
**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 6, 2019

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 6, 2019, 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 6, 2019](#)

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 6, 2019

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 Third Quarter Preliminary Financial Results

Conference Call to Begin Today at 9:00 AM ET

- **3Q 2019 Total Revenues of \$14.6 million; +227% vs. 3Q 2018**
 - **3Q 2019 Afrezza Net Revenue was \$6.4 million; +46% vs. 3Q 2018**
 - **Afrezza sold to our marketing partner in Brazil for launch was \$0.7 million**
 - **3Q 2019 Collaborations and Services Revenue was \$8.2 million**
- **Debt financing completed providing up to \$75.0 million in non-dilutive capital**
- **Received second \$12.5 million milestone payment from United Therapeutics in November 2019**
- **Advanced Technosphere® formulations of sumatriptan and tadalafil into nonclinical pharmacology studies**

WESTLAKE VILLAGE, California November 6, 2019 (GLOBE NEWSWIRE) — MannKind Corporation (NASDAQ:MNKD) today reported preliminary financial results for the quarter and nine months ended September 30, 2019.

“I am excited to see MannKind continue its transformation, with another quarter of double-digit growth in Afrezza revenue, year over year, and aggregate net revenue of \$14.6 million,” said Michael Castagna, Chief Executive Officer of MannKind Corporation. “In the third quarter, we completed our recapitalization and achieved several key milestones, such as booking our first international sale of Afrezza to Brazil, seeing the first PAH patient dosed with TreT and progressing two pipeline compounds into nonclinical testing.”

Third Quarter 2019 Results

Net revenues were \$14.6 million for the third quarter of 2019, reflecting Afrezza net revenue of \$6.4 million and collaborations and services revenue of \$8.2 million. Afrezza net revenue increased 46% compared to \$4.4 million in the third quarter of 2018, primarily driven by higher product demand (including the first shipment to Brazil), a more favorable mix of Afrezza cartridges and price.

Collaborations and services revenue increased \$8.1 million compared to the third quarter of 2018, primarily driven by the license agreement with United Therapeutics, which began in the fourth quarter of 2018.

On a GAAP basis, Afrezza gross loss was \$0.7 million for the third quarter of 2019 compared to a gross loss of \$0.9 million in the same period in 2018. Afrezza cost of goods sold for the third quarter of 2019 included a one-time fee of \$2.75 million recorded in connection with the amendment of the Company’s insulin supply agreement with Amphastar in August 2019. As a result, on a non-GAAP basis, gross profit was \$2.1 million or 33% for the third quarter of 2019.

Research and development (R&D) expenses for the third quarter of 2019 were \$1.6 million compared to \$2.0 million for the third quarter of 2018. This 23% decrease was primarily attributable to a \$0.4 million decrease in clinical trial spending.

Selling, general and administrative (SG&A) expenses for the third quarter of 2019 were \$16.7 million compared to \$19.4 million for the third quarter of 2018. This decrease of \$2.7 million, or 14%, was primarily attributable to a \$0.8 million decrease in personnel-related costs and a \$1.9 million decrease in Afrezza marketing costs.

Interest expense on notes for the third quarter of 2019 was \$4.1 million compared to \$1.0 million for the third quarter of 2018. This \$3.1 million increase or 316% was primarily attributable to a \$3.4 million charge realized as a result of achieving of a sales milestone in the third quarter of 2019 under the Company’s milestone agreement with Deerfield.

The net loss for the third quarter of 2019 was \$10.4 million, or \$0.05 per share compared to a \$24.2 million net loss in the third quarter of 2018 or \$0.16 per share. The decrease was primarily the result of increased total revenues from higher Afrezza commercial demand and from the licensing and research agreements with United Therapeutics.

