
**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 26, 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.

Item 2.02. Results of Operations and Financial Condition.

On February 26, 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 February 26, 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: February 26, 2019

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



MannKind Corporation Fourth Quarter and Year-End 2018 Earnings Call
Conference Call to Begin Today at 9:00 AM ET

- **4Q 2018 Total Revenues were \$16.0 million; 254% growth vs. 4Q 2017**
 - **4Q 2018 Afrezza Net Revenue was \$5.7 million; 28% growth vs. 4Q 2017 on a GAAP basis and 86% when adjusted for a one-time change in estimate recognized in 4Q 2017**
 - **4Q 2018 Collaborations and Services Revenue was \$10.3 million**
- **2018 Total Revenues were \$27.9 million; 137% growth vs. 2017**
 - **2018 Afrezza Net Revenue was \$17.3 million; 88% growth vs. 2017**
 - **2018 Collaborations and Services Revenue was \$10.6 million**
- **Ended 2018 with \$71.7 million in cash, cash equivalents and restricted cash**
- **Received \$57.2 million in 2018 from license and research agreements with United Therapeutics and Cipla**
- **Achieved first-ever quarterly Afrezza gross profit in 4Q 2018**
- **Reduced insulin purchase commitments for 2018 and 2019 by approximately \$11.5 million**

WESTLAKE VILLAGE, CA, February 26, 2019 (GLOBE NEWSWIRE) — MannKind Corporation (NASDAQ:MNKD) today reported financial results for the fourth quarter and full year ended December 31, 2018.

Fourth Quarter Results

For the fourth quarter of 2018, total revenues were \$16.0 million, reflecting Afrezza net revenue of \$5.7 million and collaboration and services revenue of \$10.3 million. Afrezza net revenue increased 28% on a GAAP basis compared to \$4.5 million for the fourth quarter of 2017. In the fourth quarter of 2017, we recognized a \$1.4 million change in estimate to Afrezza net revenue; when this adjustment is excluded, Afrezza net revenue increased 86% (non-GAAP) compared to the fourth quarter of 2017, primarily driven by higher product demand and a more favorable mix of cartridges. Collaborations and services revenue increased \$10.2 million primarily attributable to the United Therapeutics licensing and research agreements.

Afrezza cost of goods sold (COGS) was \$5.0 million for the fourth quarter of both 2018 and 2017. Afrezza COGS in the fourth quarter of 2018 reflected a one-time charge of \$2.0 million related to an amendment fee associated with our insulin supply agreement, offset by lower inventory write-offs in 2018 of \$0.8 million and \$0.7 million lower spending associated with manufacturing absorption. Afrezza gross profit was \$0.7 million for the fourth quarter, the first quarterly gross profit recognized from Afrezza sales. When the one-time charge of \$2.0 million related to the amendment fee is excluded, Afrezza gross profit was \$2.7 million (non-GAAP) for the fourth quarter.

Research and development (R&D) expenses for the fourth quarter of 2018 were \$1.1 million compared to \$3.5 million for the fourth quarter of 2017. The decrease of \$2.4 million was primarily due to \$0.8 million associated with the United Therapeutics research agreement, which was classified as a cost of collaborations and services revenue, and a decrease in spending of \$0.8 million related to clinical trials.

Selling, general and administrative (SG&A) expenses were \$18.0 million for the fourth quarter of 2018 compared to \$23.3 million for the fourth quarter of 2017. The decrease of \$5.3 million was primarily due to \$5.0 million in selling expenses associated with our first direct-to-consumer television advertising campaign in the fourth quarter of 2017.

Interest expense on notes (facility financing obligation and senior convertible notes) was \$0.6 million for the fourth quarter of 2018 compared to \$2.1 million for the fourth quarter of 2017. The \$1.5 million decrease was primarily due to a reduction in the debt principal balances.

The net loss for the fourth quarter of 2018 was \$9.7 million, or \$0.06 per share, compared to the \$32.8 million net loss in the fourth quarter of 2017, or \$0.28 per share. The lower net loss is mainly attributable to an increase in total revenues of \$11.5 million and a decrease in total expenses of \$9.6 million.

