

**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 4, 2020

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)

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 4, 2020, MannKind Corporation issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

Exhibit 99.1. [Press release dated November 4, 2020](#)

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 4, 2020

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



MannKind Corporation Reports 2020 Third Quarter Financial Results

Conference Call to Begin Today at 5:00 PM ET

- 3Q 2020 U.S. Afrezza Net Revenue of \$7.3 million; +27% vs. 3Q 2019
- 3Q YTD 2020 U.S. Afrezza Net Revenue of \$22.1 million; +31% vs. 3Q YTD 2019
- Cash and cash equivalents of \$52.4 million at September 30, 2020
- On track to complete Treprostinil Technosphere development activities in 4Q 2020
- Expanded Afrezza commercial and medical teams
- YTD Afrezza scientific presentations and publications total 14

WESTLAKE VILLAGE, Calif., November 4, 2020 (GLOBE NEWSWIRE) -- MannKind Corporation (NASDAQ:MNKD) today reported financial results for the quarter and nine months ended September 30, 2020.

“Our employees continue to execute in a tumultuous Covid-19 environment,” said Michael Castagna, Chief Executive Officer. “As we head toward year-end, our focus remains on two significant drivers of value for shareholders: enabling healthcare providers to increase their prescribing of Afrezza and supporting United Therapeutics as they move the TreT clinical program to completion, including manufacturing TreT clinical supplies.”

Third Quarter 2020 Results

Total revenues were \$15.4 million for the third quarter of 2020, reflecting Afrezza net revenue of \$7.3 million and collaboration and services revenue of \$8.1 million. Afrezza U.S net revenue of \$7.3 million increased 27% compared to \$5.7 million in the third quarter of 2019, driven by higher product demand, a favorable mix of cartridges, and price. The first sale of Afrezza to the Company’s marketing partner in Brazil was completed in the third quarter of 2019 for \$0.7 million; there were no international sales in the third quarter of 2020. Collaboration and services revenue for the third quarter of 2020 decreased \$0.1 million compared to the third quarter of 2019.

Afrezza gross profit for the third quarter of 2020 was \$3.7 million compared to a loss of \$0.7 million in the same period of 2019, an increase of \$4.4 million that was driven primarily by higher Afrezza revenue combined with a reduction in cost of goods sold, primarily attributable to a \$2.8 million amendment fee associated with our insulin supply agreement in 2019. Non-GAAP gross margin in the third quarter of 2020 increased to 51% from 32% for the same quarter in 2019.

Selling, general and administrative expenses for the third quarter of 2020 were \$13.9 million compared to \$16.7 million for the third quarter of 2019. This 17% decrease was primarily due to a \$1.2 million reduction in promotional and marketing activities and a \$0.8 million decrease in professional costs.

Interest expense for the third quarter of 2020 was \$2.4 million compared to \$5.3 million for the third quarter of 2019. This \$2.9 million decrease was primarily attributable to a \$3.4 million milestone obligation that occurred in the third quarter of 2019, partially offset by interest expense from the MidCap Credit Facility.

A loss on foreign currency translation for the third quarter of 2020 was \$3.9 million compared to a \$3.8 million gain for the third quarter of 2019. The fluctuation is related to the change in the U.S. dollar to Euro foreign exchange rate on the recognized loss on insulin purchase commitments, which are denominated in Euros.

The net loss for the third quarter of 2020 was \$11.3 million, or \$0.05 per share, compared to a \$10.4 million net loss, or \$0.05 per share in the third quarter of 2019. The higher net loss was mainly attributable to the change in foreign currency translation from a gain in 2019 to a loss in 2020, partially offset by the reduction in cost of goods sold, selling, general and administrative expenses and interest expense.

Nine Months Ended September 30, 2020

Total revenues were \$46.7 million for the nine months ended September 30, 2020, reflecting Afrezza net revenue of \$22.3 million and collaboration and services revenue of \$24.4 million. Afrezza net revenue increased 27% compared to \$17.5 million for the nine months ended September 30, 2019, primarily driven by higher product demand, a more favorable mix of cartridges and price, partially offset by a reduction in sales to Biomm (Brazil). Collaboration and services revenue for the nine months ended September 30, 2020 decreased \$5.1 million compared to the same period in the prior year, primarily due to a \$5.7 million decrease in revenue recognized from the UT Research Agreement, which was substantially completed in 2019.

