MannKind Corporation Reports 2017 Fourth Quarter and Full Year Financial Results

February 27, 2018

Conference Call to Begin Today at 5:00 PM ET

- **Q4 and 2H 2017 Afrezza net revenue were $4.5 million (+238%) and $6.4 million (+240%) vs. 2016, respectively**
- **Q4 and 2H 2017 net cash used in operating activities were $30.0 million and $53.3 million, respectively**
- **Cash and Cash Equivalents were $43.9 million and Restricted Cash was $4.4 million at December 31, 2017**
- **Recapitalization plan gains momentum:**
    - Raised $57.7 million (net) in a registered direct offering in Q4
    - Restructured $27.7 million principal amount of Senior Subordinated Convertible Notes due 2018 to extend the maturity date to October 2021, lower the conversion price to $5.15 and reduce outstanding principal by $4.0 million in exchange for the issuance of common stock
    - Restructured the Facility Financing Obligation by deferring $10.0 million principal amount due October 31, 2017 to January 15, 2018, and subsequently converting $8.8 million ($5.6 million in Q4; $3.2 million in January 2018) of such principal amount into common stock, with the maturity date for the remaining $1.2 million of principal extended to May 6, 2018; and allowing for additional debt to equity conversion at market prices subject to a conversion floor of $2.75 per share and a 10 million share cap
    - Increased the Company's authorized shares from 140 million to 280 million
- **Treprostinil Technosphere® Investigational New Drug application filed with the U.S. FDA in January 2018**
- **David M. Kendall, MD, a world renowned diabetes expert, joined MannKind as Chief Medical Officer in February 2018**

WESTLAKE VILLAGE, Calif., Feb. 27, 2018 (GLOBE NEWSWIRE) -- **MannKind Corporation**(NASDAQ:MNKD) today reported financial results for the fourth quarter and full year ended December 31, 2017.

Fourth Quarter 2017 Results

For the fourth quarter of 2017, Afrezza net revenue was $4.5 million, an increase of 125% compared to the third quarter of 2017 and 238% compared to the fourth quarter of 2016. Included in the fourth quarter net revenue is a favorable adjustment for a change in estimate of $1.4 million. The change in estimate relates to obtaining new and more comprehensive data regarding the inventory in the distribution channel – specifically inventory in the retail channel. This data indicated that the amount of inventory in the distribution channel was less than had been previously estimated using syndicated prescription data. As of December 31, 2017, the amount of Afrezza shipped to wholesale and retail channels, but not yet recognized as net revenue, was $3.0 million, the same amount as September 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-K for the year ended December 31, 2017.

Cost of goods sold was $5.0 million in the fourth quarter of 2017 compared to $4.6 million in the third quarter of 2017 and $1.6 million in the fourth quarter of 2016, an increase of $0.4 million and $3.4 million respectively. Cost of goods sold during these periods is greater than the associated product sales due to the under-utilization of our manufacturing facility.

Research and development expenses were $3.5 million in the fourth quarter of 2017 compared to $4.4 million in the third quarter of 2017. The $0.9 million decrease was primarily due to a $0.6 million decrease in clinical study expenses and a $0.4 million decrease in compensation expenses. Research and development expenses were $1.6 million in the fourth quarter of 2016, representing a period-over-period increase of $1.9 million which was primarily due to a $1.3 million increase in compensation costs, a $1.4 million increase in consultant and supply costs and a $0.3 million increase in facilities costs, all due to increased clinical studies, partially offset by a decrease of $1.0 million related to a one-time FDA submission fee for a label expansion incurred in 2016 that did not recur in 2017.

Selling, general and administrative (SG&A) expenses were $23.3 million for the fourth quarter of 2017 compared to $17.7 million for the third quarter of 2017. The $5.6 million increase was primarily due to $5.0 million in selling expenses associated with our first direct-to-consumer television advertising campaign in the fourth quarter of 2017. SG&A expenses in the fourth quarter of 2016 were $15.3 million representing a period-over-period increase of $8.0 million which was primarily due to the $5.0 million DTC TV campaign and growth in our commercial infrastructure.