Full Year 2018 Results

For the full year ended December 31, 2018, total revenues were \$27.9 million, reflecting Afrezza net revenue of \$17.3 million and collaborations and service revenue of \$10.6 million. Afrezza net revenue increased 88% compared to \$9.2 million for the same period in 2017, primarily reflecting increased product demand and a more favorable mix of cartridges. Collaborations and services revenue increased \$10.3 million primarily attributable to the United Therapeutics licensing and research agreements.

Afrezza COGS for the year ended December 31, 2018 was \$19.4 million compared to \$17.2 million for the year ended December 31, 2017. The increase of \$2.2 million was primarily attributable to an increase in costs associated with increased Afrezza sales and a one-time charge of \$2.0 million related to an amendment fee associated with our insulin supply agreement, offset by a decrease of \$0.8 million in inventory write-offs.

R&D expenses for the year ended December 31, 2018 were \$8.7 million compared to \$14.1 million for the same period in 2017. This \$5.4 million decrease was primarily attributable to lower clinical trials expenses of \$2.2 million, a \$1.7 million decrease in salary-related expenses and a \$0.8 million decrease in research and development supply and services costs.

SG&A expenses were \$79.7 million for the year ended December 31, 2018 compared to \$75.0 million for the same period in 2017. The \$4.7 million increase was primarily due to an increase of \$2.9 million in headcount-related expenses associated with commercial operations, an increase in spending of \$1.7 million in our human resources, accounting, corporate communications, and office support departments, a \$1.4 million increase in medical affairs support, a \$1.3 million increase in stock-based compensation expense, and a one-time \$1.1 million expense to transition corporate support functions from Connecticut to our headquarters in California, which were partially offset by a decrease in selling expenses of \$4.7 million associated with our 2017 direct-to-consumer television advertising campaign.

Interest expense on notes (facility financing obligation and senior convertible notes) was \$5.1 million for the year ended December 31, 2018 compared to \$9.5 million for the same period in 2017. The \$4.4 million decrease was primarily due to a reduction in the debt principal balances.

The net loss for the year ended December 31, 2018 was \$87.0 million, or \$0.60 per share, compared to \$117.3 million for the year ended December 31, 2017, or \$1.13 per share. The lower net loss is mainly attributable to an increase in Afrezza net revenue of \$8.1 million, an increase in collaboration revenue of \$10.3 million and a decrease in total expenses of \$15.5 million.

“Our fourth quarter and full year 2018 results showed excellent progress in executing against our Afrezza growth plan and recognized for the first time revenues associated with our license and collaboration agreement with United Therapeutics,” said Michael Castagna, Chief Executive Officer of MannKind Corporation. “The fourth quarter of last year was the first time we reported gross profit for Afrezza and we ended the year with a strong cash position thanks to the United Therapeutics deal and a public offering of common stock and warrants in December.”

Cash and Cash Equivalents

Cash, cash equivalents and restricted cash at December 31, 2018 was \$71.7 million compared to \$48.4 million at December 31, 2017. The increase was primarily due to the net proceeds of \$26.4 million from a second quarter registered direct offering of common stock and warrants and \$37.5 million from a fourth quarter public offering of common stock and warrants, partially offset by the net cash used in operating activities of \$37.7 million (inclusive of two payments from United Therapeutics totaling \$55.0 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.

(\$ in millions)

Net Revenue - Afrezza 4Q 2017

GAAP 4Q 2017 Net Revenue - Afrezza	\$ 4.5
Change in Estimate Recorded 4Q 2017	<u>(1.4)</u>
Non-GAAP 4Q 2017 Net Revenue - Afrezza	<u>\$ 3.1</u>

Afrezza Gross Profit 4Q 2018

Afrezza Net Revenue	\$ 5.7
Afrezza Cost of Goods Sold	<u>(5.0)</u>
GAAP Afrezza Gross Profit	<u>\$ 0.7</u>

Non-GAAP % Increase in 4Q 2018 Afrezza Net Revenue		Non-GAAP Afrezza Gross Profit 4Q 2018	
GAAP 4Q 2018 Net Revenue - Afrezza	\$ 5.7	GAAP Afrezza Gross Profit	\$ 0.7
Non-GAAP 4Q 2017 Net Revenue - Afrezza	\$ 3.1	Without One-Time Fee	<u>2.0</u>
% Increase in 4Q 2018 Afrezza Net Revenue	86%	Non-GAAP Afrezza Gross Profit	<u>\$ 2.7</u>

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 (888) 394-8218 or (323) 701-0225 and use the participant passcode: 7809405. 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: 7809405#. 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. 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.