Afrezza gross profit for the nine months ended September 30, 2020 was \$10.8 million compared to \$2.1 million in the same period of 2019, an increase of \$8.7 million, or +416%, that was driven primarily by a reduction in cost of goods sold combined with higher commercial product sales. Cost of goods sold decreased by \$4.0 million, primarily attributable to a \$2.8 million amendment fee associated with our insulin supply agreement in 2019, \$0.8 million of increased 2020 manufacturing activities which resulted in a greater amount of costs capitalized to inventory and \$1.1 million in reduced 2020 manufacturing-related spending, partially offset by \$0.5 million of 2020 inventory write-offs and \$0.4 million in costs associated with higher commercial product sales. Non-GAAP gross margin for the nine months ended September 30, 2020 increased to 49% from 28% for the same period in 2019, primarily due to higher Afrezza revenue and lower cost of goods sold.

Selling, general and administrative expenses for the nine months ended September 30, 2020 were \$41.9 million compared to \$58.9 million for the same period in 2019. This 29% decrease was primarily due to \$9.3 million spent on direct-to-consumer television advertising in 2019 (which was not repeated in 2020), a \$4.1 million decrease in promotional and marketing activities, a \$1.3 million decrease in consulting costs, and a \$1.2 million decrease in personnel and employee related costs.

The loss on foreign currency translation for the nine months ended September 30, 2020 was \$4.0 million compared to a \$4.5 million gain for the same period in 2019. The fluctuation is related to the change in the U.S. dollar to Euro foreign exchange rate on the recognized loss on insulin purchase commitments, which are denominated in Euros.

The net loss for the nine months ended September 30, 2020 was \$30.8 million, or \$0.14 per share, compared to a \$37.6 million net loss, or \$0.20 per share for the same period in 2019. The lower net loss was mainly attributable to a decrease selling, general and administrative expenses, partially offset by the change in the foreign currency translation from a gain in 2019 to a loss in 2020. The reduction in the net loss per share was also impacted by a greater number of outstanding shares.

Cash, cash equivalents and restricted cash at September 30, 2020 was \$52.7 million compared to \$50.2 million at December 31, 2019, which also included short-term investments of \$20.0 million. The increase was primarily due to a milestone payment from United Therapeutics of \$12.5 million, \$15.2 million of net proceeds received from at-the-market offerings, \$11.6 million received from warrant exercises and the origination of a Paycheck Protection Program loan for \$4.9 million, offset by non-GAAP net cash used in operating activities of \$40.9 million.

Non-GAAP Measures

Certain financial information contained in this press release is presented on both a reported basis (GAAP) and a non-GAAP basis. Reported results were prepared in accordance with GAAP whereas non-GAAP measures exclude items described in the reconciliation tables below. Non-GAAP financial information is intended to portray the results of our baseline performance, supplement or enhance management, analysts and investors overall understanding of our underlying financial performance and facilitate comparisons among current and past periods. The non-GAAP financial measures are in addition to, not a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP.

	Three Months Ended September 30,			
	2020	2019	\$ Change	% Change
Net revenue — Afrezza	\$ 7,275	\$ 6,402	\$ 873	14%
Less cost of goods sold	(3,591)	(7,099)	(3,508)	(49%)
GAAP gross profit (loss) — Afrezza	3,684	(697)	4,381	*
Exclude Amphastar amendment fee	—	2,750	(2,750)	(100%)
Non-GAAP gross profit — Afrezza	\$ 3,684	\$ 2,053	\$ 1,631	79%
Non-GAAP gross margin	51%	32%		

* Not meaningful

	Nine Months Ended September 30,			
	2020	2019	\$ Change	% Change
Net revenue — Afrezza	\$ 22,260	\$ 17,543	\$ 4,717	27%
Less cost of goods sold	(11,432)	(15,446)	(4,014)	(26%)
GAAP gross profit — Afrezza	10,828	2,097	8,731	416%
Exclude Amphastar amendment fee	—	2,750	(2,750)	(100%)
Non-GAAP gross profit — Afrezza	\$ 10,828	\$ 4,847	\$ 5,981	123%
Non-GAAP gross margin	49%	28%		

	Nine Months Ended September 30,			
	2020	2019	\$ Change	% Change
Net cash used in operating activities	\$ (28,363)	\$ (83,376)	\$ 55,013	66%
Exclude UT payment received	(12,500)	(12,500)	—	—%
Exclude payment-in-kind interest on promissory notes	—	(32,822)	32,822	100%
Non-GAAP cash used in operating activities	\$ (40,863)	\$ (128,698)	\$ 87,835	68%

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 <http://www.mannkindcorp.com> under News & Events.

A telephone replay of the call will be accessible for approximately 14 days following completion of the call by dialing (844) 512-2921 or (412) 317-6671 and use the participant passcode: 3965498#. A replay will also 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 diseases such as diabetes 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. MannKind is headquartered in Westlake Village, California, and has a state-of-the-art manufacturing facility in Danbury, Connecticut. The Company also employs field sales and medical representatives across the U.S. For further information, visit www.mannkindcorp.com.

