonrecurring amendment fee related to an amendment to our Insulin Supply Agreement.

	Nine Months Ended September 30,			
	2021	2020	$ Change	% Change
Net revenue — Afrezza	$ 27,828	$ 22,260	$ 5,568	25%
Less cost of goods sold	(12,538)	(11,432)	$ 1,106	10%
GAAP gross profit — Afrezza	15,290	10,828	$ 4,462	41%
Exclude Amphastar amendment fee	2,000	—	$ 2,000	*
Non-GAAP gross profit — Afrezza	$ 17,290	$ 10,828	$ 6,462	60%
Non-GAAP gross margin	62%	49%		

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* Not meaningful

The following tables reconcile our financial measure for net loss and EPS as reported in our condensed consolidated statement of operations to a non-GAAP presentation as adjusted for the $4.9 million non-cash gain on extinguishment of the PPP loan for the three months ended September 30, 2021 and the $22.1 million non-cash loss on extinguishment of the Mann Group convertible note and the $4.9 million gain on extinguishment of the PPP loan for the nine months ended September 30, 2021, which did not result in a change in our financial position, as well as the $2.0 million Amphastar amendment fee.

	Three Months Ended September 30,			
(In thousands, except per share data)	2021	2020	$ Change	% Change
GAAP to Non-GAAP Net Loss and EPS				
Net loss	$ (4,426)	$ (11,255)	$ (6,829)	(61%)
Net loss per share - basic and diluted	$ (0.02)	$ (0.05)	$ (0.03)	(60%)
Less non-cash loss on extinguishment of debt[1]	(4,930)	—	$ (4,930)	*
Non-GAAP net loss	$ (9,356)	$ (11,255)	$ (1,899)	(17%)
Non-GAAP net loss per share - basic and diluted	$ (0.04)	$ (0.05)	$ (0.01)	(20%)
Shares used to compute non-GAAP net loss per share - basic and diluted	249,910	229,668	20,242	9%

	Nine Months Ended September 30,			
	2021	2020	$ Change	% Change
GAAP to Non-GAAP Net Loss and EPS				
Net loss	$ (52,865)	$ (30,829)	$ 22,036	71%
Net loss per share - basic and diluted	$ (0.21)	$ (0.14)	$ 0.07	50%
Less non-cash loss on extinguishment of debt, net(1)	17,200	—	$ 17,200	*
Less Amphastar amendment fee(1)	2,000	—	$ 2,000	*
Non-GAAP net loss	$ (33,665)	$ (30,829)	$ 2,836	9%
Non-GAAP net loss per share - basic and diluted	$ (0.14)	$ (0.14)	$ —	0%
Shares used to compute non-GAAP net loss per share - basic and diluted	248,624	218,559	30,065	14%

* Not meaningful

(1) There is no provision for income taxes associated with the non-cash net loss on extinguishment of debt or the Amphastar amendment fee as a result of our full valuation allowance.

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 www.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 headquartered in Westlake Village, Calif., and has a manufacturing and R&D facility in Danbury, Conn. The Company also employs field sales and medical representatives across the U.S. Please visit www.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 potential approval and commercial launch of Tyvaso DPI, MannKind’s future commercial growth and pipeline advancement, and MannKind’s ability to directly commercialize pharmaceutical products. 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, the risk that Tyvaso DPI may not be approved by the FDA on the timeline expected, or at all, 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, the impact of the COVID-19 pandemic, stock price volatility and other risks detailed in MannKind’s filings with the Securities and Exchange Commission, including under the “Risk Factors” heading of its Annual Report on Form 10-K for the year ended December 31, 2020 and subsequent periodic reports on Form 10-Q and current reports on Form 8-K, each as filed with the Securities and Exchange Commission. 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 registered trademark of United Therapeutics Corporation.

THYQUIDITY is a registered trademark of Vertice Pharma.

AFREZZA is a registered trademark of MannKind Corporation.

MannKind Contact:
Rose Alinaya, Investor Relations
(818) 661-5000
Email: ir@mannkindcorp.com

MANNKIND CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands, except share and per share data)

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 51,740	$ 67,005
Restricted cash	—	158
Short-term investments	87,312	—
Accounts receivable, net	9,445	4,218
Inventory	7,482	4,973
Prepaid expenses and other current assets	3,227	3,122
Total current assets	159,206	79,476
Property and equipment, net	30,848	25,867
Long-term investments	42,059	—
Other assets	6,094	3,265
Total assets	$ 238,207	$ 108,608
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 9,528	$ 5,582
Accrued expenses and other current liabilities	20,829	19,707
PPP loan — current	—	4,061
Deferred revenue — current	14,016	33,275
Recognized loss on purchase commitments — current	5,660	11,080
Total current liabilities	50,033	73,705
Senior convertible notes	223,580	—
MidCap credit facility	38,723	49,335
Mann Group promissory notes	18,425	63,027
Accrued interest — Mann Group promissory notes	286	4,150
PPP loan — long term	—	812
2024 convertible notes	—	5,000
Recognized loss on purchase commitments — long term	79,653	84,208
Operating lease liability	798	1,202
Deferred revenue — long term	1,552	1,662
Milestone rights liability	4,838	5,926
Deposits from customer	5,007	—
Total liabilities	422,895	289,027
Stockholders' deficit:		
Undesignated preferred stock, $0.01 par value — 10,000,000 shares authorized; no shares issued or outstanding as of September 30, 2021 and December 31, 2020	—	—
Common stock, $0.01 par value - 400,000,000 shares authorized, 250,245,831 and 242,117,089 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	2,502	2,421
Additional paid-in capital	2,914,818	2,866,303
Accumulated deficit	(3,102,008)	(3,049,143)
Total stockholders' deficit	(184,688)	(180,419)
Total liabilities and stockholders' deficit	$ 238,207	$ 108,608

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues:				
Net revenue — commercial product sales	$ 9,753	$ 7,275	$ 27,828	$ 22,260
Revenue — collaborations and services	12,458	8,077	35,099	24,441
Total revenues	22,211	15,352	62,927	46,701
Expenses:				
Cost of goods sold	3,812	3,591	12,538	11,432
Cost of revenue — collaborations and services	6,075	1,581	14,885	6,926
Research and development	3,655	1,484	8,426	4,703
Selling, general and administrative	17,221	13,899	54,690	41,919
Asset impairment	106	—	106	1,889
(Gain) loss on foreign currency translation	(2,068)	3,927	(5,003)	3,998
Loss on purchase commitments	—	—	339	—
Total expenses	28,801	24,482	85,981	70,867
Loss from operations	(6,590)	(9,130)	(23,054)	(24,166)
Other (expense) income:				
Interest income	36	18	64	165
Interest expense on notes	(2,709)	(1,057)	(10,943)	(3,212)
Interest expense on Mann Group promissory notes	(94)	(1,318)	(1,492)	(3,858)
Gain (loss) on extinguishment of debt, net	4,930	—	(17,200)	—
Other income (expense)	1	14	(240)	24
Total other income (expense)	2,164	(2,343)	(29,811)	(6,881)
Loss before provision for income taxes	(4,426)	(11,473)	(52,865)	(31,047)
Provision for income taxes	—	218	—	218
Net loss	$ (4,426)	$ (11,255)	$ (52,865)	$ (30,829)
Net loss per share - basic and diluted	$ (0.02)	$ (0.05)	$ (0.21)	$ (0.14)
Shares used to compute net loss per share - basic and diluted	249,910	229,668	248,624	218,559