The net loss for the fourth quarter of 2017 was $32.8 million, or $0.28 per share based on 116.5 million weighted average shares outstanding, compared to a $32.9 million net loss in the third quarter of 2017 or $0.31 per share based on 104.7 million weighted average shares outstanding. During the fourth quarter of 2016, we had net income of $54.0 million, or $0.56 per share based on 95.7 million weighted average shares outstanding. The net income in the fourth quarter of 2016 included net collaboration revenue of $10.2 million related to our license and collaboration agreement with Sanofi and a $72.0 million gain from the extinguishment of debt owed to Sanofi pursuant to a settlement agreement.

Full Year 2017 Results

Due to the termination of the Sanofi license and collaboration agreement in early 2016 and our commencement of commercial activities for Afrezza in the third quarter of 2016, a comparative analysis for Afrezza product revenue and commercial support between the year ended December 31, 2017 and the prior year is not meaningful.

For the year ended December 31, 2017, total net revenue of $11.7 million was comprised of $9.2 million of Afrezza net revenue, $1.7 million from the net revenue of surplus bulk insulin to a third party, $0.6 million from the sale of certain oncology intellectual property, and $0.3 million from collaboration net revenue.

Research and development expenses were $14.1 million for the year ended December 31, 2017 compared to $14.9 million for the prior year. The $0.8 million decrease was primarily due to a $3.6 million decrease in research and development expenses associated with a reduction in workforce in 2016, and a one-time FDA submission fee for label expansion of $1.0 million incurred in 2016. These decreases were partially offset by a $2.5 million increase in clinical trial expenses, a $0.7 million increase in expenses incurred for the development of manufacturing improvements.

Selling, general and administrative expenses were $75.0 million for the year ended December 31, 2017 compared to $46.9 million for the prior year, an increase of $28.1 million primarily due to the creation of a commercial support infrastructure after termination of the Sanofi license and collaboration agreement.

The loss on foreign currency translation is related to our purchase commitment for insulin which is denominated in Euros. For the year ended December 31, 2017, the loss was $13.6 million as compared to a gain of $3.4 million in the prior year, a $17.1 million change due to the unfavorable movement of the U.S. dollar-Euro exchange rate.

The net loss for the year ended December 31, 2017 was $117.3 million, or $1.13 per share based on 104.2 million weighted average shares outstanding, compared to net income for the prior year of $125.7 million, or $1.37 per share based on 92.1 million weighted average shares outstanding. The net income for the prior year included net revenue – collaboration of $171.1 million and a gain on the extinguishment of debt of $72.0 million due to the recognition of previously deferred revenue following the termination of the Sanofi license and collaboration agreement.

Cash and Cash Equivalents

Cash and cash equivalents at December 31, 2017 increased to $43.9 million compared to $22.9 million at December 31, 2016, primarily due to cash inflows of $57.7 million of net proceeds from a registered direct offering of common stock, $0.5 million through sales under the at-the-market equity offering facility, $30.6 million received from Sanofi pursuant to a settlement agreement, $16.7 million from the sale of our Valencia, CA facility, $15.4 million from a net increase of debt, and cash received from revenue of $12.5 million offset in part by commercial and general corporate spending of $95.6 million. In addition to the $43.9 million in cash and cash equivalents, the Company had $4.4 million of restricted cash at December 31, 2017 of which $3.2 million was released in January 2018 following a conversion of Facility Financing Obligation debt to equity. The net cash used in operating activities for the fourth quarter of 2017 was $30.0 million.

2H 2017 Results vs. Guidance

- Afrezza gross revenue was $8.3 million for the six months ended December 31, 2017 compared with a range of $9-$14 million.
- Afrezza net revenue was $6.4 million for the six months ended December 31, 2017 compared with a range of $6-$10 million.
- Net cash used in operating activities was $30.0 million in the fourth quarter 2017 and $23.3 million in the third quarter 2017 totaling $53.3 million compared with a range of $48-$56 million.

