mannkind

MannKind Corporation Reports 2018 Third Quarter Financial Results

11/01/18

Conference Call to Begin Today at 9:00 AM ET

- **Executed license and collaboration agreement with United Therapeutics for up to $95 million in upfront and milestone payments plus royalties**
- **Executed research agreement for a second Technosphere formulation with United Therapeutics for $10 million**
- **Fifth consecutive quarter with triple digit year-over-year Afrezza Net Revenue growth**
    - **3Q 2018 Afrezza Net Revenue was $4.4 million versus $2.0 million in 3Q 2017; 121% growth. Year-to-date Afrezza Net Revenue was $11.5 million versus $4.7 million; 144% growth.**
    - **3Q 2018 Afrezza Gross Revenue was $8.2 million versus $2.8 million in 3Q 2017; 191% growth. Year-to-date Afrezza 2018 Gross Revenue was $20.1 million versus $7.1 million; 184% growth.**
    - **3Q 2018 Afrezza TRx grew 51% versus 3Q 2017.**

WESTLAKE VILLAGE, Calif., Nov. 01, 2018 (GLOBE NEWSWIRE) -- **MannKind Corporation (NASDAQ:MNKD)** today reported financial results for the third quarter ended September 30, 2018.

"*In 3Q 2018, we executed on both of our corporate value drivers, Afrezza and Technosphere Platform, by signing a global licensing and collaboration agreement for Treprostinil Technosphere and a research agreement for an undisclosed Technosphere formulation with upfront payments from these deals received in the last two months. Our sales and marketing efforts continue to show progress in growing Afrezza sales as the 3Q revenues have more than doubled from 3Q 2017," said Michael Castagna, Chief Executive Officer of MannKind Corporation.*

Third Quarter Results

For the third quarter of 2018, Afrezza net revenue was $4.4 million, an increase of 121% compared to $2.0 million for the third quarter of 2017, reflecting increased product demand and pricing as well as a more favorable mix of cartridges.

Cost of goods sold was $5.3 million for the third quarter of 2018, an increase of 16% compared to $4.6 million for the same period in 2017, which was driven by an increased write-off of expiring inventory in the amount of $0.7 million.

Research and development (R&D) expenses for the third quarter of 2018 were $2.0 million compared to $4.4 million for the third quarter of 2017, a decrease of $2.4 million or 53%, reflecting $1.0 million in lower salary related expenses (for personnel who were engaged in research and development activities in 2017 but who have transitioned to Afrezza commercial support activities), lower clinical trial expense of $0.9 million, a decrease in headcount of $0.4 million and lower research and development supply costs of $0.2 million. These decreases were offset by increases in stock compensation expense and in travel expenses of $0.2 million.

Selling, general and administrative (SG&A) expenses were $19.4 million for the third quarter of 2018 compared to $17.7 million for the third quarter of 2017. The $1.7 million or 9% increase was primarily due to a marketing and advertising cost increase of $1.2 million, an increase in commercial operations headcount of $0.9 million, an increase in sample spending of $0.3 million which were offset by lower facility costs of $0.5 million and a decrease in general and administrative personnel severance costs of $0.4 million.

Interest expense on notes was $1.0 million for the third quarter of 2018 compared to $2.3 million for the third quarter of 2017. The $1.3 million or 57% decrease was primarily due to a reduction in the principal debt balances.

The net loss for the third quarter of 2018 was $24.2 million, or $0.16 per share, compared to the $32.9 million net loss in the third quarter of 2017 or $0.31 per share. The lower loss per share is attributable to an increase in revenues, lower expenses and an increase in shares used to compute the basic and diluted net loss per share.

Nine Months Ended Results

For the nine months ended September 30, 2018, Afrezza net revenue was $11.5 million, an increase of 144% compared to $4.7 million for the same period in 2017, reflecting increased product demand and pricing as well as a more favorable mix of cartridges.

Cost of goods sold for the nine months ended September 30, 2018 was $14.4 million compared to $12.2 million for the nine months ended September 30, 2017. This increase of $2.2 million or 18% was primarily attributable to a $1.2 million increase resulting from higher Afrezza sales, an increase of $0.9 million of excess capacity costs and a $0.4 million realized currency loss from insulin purchases which were offset by a $0.3 million settlement of a credit related to a purchase of insulin. Inventory write-offs of $1.8 million for the nine months ended September 30, 2018 remained flat compared to 2017.

R&D expenses for the nine months ended September 30, 2018 were $7.7 million compared to $10.6 million for the same period in

2017. This $3.0 million or 28% decrease was primarily attributable to a $2.2 million decrease in salary-related expenses (for personnel who were engaged in research and development activities in 2017 but who have transitioned to Afrezza commercial support activities), a decrease in headcount of $0.7 million, a decrease in research and development supply costs of $0.5 million, and a decrease in salary related expenses for personnel supporting manufacturing and production activities of $0.4 million. These decreases were offset by an increase in relocation and recruiting fees of $0.6 million plus an increase in consulting services costs of $0.4 million in connection with international regulatory activities.

SG&A expenses were $61.7 million for the nine months ended September 30, 2018 compared to $51.7 million for the same period in 2017. The $10.0 million or 19% increase was primarily due to an increase in headcount-related expenses associated with commercial operations of $3.5 million and general and administration personnel of $2.5 million, a $2.2 million increase in salary-related expenses (for personnel who were engaged in research and development activities in 2017 but who have transitioned to Afrezza commercial support activities), an increase in stock-based compensation expense of $1.9 million, a $1.1 million increase in the cost of transitioning corporate support functions from Connecticut to our headquarters in California and an increase in consulting fees in connection with corporate strategies of $0.9 million, which were offset by lower marketing expenses of $1.6 million and a decrease in facility expenses of $0.7 million.

