

**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 25, 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 February 25, 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 February 25, 2020](#)

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 25, 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 2019 Fourth Quarter and Full Year Financial Results

Conference Call to Begin Today at 9:00 AM ET

- **2019 Total Revenue of \$63.0 million**
 - 2019 Afrezza Net Revenue of \$25.3 million; +46% vs. 2018
 - 2019 Collaborations and Services Revenue of \$37.7 million; +257% vs. 2018
- **4Q 2019 Total Revenue of \$16.0 million**
 - **4Q 2019 Afrezza Net Revenue of \$7.8 million; +35% vs. 4Q 2018**
 - 4Q 2019 Afrezza Net Revenue grew 22% vs. 3Q 2019
 - 4Q 2019 Afrezza Gross Profit \$3.1 million; 40% Gross Margin
 - 4Q 2019 Collaborations and Services Revenue of \$8.2 million; -20% vs. 4Q 2018
- **\$50.2 million of Cash, Cash Equivalents, Restricted Cash, and Short-term Investments at December 31, 2019**

WESTLAKE VILLAGE, California February 25, 2020 (GLOBE NEWSWIRE) — MannKind Corporation (NASDAQ:MNKD) today reported financial results for the fourth quarter and full year ended December 31, 2019.

“We ended 2019 on a strong note with fourth quarter 2019 Afrezza net revenue of \$7.8 million, our best quarter to date,” said Michael Castagna, Chief Executive Officer of MannKind Corporation. He also noted, “Our collaboration with United Therapeutics on TreT continues to make progress along the clinical and commercial pathways that are expected to set up a filing with the FDA within 12 months.”

Fourth Quarter 2019 Results

Total revenues were \$16.0 million for the fourth quarter of 2019, reflecting Afrezza net revenue of \$7.8 million and collaborations and services revenue of \$8.2 million. Afrezza net revenue increased 35% compared to \$5.7 million in the fourth quarter of 2018, primarily driven by higher product demand and price. Collaborations and services revenue decreased \$2.1 million compared to the fourth quarter of 2018, primarily due to lower revenue from the United Therapeutics research agreement, which was substantially completed by the second quarter of 2019.

On a GAAP basis, Afrezza gross profit was \$3.1 million for the fourth quarter of 2019 compared to \$0.7 million in the same period in 2018. Afrezza cost of goods sold for the fourth quarter of 2018 included a fee of \$2.0 million recorded in connection with the amendment of our insulin supply agreement with Amphastar. As a result, on a non-GAAP basis, gross profit was \$2.7 million or 48% gross margin for the fourth quarter of 2018, compared to a GAAP basis gross margin of 40% for the fourth quarter of 2019.

Research and development (R&D) expenses for the fourth quarter of 2019 were \$2.0 million compared to \$1.1 million for the fourth quarter of 2018. This 82% increase was primarily attributable to an increase of \$0.6 million in personnel costs associated with the United Therapeutics research agreement, which was classified as a cost of collaborations and services revenue in 2018, and to an increase of \$0.3 million in maintenance costs for our research facility in Danbury, Connecticut.

Selling, general and administrative (SG&A) expenses for the fourth quarter of 2019 were \$15.7 million compared to \$18.0 million for the fourth quarter of 2018. This decrease of \$2.3 million, or 13%, was primarily attributable to a \$1.7 million decrease in personnel related costs and a \$1.1 million decrease in Afrezza marketing costs, partially offset by an increase of \$0.5 million in consulting and professional services costs.

Interest expense on debt for the fourth quarter of 2019 was \$2.3 million compared to \$1.7 million for the fourth quarter of 2018. This \$0.6 million increase, or 35%, was primarily attributable to the net increase in our debt balance as a result of our debt restructuring in the third quarter of 2019.

The net loss for the fourth quarter of 2019 was \$14.3 million, or \$0.07 per share compared to a \$9.8 million net loss in the fourth quarter of 2018 or \$0.06 per share. The increase in the net loss of \$4.5 million was primarily the result of an increased loss on foreign currency translation of \$4.0 million associated with our insulin supply agreement denominated in Euros and of an increase of \$0.6 million in interest expense.

Twelve Months Ended December 31, 2019

Total revenues were \$63.0 million for the year ended December 31, 2019, reflecting Afrezza net revenue of \$25.3 million and collaborations and services revenue of \$37.7 million. Afrezza net revenue increased 46% compared to \$17.3 million for the year ended December 31, 2018, primarily due to higher product demand, the first sale of Afrezza to our marketing partner in Brazil (Biommm), price increases as well as a more favorable mix of Afrezza cartridges. Collaborations and services revenue increased \$27.2 million compared to the full year ended December 31, 2018, which was primarily attributed to the licensing and research agreements with United Therapeutics, both of which began in the fourth quarter of 2018.