Conference Call

MannKind will host a conference call and presentation webcast to discuss these results today at 5:00 p.m. Eastern Time. To participate in the live call by telephone, please dial (888) 771-4371 or (847) 585-4405 and use the participant passcode: 46307898. Those interested in listening to the conference call live via the Internet may do so by visiting the Company's website at www.mannkindcorp.com.

A telephone replay of the call 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: 4630 7898#. 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 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

Condensed Consolidated Statements of Operations
(Audited)
(In thousands, except per share amounts)

	Three months ended December 31, 2017	Three months ended December 31, 2016	Twelve months ended December 31, 2017	Twelve months ended December 31, 2016
Revenues:				
Net revenue – commercial product sales	$ 4,466	$ 1,322	$ 9,192	$ 1,895
Net revenue – collaboration	63	10,184	250	171,965
Revenue – other	1	898	2,303	898
Total net revenues	4,530	12,404	11,745	174,758
Expenses:				
Cost of goods sold	5,018	1,553	17,228	17,121
Cost of revenue - collaboration	--	10,230	--	32,971
Research and development	3,507	1,559	14,118	14,917
Selling, general and administrative	23,278	15,333	74,959	46,928
Property and equipment impairment	--	1,259	203	1,259
Loss (gain) on foreign currency translation	1,564	(3,433)	13,641	(3,433)
(Gain) on purchase commitments	--	(2,265	(215)	(2,265)
Total expenses	33,367	24,236	119,934	107,498
(Loss) income from operations	(28,837)	(11,832)	(108,189)	67,260
Other (expense) income:				
Change in fair value of warrant liability	--	(2,510)	5,488	5,369
Interest income	115	15	293	85
Interest expense on notes	(2,056)	(3,010)	(9,494)	(15,576)
Interest expense on note payable to principal stockholder	(1,174)	(729)	(3,782)	(2,901)
(Loss) gain on extinguishment of debt	(781)	72,024	(1,611)	72,024
Other (expense) income	--	18	13	(597)
Provision for income taxes	51	--	51	--
Net (loss) income	$ (32,784)	$ 53,976	$ (117,333)	$ 125,664
Net (loss) income per share — basic	$ (0.28)	$ 0.56	$ (1.13)	$ 1.37
Net (loss) income per share — diluted	$ (0.28)	$ 0.56	$ (1.13)	$ 1.36
Shares used to compute basic net (loss) income per share	116,451	95,676	104,245	92,053
Shares used to compute diluted net (loss) income per share	116,451	96,510	104,245	92,085

MannKind Corporation
Condensed Consolidated Balance Sheets
(Audited)
(In thousands)

	December 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 43,946	$ 22,895
Restricted cash	4,409	--
Accounts receivable, net	2,789	302
Receivable from Sanofi	--	30,557
Inventory	2,657	2,331

Asset held for sale	--	16,730
Deferred costs from commercial product sales	405	309
Prepaid expenses and other current assets	3,010	4,364
Total current assets	57,216	77,488
Property and equipment, net	26,922	28,927
Other assets	437	648
Total assets	$ 84,575	$ 107,063
Liabilities and Stockholders’ Deficit		
Current liabilities		
Accounts payable	$ 6,984	$ 3,263
Accrued expenses and other current liabilities	12,449	7,937
Facility financing obligation	52,745	71,339
Deferred revenue, net	3,038	3,419
Deferred payments from collaboration - current	250	1,000
Recognized loss on purchase commitments — current	12,131	5,093
Total current liabilities	87,597	92,051
Note payable to principal stockholder	79,666	49,521
Accrued interest — note payable to principal stockholder	2,347	9,281
Senior convertible notes	24,411	27,635
Recognized loss on purchase commitments — long term	97,585	95,942
Warrant liability	--	7,381
Deferred payments from collaboration – long term	500	--
Milestone rights liability and other liabilities	7,201	8,845
Total liabilities	299,307	290,656
Total stockholders’ deficit	(214,732)	(183,593)
Total liabilities and stockholders’ deficit	$ 84,575	$ 107,063

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Primary Logo

Source: MannKind