Interest expense on notes was $4.5 million for the nine months ended September 30, 2018 compared to $7.4 million for the same period in 2017. The $2.9 million or 40% decrease was primarily due to a reduction in the principal debt balances.

The net loss for the nine months ended September 30, 2018 was $77.2 million, or $0.56 per share, compared to $84.5 million for the nine months ended September 30, 2017, or $0.84 per share. The lower net loss per share is attributable to an increase in revenues, a decrease in expenses and an increase in shares used to compute basic and diluted net loss per share.

Cash and Cash Equivalents

Cash, cash equivalents and restricted cash at September 30, 2018 was $11.0 million compared to $48.4 million at December 31, 2017, primarily due to net cash used in operating activities of $62.7 million, inclusive of $10.0 million received from United Therapeutics in September 2018, primarily offset by $26.4 million of net proceeds from a registered direct offering of 14 million shares of common stock and warrants at a purchase price of $2.00 per share and accompanying warrant.

Conference Call

MannKind will host a conference call and presentation webcast to discuss these results today at 9:00 a.m. Eastern Time. To view and listen to the earnings call webcast live via the Internet, visit the Company's website at www.mannkindcorp.com and click on the “Q3 2018 MannKind Earnings Conference Call” link in the Webcasts section of News & Events. To participate in the live call by telephone, please dial (888) 394-8218 toll-free or (323) 701-0225 toll/international and use the conference passcode: 5666425.

A telephone replay of the call will be accessible for approximately 14 days following completion of the call by dialing (844) 512-2921 toll-free or (412) 317-6671 toll/international and use the replay passcode: 5666425. 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, 2017 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,	
	2018	2017	2018	2017
Revenues:				
Net revenue - commercial product sales	$ 4,387	$ 1,981	$ 11,542	$ 4,726
Net revenue - collaborations	82	62	232	187
Revenue - other	—	—	53	2,302
Total revenues	4,469	2,043	11,827	7,215
Expenses:				
Cost of goods sold	5,303	4,575	14,406	12,210
Research and development	2,043	4,361	7,653	10,611
Selling, general and administrative	19,394	17,725	61,740	51,681
Property and equipment impairment	—	92	—	203
(Gain) Loss on foreign currency translation	(728)	3,684	(3,107)	12,077
Gain on purchase commitments	—	(215)	—	(215)
Total expenses	26,012	30,222	80,692	86,567
Loss from operations	(21,543)	(28,179)	(68,865)	(79,352)
Other (expense) income:				
Change in fair value of warrant liability	—	(1,289)	—	5,488
Interest income	144	65	305	178
Interest expense on notes	(993)	(2,310)	(4,496)	(7,438)
Interest expense on note payable to related party	(1,074)	(1,173)	(3,234)	(2,608)
Loss on extinguishment of debt	(712)	—	(765)	(830)
Other income	10	—	71	13
Total other expense	(2,625)	(4,707)	(8,119)	(5,197)
Loss before provision for income taxes	(24,168)	(32,886)	(76,984)	(84,549)
Income tax expense	—	—	(240)	—
Net loss	$ (24,168)	$ (32,886)	$ (77,224)	$ (84,549)
Net loss per share - basic and diluted	$ (0.16)	$ (0.31)	$ (0.56)	$ (0.84)
Shares used to compute basic and diluted net loss per share	153,597	104,703	138,307	100,136

MANNKIND CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands, except per share data)

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,446	$ 43,946
Restricted cash	527	4,409
Accounts receivable, net	2,752	2,789
Inventory	2,785	2,657
Deferred costs from commercial product sales	—	405
Prepaid expenses and other current assets	3,015	3,010
Total current assets	19,525	57,216
Property and equipment, net	25,632	26,922
Other assets	199	437

Total assets	$ 45,356	$ 84,575
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 5,815	$ 6,984
Accrued expenses and other current liabilities	13,434	12,449
Facility financing obligation	14,202	52,745
Deferred revenue, net	—	3,038
Deferred payments from collaboration - current	10,095	250
Recognized loss on purchase commitments - current	16,081	12,131
Total current liabilities	59,627	87,597
Note payable to related party	72,143	79,666
Accrued interest - note payable to related party	5,692	2,347
Senior convertible notes	19,133	24,411
Recognized loss on purchase commitments - long term	84,362	97,585
Deferred payments from collaboration - long term	2,638	500
Milestone rights liability	7,202	7,201
Total liabilities	250,797	299,307
Commitments and contingencies		
Stockholders' deficit:		
Undesignated preferred stock, $0.01 par value - 10,000,000 shares authorized; no shares issued or outstanding at September 30, 2018 and December 31, 2017	—	—
Common stock, $0.01 par value - 280,000,000 shares authorized, 159,497,573 and 119,053,414 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	1,594	1,192
Additional paid-in capital	2,723,232	2,638,992
Accumulated other comprehensive loss	(18)	(18)
Accumulated deficit	(2,930,249)	(2,854,898)
Total stockholders' deficit	(205,441)	(214,732)
Total liabilities and stockholders' deficit	$ 45,356	$ 84,575

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Source: MannKind