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MannKind Corporation Reports 2020 Third Quarter Financial Results

November 4, 2020

Conference Call to Begin Today at 5:00 PM ET

- 3Q 2020 U.S. Afrezza Net Revenue of \$7.3 million; +27% vs. 3Q 2019
- 3Q YTD 2020 U.S. Afrezza Net Revenue of \$22.1 million; +31% vs. 3Q YTD 2019
- Cash and cash equivalents of \$52.4 million at September 30, 2020
- On track to complete Treprostinil Technosphere development activities in 4Q 2020
- Expanded Afrezza commercial and medical teams
- YTD Afrezza scientific presentations and publications total 14

WESTLAKE VILLAGE, Calif., Nov. 04, 2020 (GLOBE NEWSWIRE) -- MannKind Corporation (NASDAQ:MNKD) today reported financial results for the quarter and nine months ended September 30, 2020.

"Our employees continue to execute in a tumultuous Covid-19 environment," said Michael Castagna, Chief Executive Officer. "As we head toward year-end, our focus remains on two significant drivers of value for shareholders: enabling healthcare providers to increase their prescribing of Afrezza and supporting United Therapeutics as they move the TreT clinical program to completion, including manufacturing TreT clinical supplies."

Third Quarter 2020 Results

Total revenues were \$15.4 million for the third quarter of 2020, reflecting Afrezza net revenue of \$7.3 million and collaboration and services revenue of \$8.1 million. Afrezza U.S net revenue of \$7.3 million increased 27% compared to \$5.7 million in the third quarter of 2019, driven by higher product demand, a favorable mix of cartridges, and price. The first sale of Afrezza to the Company's marketing partner in Brazil was completed in the third quarter of 2019 for \$0.7 million; there were no international sales in the third quarter of 2020. Collaboration and services revenue for the third quarter of 2020 decreased \$0.1 million compared to the third quarter of 2019.

Afrezza gross profit for the third quarter of 2020 was \$3.7 million compared to a loss of \$0.7 million in the same period of 2019, an increase of \$4.4 million that was driven primarily by higher Afrezza revenue combined with a reduction in cost of goods sold, primarily attributable to a \$2.8 million amendment fee associated with our insulin supply agreement in 2019. Non-GAAP gross margin in the third quarter of 2020 increased to 51% from 32% for the same quarter in 2019.

Selling, general and administrative expenses for the third quarter of 2020 were \$13.9 million compared to \$16.7 million for the third quarter of 2019. This 17% decrease was primarily due to a \$1.2 million reduction in promotional and marketing activities and a \$0.8 million decrease in professional costs.

Interest expense for the third quarter of 2020 was \$2.4 million compared to \$5.3 million for the third quarter of 2019. This \$2.9 million decrease was primarily attributable to a \$3.4 million milestone obligation that occurred in the third quarter of 2019, partially offset by interest expense from the MidCap Credit Facility.

A loss on foreign currency translation for the third quarter of 2020 was \$3.9 million compared to a \$3.8 million gain for the third quarter of 2019. The fluctuation is related to the change in the U.S. dollar to Euro foreign exchange rate on the recognized loss on insulin purchase commitments, which are denominated in Euros.

The net loss for the third quarter of 2020 was \$11.3 million, or \$0.05 per share, compared to a \$10.4 million net loss, or \$0.05 per share in the third quarter of 2019. The higher net loss was mainly attributable to the change in foreign currency translation from a gain in 2019 to a loss in 2020, partially offset by the reduction in cost of goods sold, selling, general and administrative expenses and interest expense.

Nine Months Ended September 30, 2020

Total revenues were \$46.7 million for the nine months ended September 30, 2020, reflecting Afrezza net revenue of \$22.3 million and collaboration and services revenue of \$24.4 million. Afrezza net revenue increased 27% compared to \$17.5 million for the nine months ended September 30, 2019, primarily driven by higher product demand, a more favorable mix of cartridges and price, partially offset by a reduction in sales to Biomm (Brazil). Collaboration and services revenue for the nine months ended September 30, 2020 decreased \$5.1 million compared to the same period in the prior year, primarily due to a \$5.7 million decrease in revenue recognized from the UT Research Agreement, which was substantially completed in 2019.