On a GAAP basis, Afrezza gross profit was \$5.2 million for the year ended December 31, 2019, an improvement of \$7.3 million or 347% compared to a gross loss of \$2.1 million in the same period in 2018, primarily due to an increase of \$8.0 million in net revenue and a \$2.2 million decrease in inventory write-offs, partially offset by increased costs due to higher sales and an increase of \$0.8 million in fees paid to Amphastar for amendments to our insulin supply agreement. As a result, on a non-GAAP basis, gross profit was \$8.0 million, or 32%, for the year ended December 31, 2019 compared to a gross loss of \$0.1 million, or 1%, for the full year ended December 31, 2018.

R&D expenses for the year ended December 31, 2019 were \$6.9 million compared to \$8.7 million for the year ended December 31, 2018. This decrease of \$1.8 million, or 21%, was primarily attributable to a \$1.7 million decrease in personnel related costs and a \$0.9 million decrease in clinical trial spending, partially offset by increased expenses of \$0.2 million related to the development of our BluHale inhalation profiling apparatus and increased facility maintenance and equipment repair costs of \$0.5 million.

SG&A expenses for the year ended December 31, 2019 were \$74.7 million compared to \$79.7 million for the year ended December 31, 2018. This decrease of \$5.0 million, or 6%, was primarily attributable to a \$6.6 million decrease in personnel and employee related costs, decreased consulting costs of \$2.5 million and a \$1.2 million decrease in stock-based compensation costs, which was partially offset by a \$5.6 million increase in costs for television advertising for Afrezza.

Interest income increased by \$0.5 million, or 99%, for the year ended December 31, 2019 compared to the year ended December 31, 2018, primarily due to a higher average balance on money market funds and short-term investments.

Interest expense on debt for the year ended December 31, 2019 was \$10.9 million compared to \$9.4 million for the year ended December 31, 2018. This \$1.5 million increase was primarily attributable to a \$3.4 million charge realized as a result of achieving a sales milestone in the third quarter of 2019 under our milestone agreement with Deerfield, partially offset by lower interest as a result of the repayment of the Deerfield credit facility.

The net loss for the year ended December 31, 2019 was \$51.9 million, or \$0.27 per share, compared to \$87.0 million net loss for the year ended December 31, 2018, or \$0.60 per share. The lower net loss was mainly attributable to a \$35.2 million increase in total revenues.

Cash, Cash Equivalents, Restricted Cash and Short Term Investments

Cash, cash equivalents, restricted cash, and short-term investments at December 31, 2019 was \$50.2 million compared to \$71.7 million at December 31, 2018.

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 December 31,			
	2019	2018	\$ Change	% Change
Net revenue — Afrezza	\$ 7,761	\$ 5,734	\$ 2,027	35%
Less cost of goods sold	(4,632)	(4,986)	\$ (354)	(7%)
GAAP gross profit — Afrezza	3,129	748	\$ 2,381	318%
Exclude Amphastar amendment fee	—	2,000	\$ (2,000)	(100%)
Non-GAAP gross profit — Afrezza	\$ 3,129	\$ 2,748	\$ 381	14%
Non-GAAP gross margin	40%	48%		

	Twelve Months Ended December 31,			
	2019	2018	\$ Change	% Change
Net revenue — Afrezza	\$ 25,304	\$ 17,276	\$ 8,028	46%
Less cost of goods sold	(20,078)	(19,392)	\$ 686	4%
GAAP gross profit (loss) — Afrezza	5,226	(2,116)	\$ 7,342	347%
Exclude Amphastar amendment fee	2,750	2,000	\$ 750	38%
Non-GAAP gross profit (loss) — Afrezza	\$ 7,976	\$ (116)	\$ 8,092	6,976%
Non-GAAP gross margin	32%	(1%)		

Conference Call

MannKind will host a conference call and presentation webcast to discuss these results today at 9:00 a.m. Eastern Time. To participate in the live call by telephone, please dial (800) 289-0438 or (323) 794-2423 and use the participant passcode: 1233728. 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: 1233728. 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 pulmonary arterial hypertension. MannKind is currently commercializing Afrezza® (insulin human) Inhalation Powder, the Company's first FDA-approved product and the only inhaled 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, including statements regarding 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 the 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 ability to generate significant product sales for MannKind, MannKind's ability to manage its existing cash resources or raise additional cash resources, stock price volatility and other risks detailed in MannKind's filings with the Securities and Exchange Commission, including the Annual Report on Form 10-K for the year ended December 31, 2019 and subsequent periodic reports on Form 10-Q and current reports on Form 8-K. 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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MANKIND CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except per share data)

