

MannKind Corporation Reports 2016 Third Quarter Financial Results

November 9, 2016 1:30 PM EST

VALENCIA, Calif., Nov. 09, 2016 (GLOBE NEWSWIRE) -- MannKind Corporation (NASDAQ:MNKD) (TASE:MNKD) today reported financial results for the three and nine months ended September 30, 2016.

For the three and nine months ended September 30, 2016, we recognized \$161.8 million in net revenue from our collaboration with Sanofi. This amount relates to activities from prior periods previously deferred. In the third quarter of 2016, due to the termination of the Sanofi license agreement, the remaining costs under the Sanofi License Agreement were fixed or determinable and future activity under the Sanofi Supply Agreement was reasonably estimable, which allowed for the recognition of revenue from collaboration this quarter. There are no future obligations to Sanofi. The amount of net revenue - collaboration recognized in the three and nine months ended September 30, 2016 consists of the upfront payment of \$150.0 million and milestone payments of \$50.0 million, net of \$64.8 million of net loss share with Sanofi, as well as \$17.4 million in sales of Afrezza and \$9.2 million in sales of raw insulin, both to Sanofi.

We began distributing MannKind branded Afrezza products to wholesalers during the week of July 25, 2016. For the three and nine months ended September 30, 2016, net revenue from commercial product sales represents \$0.6 million of net sales of Afrezza dispensed to patients. In addition, as of September 30, 2016, we recorded \$2.0 million in deferred revenue, of which \$1.6 million is net of estimated gross-to-net adjustments and represents product shipped to our third-party logistics provider and wholesale distributors, but not dispensed to patients as of that date. Estimated gross-to-net adjustments for the third quarter of 2016 were approximately 32%, which includes estimates of wholesaler distribution and logistics fees, prompt pay discounts, estimated government rebates and patient discount programs. Deferred revenue also includes \$0.4 million that we have received for the sale of surplus raw materials to a third party, where delivery was made after September 30, 2016.

For the three and nine months ended September 30, 2016, we recognized \$22.7 million of product costs — collaboration which was previously deferred and consisted of \$13.5 million in Afrezza manufacturing costs for product sold to Sanofi and \$9.2 million for a change in estimate in our recognized loss on purchase commitments related to the sale of raw insulin to Sanofi.

Cost of goods sold was approximately \$4.3 million for the third quarter of 2016, a decrease of 47% from the third quarter of 2015. This decrease is primarily due to a decrease in under-absorbed labor and overhead due to decreased depreciation as a result of the fixed asset impairment write-down in 2015 and decreased salaries resulting from the reduction in force in 2015 as well as a gain on purchase commitments for other material related to a change in estimate associated with the renegotiation of certain agreements and a reduction in inventory write-offs offset by a foreign currency exchange loss on recognized loss on purchase commitments for insulin purchases. Cost of goods sold was \$15.6 million for the nine months ended September 30, 2016, and included under-absorbed labor and overhead costs expensed in the period, and a foreign currency exchange loss on the recognized loss on purchase commitments for insulin offset by a gain on purchase commitments for other materials related to a change in estimate associated with the renegotiation of certain agreements. Cost of goods sold for the three and nine months ended September 30, 2016 also includes \$0.1 million attributable to commercial product sales, which consists of the manufacturing costs for Afrezza dispensed to patients. This \$0.1 million attributable to commercial product sales only includes conversion cost as we wrote off the cost of our raw materials held in inventory at the end of 2015.

During the three and nine months ended September 30, 2015, the Company did not recognize any net revenue or product costs — collaboration or net revenue — commercial product sales.

Research and development expenses were \$3.9 million for the third quarter of 2016, a decrease of 38% from the third quarter of 2015, primarily due to expense associated with the 2015 reduction in force exceeding the expense associated with the 2016 reduction in force along with curtailing certain research and development projects and facility spending offset by an increase in development work done for third parties. Research and development expenses were \$13.4 million for the nine months ended September 30, 2016, a decrease of 43% compared to the same period in 2015, primarily due to expense associated with the 2015 reduction in force exceeding the expense associated with the 2016 reduction in force along with a decrease in research and development projects and facility spending offset by an increase in development work done for third parties and tax credits.

Selling, general and administrative expenses were approximately \$13.1 million for the third quarter of 2016, an increase of 14% from the third quarter of 2015, mainly due to increased costs for the support of sales and marketing of Afrezza offset by a decrease in general and administrative expenses due to the reduction in force in 2015. Selling, general and administrative expenses for the nine months ended September 30, 2016 were \$31.6 million, a decrease of 3% from the same period in 2015, primarily due to the 2015 reduction in force, lower communication, facility and insurance costs and lower stock-based compensation expense in general and administrative expenses offset by increased costs for the support of sales and marketing of Afrezza in selling expenses.

