

MANKIND CORP

FORM 8-K (Current report filing)

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Address	30930 RUSSELL RANCH ROAD SUITE 301 WESTLAKE VILLAGE, CA, 91362
Telephone	818-661-5000
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Symbol	MNKD
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Industry	Biotechnology & Medical Research
Sector	Healthcare
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**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 7, 2017

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 301, 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 November 7, 2017, 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 7, 2017](#)

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 7, 2017

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



MannKind Corporation Reports 2017 Third Quarter Financial Results

Conference Call to Begin Today at 5:00 PM ET

WESTLAKE VILLAGE, CA, Nov. 7, 2017 (GLOBE NEWSWIRE) -- **MannKind Corporation** (NASDAQ: MNKD) today reported financial results for the third quarter and the nine months ended September 30, 2017. Third quarter highlights include:

- Afrezza net revenue grew 28% and 246% vs. 2Q 2017 and 3Q 2016, respectively
- Cash burn of \$23.3 million in 3Q 2017
- Exchanged all outstanding Series A and B Common Stock Warrants for an aggregate of 1.3 million shares of the Company's common stock
- FDA approved label changes for Afrezza

Other recent highlights include:

- Issued 10.2 million shares of the Company's common stock in a registered direct offering resulting in receipt of net proceeds of \$57.7 million
- Exchanged senior convertible notes of \$27.7 million due August 2018 for senior convertible notes of \$23.7 million due October 2021 and 973,236 shares of the Company's common stock
- Extended the maturity of \$10 million of the Deerfield obligation from October 31, 2017 to January 15, 2018
- Allowed for certain outstanding principal under the Deerfield obligation to be converted into shares of the Company's common stock (including the \$10 million due January 2018). 4 million shares have been reserved for conversion.

Third Quarter Results

For the third quarter of 2017, Afrezza net revenue of \$2.0 million grew 28% vs. the second quarter of 2017 and 246% vs. the third quarter of 2016 (the first quarter for MannKind sales and commercial support of Afrezza after the termination of the Sanofi agreement). As of September 30, 2017, the amount of Afrezza shipped to the wholesale and retail channels, but not yet recognized as revenue, was \$3.0 million, an increase of \$0.4 million from June 30, 2017. A reconciliation of gross to net revenues can be found in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of the Form 10-Q for the quarter ended September 30, 2017.

Cost of goods sold was \$4.6 million in the third quarter of 2017 compared to (i) \$5.1 million in the second quarter of 2017, a decrease of \$0.5 million primarily related to a write-down of inventory in the second quarter, and (ii) \$4.4 million in the third quarter of 2016, an increase of \$0.2 million.

Research and development expenses were \$4.4 million in the third quarter of 2017 compared to (i) \$3.1 million in the second quarter of 2017, an increase of \$1.3 million primarily related to starting the Time in Range ("STAT" study) and the pediatric study, and (ii) \$4.0 million in the third quarter of 2016, an increase of \$0.4 million, primarily due to increases in clinical trials partially offset by a decrease in compensation expense related to a reduction in workforce in the fourth quarter of 2016.

Selling, general and administrative expenses were \$17.7 million for the third quarter of 2017 compared to (i) \$18.6 million for the second quarter of 2017, a decrease of \$1.1 million primarily from a reduction in commercial support expenses and (ii) \$13.1 million in the third quarter of 2016, an increase of \$4.6 million primarily due to scaling up the Afrezza commercial infrastructure during the first quarter of 2017. The net loss for the third quarter of 2017 was \$32.9 million, or a loss of \$0.31 per share based on 104.7 million weighted average shares outstanding, compared to net income of \$126.5 million, or \$1.32 per share on 95.6 million weighted average shares outstanding in the third quarter of 2016. The net income in the third quarter of 2016 included net revenue – collaboration of \$161.8 million related to the termination of the Sanofi agreement.

Nine Months Results

Due to the termination of the Sanofi agreement in early 2016 and MannKind's commencement of commercial activities for Afrezza in the third quarter of 2016, a comparative analysis for sales and commercial support between the nine months ended September 30, 2017 and September 30, 2016 is not meaningful.

For the nine months ended September 30, 2017, total net revenue of \$7.2 million was comprised of \$4.7 million of Afrezza net sales, \$1.7 million from the net sales of surplus bulk insulin to a third party, \$0.6 million from the sale of certain oncology intellectual property, and \$0.2 million from collaboration net revenue.

Cost of goods sold was \$12.2 million for the nine months ended September 30, 2017 compared to \$12.9 million for the same period in 2016, a decrease of \$0.7 million.

Research and development expenses were \$10.6 million for the nine months ended September 30, 2017 compared to \$13.4 million for the same period in 2016, a decrease of \$2.7 million or 21%, due primarily to a decrease in compensation expense of \$5.1 million as a result of the reduction in workforce in the fourth quarter of 2016. This decrease was partially offset by a \$2 million increase in clinical trials expense.

Selling, general and administrative expenses were \$51.7 million for the nine months ended September 30, 2017 compared to \$31.6 million for the same period in 2016, an increase of \$20.1 million due to the change in the commercial support structure after termination of the Sanofi agreement in 2016.

The net loss for the nine months ended September 30, 2017 was \$84.5 million, or a loss of \$0.84 per share based on 100.1 million weighted average shares outstanding, compared to net income of \$71.7 million, or \$0.79 per share on 90.8 million weighted average shares outstanding at September 30, 2016.

