

**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, 2021

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, 2021, MannKind Corporation issued a press release, a copy of which is furnished herewith 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, 2021](#)

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: February 25, 2021

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 Fourth Quarter and Full Year Financial Results
Conference Call to Begin Today at 9:00 AM ET

- **4Q 2020 Afrezza Net Revenue of \$10.1 million; +30% vs. 4Q 2019**
 - **Sequential Quarter Growth +38% vs. 3Q 2020**
- **2020 Total Revenues of \$65.1 million**
 - **2020 Afrezza Net Revenue of \$32.3 million; +28% vs. 2019**
 - **2020 Afrezza Gross Profit \$17.2 million; 53% Gross Margin**
- **\$67.2 million of Cash, Cash Equivalents and Restricted Cash at December 31, 2020**
- **Acquired QrumPharma Inc. for \$12.8 million in cash and stock**
- **Entered into an agreement to co-promote Thyquidity beginning 1Q 2021**

WESTLAKE VILLAGE, California February 25, 2021 (GLOBE NEWSWIRE) — MannKind Corporation (NASDAQ:MNKD) today reported financial results for the fourth quarter and full year ended December 31, 2020.

“Our fourth quarter produced exceptional results, with \$10.1 million in Afrezza net revenue and positive clinical data for Tyvaso DPI from the BREEZE study conducted by United Therapeutics,” said Michael Castagna, Chief Executive Officer of MannKind Corporation. “UT also announced their plan to submit a new drug application for Tyvaso DPI to the FDA in April 2021. During the fourth quarter, we solidified our new direction with the acquisition of QrumPharma, which added a nebulized version of clofazimine to our pipeline of therapies for orphan lung diseases, and we entered into a collaboration agreement with Vertice for the co-promotion of Thyquidity, which is indicated for hyperthyroidism and is expected to expand our reach into endocrine diseases.”

Fourth Quarter 2020 Results

Total revenues were \$18.4 million for the fourth quarter of 2020, reflecting Afrezza net revenue of \$10.1 million and collaborations and services revenue of \$8.4 million. Afrezza net revenue increased 30% compared to \$7.8 million in the fourth quarter of 2019, primarily driven by higher product demand with a more favorable mix of Afrezza cartridges and more favorable gross-to-net deductions. Collaborations and services revenue increased \$0.2 million compared to the fourth quarter of 2019.

Afrezza gross profit for the fourth quarter of 2020 was \$6.4 million compared to \$3.1 million in the same period of 2019, an increase of \$3.3 million, or 105%, that was driven by a combination of increased Afrezza revenue and a reduction in cost of goods sold.

In-process research and development expense for the fourth quarter of 2020 was \$13.2 million, reflecting the acquisition of QrumPharma for approximately \$12.8 million in total consideration and approximately \$0.4 million in transaction costs. The acquisition of QrumPharma was accounted for as an asset acquisition and expensed on the date of acquisition as substantially all of the fair value of the assets acquired was concentrated in a single asset that consisted of in-process research and development in a pre-clinical development state.

Research and development expenses for the fourth quarter of 2020 were \$1.5 million compared to \$2.0 million for the fourth quarter of 2019. This decrease was mainly related to lower clinical trial spending.

Selling, general and administrative expenses for the fourth quarter of 2020 were \$17.1 million compared to \$15.7 million for the fourth quarter of 2019. This increase of \$1.4 million, or 9%, was primarily attributable to a \$1.2 million increase in personnel costs related to the expansion of our sales and medical field force.

During the fourth quarter of 2020, loss on foreign currency translation for insulin purchase commitments, which are denominated in Euros, was \$4.0 million compared to \$2.6 million for the fourth quarter of 2019. The fluctuation was due to a change in the U.S. dollar to Euro foreign exchange rate.

Interest expense on debt for the fourth quarter of 2020 was \$2.4 million compared to \$2.3 million for the fourth quarter of 2019.

The net loss for the fourth quarter of 2020 was \$26.4 million, or \$0.11 per share, compared to \$14.3 million in the fourth quarter of 2019, or \$0.07 per share. The increase in the net loss of \$12.1 million was primarily due to the write-off of in-process research and development related to the acquisition of QrumPharma. On a non-GAAP basis, excluding the expense incurred for the acquisition of QrumPharma, the net loss for the fourth quarter of 2020 was \$13.2 million, or \$0.06 per share.

Twelve Months Ended December 31, 2020

Total revenues were \$65.1 million for the year ended December 31, 2020, reflecting Afrezza net revenue of \$32.3 million and collaborations and services revenue of \$32.8 million. Afrezza net revenue increased 28% compared to \$25.3 million for the year ended December 31, 2019, primarily driven by higher product demand with a more favorable mix of Afrezza cartridges, a price increase and more favorable gross-to-net deductions, all of which was partially offset by a reduction in sales to Biomm (Brazil). Collaborations and services revenue decreased \$4.9 million compared to the full year ended December 31, 2019, primarily driven by a \$5.8 million decrease in revenue recognized from the UT Research Agreement, which was substantially completed in the second quarter of 2019.