MANKIND CORPORATION AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands except per share data)

	Three months ended December 31,		Twelve months ended December 31,	
	2018	2017	2018	2017
Revenues:				
Net revenue - commercial product sales	\$ 5,734	\$ 4,466	\$ 17,276	\$ 9,192
Revenue - collaborations and services	10,298	63	10,583	250
Revenue - other	—	1	—	2,303
Total revenues	16,032	4,530	27,859	11,745
Expenses:				
Cost of goods sold	4,996	5,018	19,402	17,228
Cost of revenue - collaborations and services	1,077	—	1,077	—
Research and development	1,083	3,507	8,737	14,118
Selling, general and administrative	17,973	23,278	79,716	74,959
Property and equipment impairment	—	—	—	203
(Gain) loss on foreign currency translation	(1,361)	1,564	(4,468)	13,641
Gain on purchase commitments	(10)	—	(10)	(215)
Total expenses	23,758	33,367	104,454	119,934
(Loss) income from operations	(7,726)	(28,837)	(76,595)	(108,189)
Other (expense) income:				
Change in fair value of warrant liability	—	—	—	5,488
Interest income	196	115	501	293
Interest expense on notes	(620)	(2,056)	(5,116)	(9,494)
Interest expense on note payable to related party	(1,089)	(1,174)	(4,323)	(3,782)
(Loss) gain on extinguishment of debt	—	(781)	(765)	(1,611)
Other income (expense)	(508)	—	(437)	13
Total other (expense) income	(2,021)	(3,896)	(10,140)	(9,093)
(Loss) income before income tax expense	(9,747)	(32,733)	(86,735)	(117,282)
Provision for income taxes	—	51	240	51
Net (loss) income	\$ (9,747)	\$ (32,784)	\$ (86,975)	\$ (117,333)
Net (loss) income per share - basic	\$ (0.06)	\$ (0.28)	\$ (0.60)	\$ (1.13)
Net (loss) income per share - diluted	\$ (0.06)	\$ (0.28)	\$ (0.60)	\$ (1.13)
Shares used to compute basic net (loss) income per share	161,397	116,451	144,136	104,245
Shares used to compute diluted net (loss) income per share	161,397	116,451	144,136	104,245

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

	December 31,	
	2018	2017
(In thousands except per share data)		
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 71,157	\$ 43,946
Restricted cash	527	4,409
Accounts receivable, net	4,017	2,789
Inventory	3,597	2,657
Deferred costs from commercial product sales	—	405
Prepaid expenses and other current assets	2,556	3,010
Total current assets	<u>81,854</u>	<u>57,216</u>
Property and equipment, net	25,602	26,922
Other assets	249	437
Total assets	<u>\$ 107,705</u>	<u>\$ 84,575</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 5,379	\$ 6,984
Accrued expenses and other current liabilities	15,022	12,449
Facility financing obligation	11,298	52,745
Deferred revenue, net	—	3,038
Deferred payments from collaborations - current	36,885	250
Recognized loss on purchase commitments - current	6,657	12,131
Total current liabilities	<u>75,241</u>	<u>87,597</u>
Note payable to related party	72,089	79,666
Accrued interest - note payable to related party	6,835	2,347
Senior convertible notes	19,099	24,411
Recognized loss on purchase commitments - long term	91,642	97,585
Deferred payments from collaborations - long term	10,680	500
Milestone rights liability	7,201	7,201
Total liabilities	<u>282,787</u>	<u>299,307</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, 2018 and 2017	—	—
Common stock, \$0.01 par value - 280,000,000 shares authorized, 187,029,967 and 119,053,414 shares issued and outstanding at December 31, 2018 and 2017, respectively	1,870	1,192
Additional paid-in capital	2,763,067	2,638,992
Accumulated other comprehensive loss	(19)	(18)
Accumulated deficit	(2,940,000)	(2,854,898)
Total stockholders' deficit	<u>(175,082)</u>	<u>(214,732)</u>
Total liabilities and stockholders' deficit	<u>\$ 107,705</u>	<u>\$ 84,575</u>

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