Afrezza gross profit for the nine months ended September 30, 2020 was \$10.8 million compared to \$2.1 million in the same period of 2019, an increase of \$8.7 million, or +416%, that was driven primarily by a reduction in cost of goods sold combined with higher commercial product sales. Cost of goods sold decreased by \$4.0 million, primarily attributable to a \$2.8 million amendment fee associated with our insulin supply agreement in 2019, \$0.8 million of increased 2020 manufacturing activities which resulted in a greater amount of costs capitalized to inventory and \$1.1 million in reduced 2020 manufacturing-related spending, partially offset by \$0.5 million of 2020 inventory write-offs and \$0.4 million in costs associated with higher commercial product sales. Non-GAAP gross margin for the nine months ended September 30, 2020 increased to 49% from 28% for the same period in 2019, primarily due to higher Afrezza revenue and lower cost of goods sold.

Selling, general and administrative expenses for the nine months ended September 30, 2020 were \$41.9 million compared to \$58.9 million for the same period in 2019. This 29% decrease was primarily due to \$9.3 million spent on direct-to-consumer television advertising in 2019 (which was not repeated in 2020), a \$4.1 million decrease in promotional and marketing activities, a \$1.3 million decrease in consulting costs, and a \$1.2 million decrease in personnel and employee related costs.

The loss on foreign currency translation for the nine months ended September 30, 2020 was \$4.0 million compared to a \$4.5 million gain for the same period in 2019. The fluctuation is related to the change in the U.S. dollar to Euro foreign exchange rate on the recognized loss on insulin purchase commitments, which are denominated in Euros.

The net loss for the nine months ended September 30, 2020 was \$30.8 million, or \$0.14 per share, compared to a \$37.6 million net loss, or \$0.20 per share for the same period in 2019. The lower net loss was mainly attributable to a decrease selling, general and administrative expenses, partially offset by the change in the foreign currency translation from a gain in 2019 to a loss in 2020. The reduction in the net loss per share was also impacted by a greater number of outstanding shares.

Cash, cash equivalents and restricted cash at September 30, 2020 was \$52.7 million compared to \$50.2 million at December 31, 2019, which also included short-term investments of \$20.0 million. The increase was primarily due to a milestone payment from United Therapeutics of \$12.5 million, \$15.2 million of net proceeds received from at-the-market offerings, \$11.6 million received from warrant exercises and the origination of a Paycheck Protection Program loan for \$4.9 million, offset by non-GAAP net cash used in operating activities of \$40.9 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.

	Three Months Ended September 30,							
						\$	%	
	2020			2019	C	hange	Change	
Net revenue — Afrezza	\$	7,275	\$	6,402	\$	873	14 %	
Less cost of goods sold		(3,591)		(7,099)	\$	(3,508)	(49 %)	
GAAP gross profit (loss) — Afrezza		3,684		(697)	\$	4,381	*	
Exclude Amphastar amendment fee				2,750	\$	(2,750)	(100 %)	
Non-GAAP gross profit — Afrezza	\$	3,684	\$	2,053	\$	1,631	79%	
Non-GAAP gross margin		51 %		32 %	-			

* Not meaningful

		Nine Months Ended September 30,							
		2020		2019	С	\$ hange	% Change		
Net revenue — Afrezza	\$	22,260	\$	17,543	\$	4,717	27 %		
Less cost of goods sold		(11,432)		(15,446)	\$	(4,014)	(26 %)		
GAAP gross profit — Afrezza		10,828		2,097	\$	8,731	416 %		
Exclude Amphastar amendment fee		—		2,750	\$	(2,750)	(100 %)		
Non-GAAP gross profit — Afrezza	\$	10,828	\$	4,847	\$	5,981	123%		
Non-GAAP gross margin		49 %		28 %	-				

	Nine Months Ended September 30,									
						\$	%			
	2020			2019		Change	Change			
Net cash used in operating activities	\$	(28,363)	\$	(83,376)	\$	55,013	66 %			
Exclude UT payment received		(12,500)		(12,500)	\$	_	%			
Exclude payment-in-kind interest on promissory notes		_		(32,822)	\$	32,822	100 %			
Non-GAAP cash used in operating activities	\$	(40,863)	\$	(128,698)	\$	87,835	68 %			