Nine Months Ended September 30, 2019

Net revenues were \$47.0 million for the nine months ended September 30, 2019, reflecting Afrezza net revenue of \$17.5 million and collaborations and services revenue of \$29.5 million. Afrezza net revenue increased 52% compared to \$11.5 million for the nine months ended September 30, 2018, primarily due to higher product demand (including the first shipment to Brazil), a more favorable mix of Afrezza cartridges and price. Collaborations and services revenue increased \$29.3 million compared to the nine months ended September 30, 2018, which was primarily attributed to the licensing agreement (\$23.3 million) and research agreement (\$5.9 million) with United Therapeutics, both of which began in the fourth quarter of 2018.

On a GAAP basis, Afrezza gross profit was \$2.1 million for the nine months ended September 30, 2019, an improvement of \$5.0 million or 173% compared to a gross loss of \$2.9 million in the same period in 2018, primarily due to an increase of \$6.0 million in net revenue, a \$1.8 million decrease in inventory write-offs, partially offset by increased costs due to higher sales and the Amphastar one-time amendment fee of \$2.75 million in the third quarter of 2019. As a result, on a non-GAAP basis, gross profit was \$4.9 million or 28% for the nine months ended September 30, 2019.

R&D expenses for the nine months ended September 30, 2019 were \$4.9 million compared to \$7.7 million for the nine months ended September 30, 2018. This \$2.8 million or 36% decrease was primarily attributable to a \$1.0 million decrease in personnel-related costs and a \$1.1 million decrease in clinical trial spending.

SG&A expenses for the nine months ended September 30, 2019 were \$58.9 million compared to \$61.7 million for the nine months ended September 30, 2018. This decrease of \$2.7 million or 5% was primarily attributable to a \$6.1 million decrease in personnel related costs, \$1.9 million decrease in professional fees, a \$1.0 million decrease in stock-based compensation costs offset by a \$6.8 million increase in costs for a television campaign for Afrezza.

Interest income increased by \$0.5 million or 160% for the nine months ended September 30, 2019 primarily attributable to a higher balance on money market funds and other short-term investments.

Interest expense on notes for the nine months ended September 30, 2019 was \$5.3 million compared to \$4.5 million for the nine months ended September 30, 2018. This \$0.8 million increase was primarily attributable to a \$3.4 million charge realized as a result of achieving of a sales milestone in the third quarter of 2019 under the Company's milestone agreement with Deerfield, partially offset by a reduction in debt principal balances.

The net loss for the nine months ended September 30, 2019 was \$37.6 million, or \$0.20 per share compared to a \$77.2 million net loss for the nine months ended September 30, 2018 or \$0.56 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 September 30, 2019 was \$50.4 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 September 30,

(\$ in million)	2019	2018	<i>\$ Chg</i>	<i>% Chg</i>
Net Revenue - Afrezza	\$ 6.4	\$ 4.4	\$ 2.0	45%
Cost of Goods Sold	(7.1)	(5.3)	(1.8)	-34%
GAAP Gross Profit (Loss) - Afrezza	\$ (0.7)	\$ (0.9)	0.2	22%
Exclude Amphastar Amendment Fee	2.8	-	2.8	
Non-GAAP Gross Profit (Loss) - Afrezza	\$ 2.1	\$ (0.9)	\$ 3.0	333%
Non-GAAP Gross Margin	33%	-20%		

Nine Months Ended September 30,

(\$ in million)	2019	2018	<i>\$ Chg</i>	<i>% Chg</i>
Net Revenue - Afrezza	\$ 17.5	\$ 11.5	\$ 6.0	52%
Cost of Goods Sold	(15.4)	(14.4)	(1.0)	-7%
GAAP Gross Profit (Loss) - Afrezza	\$ 2.1	\$ (2.9)	5.0	172%
Exclude Amphastar Amendment Fee	2.8	-	2.8	
Non-GAAP Gross Profit (Loss) - Afrezza	\$ 4.9	\$ (2.9)	\$ 7.8	269%
Non-GAAP Gross Margin	28%	-25%		

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 (866) 548-4713 or (323) 794-2093 and use the participant passcode: 8987532. 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: 8987532. 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, 2018 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.