Cash and Cash Equivalents

Cash and cash equivalents at September 30, 2017 decreased to \$20.1 million from \$43.4 million at June 30, 2017, primarily due to cash burn for the third quarter of 2017 of \$23.3 million. The cash balance as of September 30, 2017 does not include \$57.7 million of net proceeds received from the registered direct offering of the Company's common stock completed in October 2017.

Afrezza Label Change

On September 29, 2017, the U.S. FDA approved an update to the Afrezza prescribing information for the inclusion of study data that describes the time action profile by dosage strength; clarity on "Starting" and "Adjusting" mealtime doses; and updated pregnancy and lactation guidance.

Conference Call

MannKind will host a conference call and presentation webcast to discuss these results today at 5:00 p.m. Eastern Time. To view and listen to the earnings call webcast, visit MannKind's website at <http://www.mannkindcorp.com> and click on the "Q3 2017 MannKind Earnings Conference Call" link in the Webcast section of News & Events. To participate in the live call by telephone, please dial (888) 771-4371 or (847) 585-4405 and use the participant passcode: 44096374.

A telephone replay will be accessible for approximately 14 days following completion of the call by dialing (888) 843-7419 or (630) 652-3042 and use the participant passcode: 4409 6374#. 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, 2016 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.

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,	
	2017	2016	2017	2016
Revenues:				
Net revenue - commercial product sales	\$ 1,981	\$ 573	\$ 4,726	\$ 573
Net revenue - collaboration	62	161,781	187	161,781
Revenue - other	—	—	2,302	—
Total revenues	2,043	162,354	7,215	162,354
Expenses:				
Cost of goods sold	4,575	4,394	12,210	12,912
Product costs - collaboration	—	22,742	—	22,742
Research and development	4,361	3,917	10,611	13,357
Selling, general and administrative	17,725	13,135	51,681	31,595
Property and equipment impairment	92	—	203	695
Loss on foreign currency translation	3,684	1,012	12,077	3,035
Gain on purchase commitment	(215)	(1,075)	(215)	(1,075)
Total expenses	30,222	44,125	86,567	83,261
(Loss) income from operations	(28,179)	118,229	(79,352)	79,093
Other income (expense):				
Change in fair value of warrant liability	(1,289)	13,185	5,488	7,879
Interest income	65	28	178	70
Interest expense on notes	(2,310)	(4,166)	(7,438)	(12,567)
Interest expense on note payable to principal stockholder	(1,173)	(729)	(2,608)	(2,172)
Loss on extinguishment of debt	—	—	(830)	—
Other (expense) income	—	(27)	13	(613)
Total other (expense) income	(4,707)	8,291	(5,197)	(7,403)
(Loss) income before benefit for income taxes	(32,886)	126,520	(84,549)	71,690
Income tax benefit	—	—	—	—
Net (loss) income	\$ (32,886)	\$ 126,520	\$ (84,549)	\$ 71,690
Net (loss) income per share - basic	\$ (0.31)	\$ 1.32	\$ (0.84)	\$ 0.79
Net (loss) income per share - diluted	\$ (0.31)	\$ 1.31	\$ (0.84)	\$ 0.79
Shares used to compute basic net (loss) income per share	104,703	95,627	100,136	90,838
Shares used to compute diluted net (loss) income per share	104,703	96,549	100,136	90,873

MANNKIND CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except par value and share data)

ASSETS	September 30, 2017	December 31, 2016
Current assets:		
Cash and cash equivalents	\$ 20,092	\$ 22,895
Accounts receivable, net	1,804	302
Receivable from Sanofi	—	30,557
Inventory	3,129	2,331
Asset held for sale	—	16,730
Deferred costs from commercial product sales	543	309
Prepaid expenses and other current assets	3,061	4,364
Total current assets	28,629	77,488
Property and equipment - net	27,374	28,927
Other assets	480	648
Total assets	<u>\$ 56,483</u>	<u>\$ 107,063</u>
 LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 5,283	\$ 3,263
Accrued expenses and other current liabilities	12,492	7,937
Facility financing obligation	57,942	71,339
Deferred revenue - net	3,021	3,419
Deferred payments from collaboration - current	250	1,000
Recognized loss on purchase commitments - current	12,480	5,093
Total current liabilities	91,468	92,051
Note payable to principal stockholder	79,666	49,521
Accrued interest - note payable to principal stockholder	1,173	9,281
Senior convertible notes	27,657	27,635
Recognized loss on purchase commitments - long term	99,769	95,942
Deferred payments from collaboration - long term	563	—
Warrant liability	—	7,381
Milestone rights liability and other liabilities	7,202	8,845
Total liabilities	<u>307,498</u>	<u>290,656</u>
Stockholders' deficit:		
Undesignated preferred stock, \$0.01 par value - 10,000,000 shares authorized; no shares issued or outstanding at September 30, 2017 and December 31, 2016	—	—
Common stock, \$0.01 par value - 140,000,000 shares authorized, 104,707,116 and 95,680,831 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	1,047	957
Additional paid-in capital	2,570,072	2,553,039
Accumulated other comprehensive loss	(20)	(24)
Accumulated deficit	(2,822,114)	(2,737,565)
Total stockholders' deficit	(251,015)	(183,593)
Total liabilities and stockholders' deficit	<u>\$ 56,483</u>	<u>\$ 107,063</u>

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