Afrezza gross profit was \$17.2 million for the year ended December 31, 2020, an increase of \$12.0 million, or 230%, compared to a gross profit of \$5.2 million in the same period in 2019, primarily due higher commercial product sales combined with a reduction in cost of goods sold.

In-process research and development expense for the year ended December 31, 2020 was \$13.2 million, reflecting the research and development acquired and expensed from the acquisition of QrumPharma for approximately \$12.8 million in total consideration and approximately \$0.4 million in transaction costs.

Research and development expenses for the year ended December 31, 2020 were \$6.2 million compared to \$6.9 million for the year ended December 31, 2019. This decrease of \$0.7 million, or 9%, was primarily attributable to lower clinical trial spending.

Selling, general and administrative expenses for the year ended December 31, 2020 were \$59.0 million compared to \$74.7 million for the year ended December 31, 2019. This decrease of \$15.6 million, or 21%, was primarily attributable a \$9.3 million decrease in costs for television advertising for Afrezza, a \$4.1 million decrease in promotional and marketing activities in response to the COVID-19 pandemic and a \$2.5 million decrease in professional fees.

An impairment of \$1.9 million was recognized for the year ended December 31, 2020 on a commitment asset and debt issuance costs related to future funding commitments of the MidCap Credit Facility. There were no asset impairments for the year ended December 31, 2019.

For the year ended December 31, 2020, foreign currency translation for insulin purchase commitments, which are denominated in Euros, resulted in a loss of \$8.0 million compared to a gain of \$1.9 million for the year ended December 31, 2019. The fluctuation was due to a change in the U.S. dollar to Euro foreign exchange rate.

Interest expense on debt for the year ended December 31, 2020 was \$9.5 million compared to \$10.9 million for the year ended December 31, 2019. This \$1.4 million decrease was primarily attributable to a \$3.4 million milestone obligation

to Deerfield that was achieved in the third quarter of 2019 and a decrease of \$0.8 million of interest expense related to the Deerfield Credit Facility, which was extinguished in the third quarter of 2019. This decrease was partially offset by an increase in interest expense from the MidCap Credit Facility of \$2.3 million and an increase in interest expense from our Mann Group promissory notes of \$0.6 million in 2020.

The net loss for the year ended December 31, 2020 was \$57.2 million, or \$0.26 per share, compared to \$51.9 million net loss for the year ended December 31, 2019, or \$0.27 per share. The higher net loss was mainly attributable to the write-off of in-process research and development related to the acquisition of QrumPharma and a loss on foreign currency translation related to insulin purchase commitments denominated in Euros, offset by a decrease in selling, general and administrative expenses. On a non-GAAP basis, excluding the expense incurred for the acquisition of QrumPharma, the net loss for the year ended December 31, 2020 was \$44.0 million, or \$0.20 per share.

Cash, cash equivalents, restricted cash, and short-term investments at December 31, 2020 was \$67.2 million compared to \$50.2 million at December 31, 2019.

Debt Reductions Subsequent to December 31, 2020

Pursuant to the terms of the senior convertible notes, the Company forced the conversion of all \$5.0 million in principal of such notes into 1,666,667 shares of the Company's common stock.

In addition, the Mann Group converted \$9.6 million of principal and \$0.4 million of accrued interest on its convertible promissory note into 4.0 million shares of the Company's common stock. As of the date hereof, \$53.4 million in principal remains outstanding under the promissory notes held by the Mann Group (\$18.4 of which is convertible).

Sale-Leaseback of the Danbury Manufacturing Facility

Subsequent to December 31, 2020, the Company entered into a non-binding letter of intent ("LOI") with a third party to sell and lease back a portion of the Company's Danbury manufacturing facility and administrative offices. The terms of the LOI include a sales price of approximately \$95 million - \$105 million, a lease term of 20 years with four 5-year renewal options, and annual rent of approximately \$10 million - \$11 million at the beginning of the lease. If the transaction is completed, the Company intends to use the proceeds for general corporate purposes, and may also pay down a portion of its senior secured debt. The completion of the transactions contemplated by the LOI is subject to certain conditions, including the negotiation of satisfactory definitive agreements and satisfactory results of the buyer's inspections and other investigations, all of which are anticipated to be completed during the first quarter of 2021. However, there can be no assurances that this proposed transaction will be completed in the timeframe or on the principal terms set forth above, or at all.