Forward-Looking Statements

This press release contains forward-looking statements that involve risks and uncertainties. Words such as "believes," "anticipates," "plans," "expects," "intends," "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 detailed in MannKind's filings with the SEC, including risks related to the COVID-19 pandemic. For a discussion of these and other factors, please refer to MannKind's annual report on Form 10-K for the year ended December 31, 2019 as well as MannKind's other filings with the SEC. 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.

Company Contact:

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

ASSETS	September 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 52,398	\$ 29,906
Restricted cash	316	316
Short-term investments	—	19,978
Accounts receivable, net	4,135	3,513
Inventory	4,881	4,155
Prepaid expenses and other current assets	4,616	2,889
Total current assets	66,346	60,757
Property and equipment, net	25,736	26,778
Other assets	3,599	6,190
Total assets	<u>\$ 95,681</u>	<u>\$ 93,725</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 5,797	\$ 4,789
Accrued expenses and other current liabilities	15,814	15,904
Short-term notes payable	45,379	5,028
Deferred revenue — current	28,867	32,503
Recognized loss on purchase commitments — current	10,267	7,394
Total current liabilities	106,124	65,618
Promissory notes	70,025	70,020
Accrued interest — promissory notes	5,854	2,002
Long-term Midcap credit facility	—	38,851
Senior convertible notes	5,000	5,000
Paycheck Protection Program loan — long term	1,421	—
Recognized loss on purchase commitments — long term	84,529	84,639
Operating lease liability	1,523	2,514
Deferred revenue — long term	1,699	8,344
Milestone rights liability	5,926	7,263
Total liabilities	<u>282,101</u>	<u>284,251</u>
Stockholders' deficit:		
Undesignated preferred stock, \$0.01 par value — 10,000,000 shares authorized; no shares issued or outstanding as of September 30, 2020 and December 31, 2019	—	—
Common stock, \$0.01 par value - 400,000,000 and 280,000,000 shares authorized, 230,922,513 and 211,787,573 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	2,309	2,118
Additional paid-in capital	2,834,003	2,799,278
Accumulated other comprehensive loss	—	(19)
Accumulated deficit	(3,022,732)	(2,991,903)
Total stockholders' deficit	<u>(186,420)</u>	<u>(190,526)</u>
Total liabilities and stockholders' deficit	<u>\$ 95,681</u>	<u>\$ 93,725</u>

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

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Revenues:				
Net revenue — commercial product sales	\$ 7,275	\$ 6,402	\$ 22,260	\$ 17,543
Revenue — collaborations and services	8,077	8,193	24,441	29,502
Total revenues	<u>15,352</u>	<u>14,595</u>	<u>46,701</u>	<u>47,045</u>
Expenses:				
Cost of goods sold	3,591	7,099	11,432	15,446
Cost of revenue — collaborations and services	1,581	1,836	6,926	5,512
Research and development	1,484	1,580	4,703	4,879
Selling, general and administrative	13,899	16,666	41,919	58,948
Asset impairment	—	—	1,889	—
Loss (gain) on foreign currency translation	3,927	(3,807)	3,998	(4,495)
Total expenses	<u>24,482</u>	<u>23,374</u>	<u>70,867</u>	<u>80,290</u>
Loss from operations	<u>(9,130)</u>	<u>(8,779)</u>	<u>(24,166)</u>	<u>(33,245)</u>
Other (expense) income:				
Interest income	18	220	165	794
Interest expense on notes	(1,057)	(4,126)	(3,212)	(5,283)
Interest expense on promissory notes	(1,318)	(1,162)	(3,858)	(3,351)
Gain on extinguishment of debt	—	3,529	—	3,529
Other income (expense)	14	(52)	24	(84)
Total other expense	<u>(2,343)</u>	<u>(1,591)</u>	<u>(6,881)</u>	<u>(4,395)</u>
Loss before provision for income taxes	<u>(11,473)</u>	<u>(10,370)</u>	<u>(31,047)</u>	<u>(37,640)</u>
Benefit for income taxes	218	—	218	—
Net loss	<u>\$ (11,255)</u>	<u>\$ (10,370)</u>	<u>\$ (30,829)</u>	<u>\$ (37,640)</u>
Net loss per share - basic and diluted	<u>\$ (0.05)</u>	<u>\$ (0.05)</u>	<u>\$ (0.14)</u>	<u>\$ (0.20)</u>
Shares used to compute basic and diluted net loss per share	<u>229,668</u>	<u>199,906</u>	<u>218,559</u>	<u>191,786</u>