Included in the three months ended September 30, 2016 is a \$13.2 million benefit from a decrease in the fair value of the warrant liability from June 30, 2016. Included in the nine months ended September 30, 2016 is a \$7.9 million benefit from a decrease in the fair value of the warrant liability from May 12, 2016, the date the warrants were issued.

The net income for the three and nine months ended September 30, 2016 was \$126.5 million and \$71.7 million, or basic net income of \$0.26 and \$0.16 per share, based on 478.1 and 454.2 million weighted average shares outstanding, compared with a net loss of \$31.9 million and \$91.4 million for the same periods in 2015, or basic net loss of \$0.08 and \$0.23 per share, based on 405.2 and 401.7 million weighted average shares outstanding. The number of common shares outstanding at September 30, 2016 was 478.4 million.

Cash and cash equivalents at September 30, 2016 were \$35.5 million, compared to \$59.1 million at December 31, 2015. Currently, \$30.1 million remains available for borrowing under the amended loan arrangement with The Mann Group along with \$50.0 million available under the at-the-market facility.

Conference Call and Presentation Webcast

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 webcast, visit MannKind's website at http://www.mannkindcorp.com and click on the "Q3 2016 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: 41477573.

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: 4147 7573#. A replay will also be available on MannKind's website for 14 days.

About MannKind Corporation

MannKind Corporation (NASDAQ:MNKD) (TASE:MNKD) focuses on the discovery, development and commercialization of therapeutic products for patients with diseases such as diabetes. MannKind maintains a website at http://www.mannkindcorp.com to which MannKind regularly posts copies of its press releases as well as additional information about MannKind. Interested persons can subscribe on the MannKind website to e-mail alerts that are sent automatically when MannKind issues press releases, files its reports with the Securities and Exchange Commission or posts certain other information to the website.

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, 2015 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 par value and share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue:				
Net revenue - collaboration	\$ 161,781	\$ -	\$ 161,781	\$ -
Net revenue - commercial product sales	573	-	573	-
Total net revenue	162,354	_	162,354	
Expense:	,		, , , , ,	
Product costs - collaboration	22,742	_	22,742	_
Cost of goods sold	4,331	8,115	15,567	15,688
Research and development	3,917	6,341	13,357	23,455
Selling, general and administrative	13,135	11,547	31,595	32,649
Total expenses	44,125	26,003	83,261	71,792
Income (loss) from operations	118,229	(26,003)	79,093	(71,792)
Change in fair value of warrant liability	13,185	-	7,879	-
Interest income	28	2	70	8
Interest expense on notes	(4,166)	, ,	, ,	(17,899)
Interest expense on note payable to our principal stockholder	(729)	, ,	, ,	(2,164)
Loss on extinguishment of debt	-	(1,049)		(1,049)
Other (expense) income	(27)	67	(613)	1,470
Net income (loss)	\$ 126,520	\$ (31,857)	71,690	(91,426)
Net income (loss) per share - basic	\$ 0.26	\$ (0.08)	\$ 0.16	\$ (0.23)
Net income (loss) per share - diluted	\$ 0.26	\$ (0.08)	\$ 0.16	\$ (0.23)
Shares used to compute basic net income (loss) per share	478,137	405,199	454,188	401,734
Shares used to compute diluted net income (loss) per share	482,744	405,199	454,366	401,734

MannKind Corporation and Subsidiaries Condensed Consolidated Balance Sheets (Unaudited)

(in thousands, except par value and share data)

	Sep	tember 30, 2016	De	cember 31, 2015
ASSETS				
Current assets:				
Cash and cash equivalents	\$	35,530	\$	59,074
Accounts receivable		3,137		23
Inventory		5,124		-
Deferred costs from collaboration		_		13,539
Deferred costs from commercial product sales		279		_
Prepaid expenses and other current assets		4,534		4,018
Total current assets		48,604		76,654
Property and equipment - net		46,825		48,749
Other assets		702		1,009
Total assets	\$	96,131	\$	126,412
LIABILITIES AND STOCKHOLDERS' DEFICIT Current liabilities:				
Accounts payable	\$	5,093	\$	15,599
Accrued expenses and other current liabilities		14,164		7,929
Facility financing obligation		70,888		74,582
Deferred sales from collaboration		-		17,503
Deferred payments from collaboration		462		140,231
Deferred revenue		2,014		_
Recognized loss on purchase commitments - current		8,340		12,475
Warrant liability		4,871		-
Total current liabilities		105,832		268,319
Note payable to our principal stockholder		49,521		49,521
Sanofi loan facility and loss share obligation		71,210		62,371
Senior convertible notes - long term Recognized loss on purchase commitments - long term		27,629 63,229		27,613 53,692
Other liabilities		17,397		15,225
Total liabilities		334,818		476,741
Stockholders' deficit		(000 00=)		(050.000)
		(238,687)		(350,329)
Total liabilities and stockholders' deficit	\$	96,131	\$	126,412

Company Contact:

Rose Alinaya

SVP, Finance

661-775-5300

ralinaya@mannkindcorp.com