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,		Twelve Months Ended December 31,	
	2020	2019	2020	2019
Net loss	\$ (26,411)	\$ (14,263)	\$ (57,240)	\$ (51,903)
GAAP net loss per share — basic and diluted	\$ (0.11)	\$ (0.07)	\$ (0.26)	\$ (0.27)
Net loss	\$ (26,411)	\$ (14,263)	\$ (57,240)	\$ (51,903)
Less in-process research and development	13,233	—	13,233	—
Non-GAAP net loss	\$ (13,178)	\$ (14,263)	\$ (44,007)	\$ (51,903)
Non-GAAP net loss per share — basic and diluted	\$ (0.06)	\$ (0.07)	\$ (0.20)	\$ (0.27)

Conference Call

MannKind will host a conference call and presentation webcast to discuss these results today at 9:00 a.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 replay will 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 endocrine 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. Afrezza is also available by prescription in Brazil where it is commercialized by the Company's partner Biomm SA. 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, 2020 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.

Tyvaso DPI (formerly known as TreT) is an investigational combination product that is not approved for any use in any country. The Tyvaso DPI tradename is pending final FDA review.

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

	December 31,	
	2020	2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 67,005	\$ 29,906
Restricted cash	158	316
Short-term investments	—	19,978
Accounts receivable, net	4,218	3,513
Inventory	4,973	4,155
Prepaid expenses and other current assets	3,122	2,889
Total current assets	79,476	60,757
Property and equipment, net	25,867	26,778
Other assets	3,265	6,190
Total assets	\$ 108,608	\$ 93,725
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 5,582	\$ 4,789
Accrued expenses and other current liabilities	19,707	15,904
Paycheck Protection Program loan — current	4,061	—
Short-term note payable	—	5,028
Deferred revenue — current	33,275	32,503
Recognized loss on purchase commitments — current	11,080	7,394
Total current liabilities	73,705	65,618
Promissory notes	63,027	70,020
Accrued interest — promissory notes	4,150	2,002
Long-term Midcap credit facility	49,335	38,851
Senior convertible notes	5,000	5,000
Recognized loss on purchase commitments — long term	84,208	84,639
Operating lease liability	1,202	2,514
Deferred revenue — long term	1,662	8,344
Milestone rights liability	5,926	7,263
Long-term debt - other	812	—
Total liabilities	289,027	284,251
Stockholders' deficit:		
Undesignated preferred stock, \$0.01 par value — 10,000,000 shares authorized; no shares issued or outstanding at December 31, 2020 and 2019	—	—
Common stock, \$0.01 par value — 400,000,000 and 280,000,000 shares authorized, 242,117,089 and 211,787,573 shares issued and outstanding at December 31, 2020 and 2019, respectively	2,421	2,118
Additional paid-in capital	2,866,303	2,799,278
Accumulated other comprehensive loss	—	(19)
Accumulated deficit	(3,049,143)	(2,991,903)
Total stockholders' deficit	(180,419)	(190,526)
Total liabilities and stockholders' deficit	\$ 108,608	\$ 93,725

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

	<u>Three Months Ended December 31,</u>		<u>Twelve Months Ended December 31,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Revenues:				
Net revenue — commercial product sales	\$ 10,064	\$ 7,761	\$ 32,324	\$ 25,304
Revenue — collaborations and services	8,379	8,232	32,820	37,734
Total revenues	<u>18,443</u>	<u>15,993</u>	<u>65,144</u>	<u>63,038</u>
Expenses:				
Cost of goods sold	3,652	4,632	15,084	20,078
Cost of revenue — collaborations and services	2,631	2,389	9,557	7,901
Research and development	1,545	2,021	6,248	6,900
Acquired In-Process R&D	13,233	—	13,233	—
Selling, general and administrative	17,121	15,721	59,040	74,669
Impairment of commitment asset	—	—	1,889	—
Loss (gain) on foreign currency translation	4,008	2,582	8,006	(1,913)
Total expenses	<u>42,190</u>	<u>27,345</u>	<u>113,057</u>	<u>107,635</u>
Loss from operations	<u>(23,747)</u>	<u>(11,352)</u>	<u>(47,913)</u>	<u>(44,597)</u>
Other (expense) income:				
Interest income	2	203	167	997
Interest expense on notes	(1,104)	(1,021)	(4,316)	(6,304)
Interest expense on promissory notes	(1,297)	(1,251)	(5,155)	(4,602)
(Loss) gain on extinguishment of debt	(264)	—	(264)	3,529
Other expense	(1)	(842)	23	(926)
Total other expense	<u>(2,664)</u>	<u>(2,911)</u>	<u>(9,545)</u>	<u>(7,306)</u>
Loss before income tax expense	<u>(26,411)</u>	<u>(14,263)</u>	<u>(57,458)</u>	<u>(51,903)</u>
Benefit from income taxes	—	—	218	—
Net loss	<u>\$ (26,411)</u>	<u>\$ (14,263)</u>	<u>\$ (57,240)</u>	<u>\$ (51,903)</u>
Net loss per share — basic and diluted	<u>\$ (0.11)</u>	<u>\$ (0.07)</u>	<u>\$ (0.26)</u>	<u>\$ (0.27)</u>
Shares used to compute net loss per share — basic and diluted	<u>234,575</u>	<u>206,689</u>	<u>222,585</u>	<u>195,584</u>