Conference Call

MannKind will host a conference call and presentation webcast to discuss these results today at 5:00 p.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 <u>http://www.mannkindcorp.com</u> 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: 3965498#. 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 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. 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. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon 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 various risks and uncertainties detailed in MannKind's filings with the SEC, including risks related to the COVID-19 pandemic. For a discussion of these and other factors, please refer to MannKind's annual report on Form 10-K for the year ended December 31, 2019 as well as MannKind's other filings with the SEC. 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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MANNKIND CORPORATION AND SUBSIDIARY CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

(In thousands, except per share data)

	September 30, 2020			December 31, 2019		
ASSETS						
Current assets:						
Cash and cash equivalents	\$	52,398	\$	29,906		
Restricted cash		316		316		
Short-term investments		—		19,978		
Accounts receivable, net		4,135		3,513		
Inventory		4,881		4,155		
Prepaid expenses and other current assets		4,616		2,889		
Total current assets		66,346		60,757		
Property and equipment, net		25,736		26,778		
Other assets		3,599		6,190		
Total assets	\$	95,681	\$	93,725		
LIABILITIES AND STOCKHOLDERS' DEFICIT						
Current liabilities:						
Accounts payable	\$	5,797	\$	4,789		
Accrued expenses and other current liabilities		15,814		15,904		
Short-term notes payable		45,379		5,028		
Deferred revenue — current		28,867		32,503		
Recognized loss on purchase commitments — current		10,267		7,394		
Total current liabilities		106,124		65,618		
Promissory notes		70,025		70,020		
Accrued interest — promissory notes		5,854		2,002		
Long-term Midcap credit facility		_		38,851		
Senior convertible notes		5,000		5,000		
Paycheck Protection Program loan — long term		1,421		—		
Recognized loss on purchase commitments — long term		84,529		84,639		
Operating lease liability		1,523		2,514		
Deferred revenue — long term		1,699		8,344		
Milestone rights liability		5,926		7,263		
Total liabilities		282,101		284,251		

Stockholders' deficit:

Undesignated preferred stock, \$ par value — shares authorized;

shares issued or outstanding as of September 30, 2020 and December 31,

2019	—	—
Common stock, \$ par value - 400,000,000 and 280,000,000 shares authorized, 230,922,513 and 211,787,573 shares issued and outstanding		
at September 30, 2020 and December 31, 2019, respectively	2,309	2,118
Additional paid-in capital	2,834,003	2,799,278
Accumulated other comprehensive loss	_	(19)
Accumulated deficit	(3,022,732)	(2,991,903)
Total stockholders' deficit	 (186,420)	 (190,526)
Total liabilities and stockholders' deficit	\$ 95,681	\$ 93,725

MANNKIND CORPORATION AND SUBSIDIARY CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

(In thousands, except per share data)

	Three Months Ended September 30,					Nine Months Ended September 30,			
	2020		2019		2020			2019	
Revenues:									
Net revenue — commercial product sales	\$	7,275	\$	6,402	\$	22,260	\$	17,543	
Revenue — collaborations and services		8,077		8,193		24,441		29,502	
Total revenues		15,352		14,595		46,701		47,045	
Expenses:									
Cost of goods sold		3,591		7,099		11,432		15,446	
Cost of revenue — collaborations and services		1,581		1,836		6,926		5,512	
Research and development		1,484		1,580		4,703		4,879	
Selling, general and administrative		13,899		16,666		41,919		58,948	
Asset impairment		—		—		1,889		—	
Loss (gain) on foreign currency translation		3,927		(3,807)		3,998		(4,495)	
Total expenses		24,482		23,374		70,867		80,290	
Loss from operations		(9,130)		(8,779)		(24,166)		(33,245)	
Other (expense) income:									
Interest income		18		220		165		794	
Interest expense on notes		(1,057)		(4,126)		(3,212)		(5,283)	
Interest expense on promissory notes		(1,318)		(1,162)		(3,858)		(3,351)	
Gain on extinguishment of debt		_		3,529		_		3,529	
Other income (expense)		14		(52)		24		(84)	
Total other expense		(2,343)		(1,591)		(6,881)		(4,395)	
Loss before provision for income taxes		(11,473)		(10,370)		(31,047)		(37,640)	
Benefit for income taxes		218		_		218		_	
Net loss	\$	(11,255)	\$	(10,370)	\$	(30,829)	\$	(37,640)	
Net loss per share - basic and diluted	\$	(0.05)	\$	(0.05)	\$	(0.14)	\$	(0.20)	
Shares used to compute basic and diluted net loss per share		229,668		199,906		218,559		191,786	



Source: MannKind