	<u>Three Months Ended December 31,</u>		<u>Twelve Months Ended December 31,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Revenues:				
Net revenue — commercial product sales	\$ 7,761	\$ 5,734	\$ 25,304	\$ 17,276
Revenue — collaborations and services	8,232	10,351	37,734	10,583
Revenue — other	—	(53)	—	—
Total revenues	<u>15,993</u>	<u>16,032</u>	<u>63,038</u>	<u>27,859</u>
Expenses:				
Cost of goods sold	4,632	4,986	20,078	19,392
Cost of revenue — collaborations and services	2,389	1,077	7,901	1,077
Research and development	2,021	1,084	6,900	8,737
Selling, general and administrative	15,721	17,976	74,669	79,716
Loss (gain) on foreign currency translation	2,582	(1,361)	(1,913)	(4,468)
Total expenses	<u>27,345</u>	<u>23,762</u>	<u>107,635</u>	<u>104,454</u>
Loss from operations	<u>(11,352)</u>	<u>(7,730)</u>	<u>(44,597)</u>	<u>(76,595)</u>
Other (expense) income:				
Interest income	204	196	997	501
Interest expense on notes	(1,021)	(620)	(6,304)	(5,116)
Interest expense on promissory notes	(1,251)	(1,089)	(4,602)	(4,323)
Gain (loss) on extinguishment of debt	—	—	3,529	(765)
Other expense	(843)	(508)	(926)	(437)
Total other expense	<u>(2,911)</u>	<u>(2,021)</u>	<u>(7,306)</u>	<u>(10,140)</u>
Loss before income tax expense	<u>(14,263)</u>	<u>(9,751)</u>	<u>(51,903)</u>	<u>(86,735)</u>
Provision for income taxes	—	—	—	240
Net loss	<u>\$ (14,263)</u>	<u>\$ (9,751)</u>	<u>\$ (51,903)</u>	<u>\$ (86,975)</u>
Net loss per share — basic and diluted	<u>\$ (0.07)</u>	<u>\$ (0.06)</u>	<u>\$ (0.27)</u>	<u>\$ (0.60)</u>
Shares used to compute net loss per share — basic and diluted	<u>206,689</u>	<u>161,397</u>	<u>195,584</u>	<u>144,136</u>

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

	December 31,	
	2019	2018
	(In thousands except per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 29,906	\$ 71,157
Restricted cash	316	527
Short-term investments	19,978	—
Accounts receivable, net	3,513	4,017
Inventory	4,155	3,597
Prepaid expenses and other current assets	2,889	2,556
Total current assets	<u>60,757</u>	<u>81,854</u>
Property and equipment, net	26,778	25,602
Other assets	6,190	249
Total assets	<u>\$ 93,725</u>	<u>\$ 107,705</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 4,789	\$ 5,379
Accrued expenses and other current liabilities	15,904	15,022
Facility financing obligation	—	11,298
Short-term note payable	5,028	—
Deferred revenue — current	32,503	36,885
Recognized loss on purchase commitments — current	7,394	6,657
Total current liabilities	<u>65,618</u>	<u>75,241</u>
Promissory notes	70,020	72,089
Accrued interest — promissory notes	2,002	6,835
Long-term Midcap credit facility	38,851	—
Senior convertible notes	5,000	19,099
Recognized loss on purchase commitments — long term	84,639	91,642
Operating lease liability	2,514	—
Deferred revenue — long term	8,344	10,680
Milestone rights liability	7,263	7,201
Total liabilities	<u>284,251</u>	<u>282,787</u>
Commitments and contingencies		
Stockholders' deficit:		
Undesignated preferred stock, \$0.01 par value — 10,000,000 shares authorized; no shares issued or outstanding at December 31, 2019 and 2018	—	—
Common stock, \$0.01 par value — 280,000,000 shares authorized, 211,787,573 and 187,029,967 shares issued and outstanding at December 31, 2019 and 2018, respectively	2,118	1,870
Additional paid-in capital	2,799,278	2,763,067
Accumulated other comprehensive loss	(19)	(19)
Accumulated deficit	(2,991,903)	(2,940,000)
Total stockholders' deficit	<u>(190,526)</u>	<u>(175,082)</u>
Total liabilities and stockholders' deficit	<u>\$ 93,725</u>	<u>\$ 107,705</u>