Company Contact:
818-661-5000
ir@mannkindcorp.com

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,	
	2019	2018	2019	2018
Revenues:				
Net revenue - commercial product sales	\$ 6,402	\$ 4,387	\$ 17,543	\$ 11,542
Revenue - collaborations and services	8,193	82	29,502	232
Revenue - other	—	—	—	53
Total revenues	<u>14,595</u>	<u>4,469</u>	<u>47,045</u>	<u>11,827</u>
Expenses:				
Cost of goods sold	7,099	5,303	15,446	14,406
Cost of revenue - collaborations and services	1,836	—	5,512	—
Research and development	1,580	2,043	4,879	7,653
Selling, general and administrative	16,666	19,394	58,948	61,740
Gain on foreign currency translation	(3,807)	(728)	(4,495)	(3,107)
Total expenses	<u>23,374</u>	<u>26,012</u>	<u>80,290</u>	<u>80,692</u>
Loss from operations	<u>(8,779)</u>	<u>(21,543)</u>	<u>(33,245)</u>	<u>(68,865)</u>
Other (expense) income:				
Interest income	220	144	794	305
Interest expense on notes	(4,126)	(993)	(5,283)	(4,496)
Interest expense on promissory notes	(1,162)	(1,074)	(3,351)	(3,234)
Gain (loss) on extinguishment of debt	3,529	(712)	3,529	(765)
Other income (expense)	(52)	10	(84)	71
Total other expense	<u>(1,591)</u>	<u>(2,625)</u>	<u>(4,395)</u>	<u>(8,119)</u>
Loss before provision for income taxes	<u>(10,370)</u>	<u>(24,168)</u>	<u>(37,640)</u>	<u>(76,984)</u>
Provision for income taxes	—	—	—	(240)
Net loss	<u>\$ (10,370)</u>	<u>\$ (24,168)</u>	<u>\$ (37,640)</u>	<u>\$ (77,224)</u>
Net loss per share - basic and diluted	<u>\$ (0.05)</u>	<u>\$ (0.16)</u>	<u>\$ (0.20)</u>	<u>\$ (0.56)</u>
Shares used to compute basic and diluted net loss per share	<u>199,906</u>	<u>153,597</u>	<u>191,786</u>	<u>138,307</u>

MANNKIND CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

(In thousands, except per share data)

	September 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 30,173	\$ 71,157
Restricted cash	316	527
Short-term investments	19,885	—
Accounts receivable, net	4,093	4,017
Inventory	3,692	3,597
Prepaid expenses and other current assets	3,584	2,556
Total current assets	61,743	81,854
Property and equipment, net	27,126	25,602
Right-of-use and other assets	6,271	249
Total assets	\$ 95,140	\$ 107,705
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 11,664	\$ 5,379
Accrued expenses and other current liabilities	14,298	15,022
Facility financing obligation	—	11,298
Senior convertible notes - current	2,520	—
Deferred revenue - current	32,212	36,885
Recognized loss on purchase commitments - current	3,593	6,657
Total current liabilities	\$ 64,287	\$ 75,241
Senior convertible notes	7,437	19,099
Credit facility	38,798	—
Promissory notes	70,019	72,089
Accrued interest - promissory notes	807	6,835
Recognized loss on purchase commitments - long term	85,858	91,642
Deferred revenue - long term	2,631	10,680
Milestone rights liability	7,263	7,201
Operating lease liabilities	2,746	—
Total liabilities	\$ 279,846	\$ 282,787
Commitments and contingencies		
Stockholders' deficit:		
Common stock, \$0.01 par value - 280,000,000 shares authorized, 206,407,551 and 187,029,967 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	\$ 2,064	\$ 1,870
Additional paid-in capital	2,790,890	2,763,067
Accumulated other comprehensive loss	(20)	(19)
Accumulated deficit	(2,977,640)	(2,940,000)
Total stockholders' deficit	\$ (184,706)	\$ (175,082)
Total liabilities and stockholders' deficit	\$ 95,140	\$ 107,705