



MannKind Corporation Reports 2021 Second Quarter Financial Results

08/11/21

Conference Call to Begin Today at 5:00 PM ET

- **2Q 2021 Total Revenues of \$23.3 million; +54% vs. 2Q 2020**
- **2Q 2021 Afrezza Net Revenue of \$10.0 million; +43% vs. 2Q 2020**
- **\$201.4 million of Cash, Cash Equivalents and Investments at June 30, 2021**

WESTLAKE VILLAGE, Calif., Aug. 11, 2021 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq:MNKD)** today reported financial results for the quarter and six months ended June 30, 2021.

"I am really proud of how our team has executed so far in 2021 supporting the growth of Afrezza and preparing for the potential commercial launch of Tyvaso DPI," said Michael Castagna, Chief Executive Officer of MannKind Corporation. "With the issuance of the convertible debt in the first quarter and the pay-down and restructuring of our legacy debt in the second quarter, we have a stronger balance sheet with lower interest expense which sets the company up for commercial growth and pipeline advancement."

Second Quarter 2021 Results

Total revenues were \$23.3 million for the second quarter of 2021, an increase of \$8.2 million, or 54%, reflecting Afrezza net revenue of \$10.0 million and collaboration and services revenue of \$13.3 million. Afrezza net revenue increased \$3.0 million, or 43%, compared to \$7.0 million in the second quarter of 2020 as a result of higher prescription demand, the negative effects of the COVID-19 pandemic in the prior year period, a more favorable mix of Afrezza cartridges, and price (including a lower gross-to-net deduction percentage of gross sales). Collaboration and services revenue for the second quarter of 2021 increased \$5.2 million, or 64%, compared to the second quarter of 2020, primarily due to the Company's collaboration with United Therapeutics.

Afrezza gross profit for the second quarter of 2021 was \$5.6 million compared to \$3.3 million in the same period of 2020, a 68% increase that was driven primarily by higher Afrezza revenue and increased manufacturing activities which resulted in a higher amount of costs capitalized to inventory, partially offset by a \$2.0 million fee for an amendment of the Company's insulin supply agreement. Gross margin in the second quarter of 2021 was 56% compared to 47% for the same period in 2020. On a non-GAAP basis, which excludes the \$2.0 million insulin supply amendment fee, gross margin was 76% for the second quarter of 2021 compared to 47% for the same period in 2020.

Research and development ("R&D") expenses for the second quarter of 2021 were \$2.3 million compared to \$1.5 million for the second quarter of 2020. This increase of \$0.9 million, or 59%, was attributable to increased development activity related to our product pipeline.

Selling, general and administrative ("SG&A") expenses for the second quarter of 2021 were \$20.1 million compared to \$13.7 million for the second quarter of 2020, an increase of \$6.4 million, or 47%, as we expanded our investment behind Afrezza and lowered expenses in the prior year period when we voluntarily reduced compensation and field force activities in response to the onset of the COVID-19 pandemic. As we continued to re-engage our selling activities behind Afrezza, we increased promotional and marketing expenses by \$1.8 million and patient support services by \$0.6 million. Personnel expenses increased \$4.4 million due to the favorable impact of lower spending during the COVID-19 pandemic as well as increased headcount and stock compensation. The increased spending in SG&A in the second quarter of 2021 was partially offset by a reduction for the promotional cost for Thyquidity that was recognized as cost of revenue — collaboration and services in 2021.

For the second quarter of 2021, the loss on foreign currency translation for insulin purchase commitments denominated in Euros was \$0.9 million compared to \$1.9 million for the second quarter of 2020. The fluctuation was due to the change in the U.S. dollar to Euro foreign exchange rate.

Interest expense on debt for the second quarter of 2021 was \$3.2 million compared to \$2.4 million for the second quarter of 2020. This increase of \$0.8 million was the result of interest on the \$230.0 million 2.5% senior convertible notes, partially offset by a decrease in interest due to the repayment of \$35.1 million of outstanding principal under the Mann Group non-convertible promissory note and the repayment of \$10.0 million outstanding principal under the MidCap credit facility in the second quarter of 2021. In addition, the Company reduced the interest rates under the MidCap credit facility and the Mann Group convertible note through amendments to the respective agreements in the second quarter of 2021.

Loss on extinguishment of debt, a non-cash expense item, for the three months ended June 30, 2021 was \$22.1 million as a result of the amendment to the Mann Group convertible note. The accounting for the \$22.1 million loss on extinguishment did not result in a change in the financial position of the Company.

The net loss for the second quarter of 2021 was \$35.5 million, or \$0.14 per share, compared to a \$10.3 million net loss in the second quarter of 2020, or \$0.05 per share. The increased net loss of \$25.3 million was primarily due to a non-cash loss on extinguishment of the Mann Group convertible note of \$22.1 million as well as an increase in SG&A expenses and cost of revenue

— collaboration and services, partially offset by an increase in Afrezza net revenue and revenues from collaboration and services. Non-GAAP net loss, adjusted to exclude the \$22.1 million non-cash loss on extinguishment of the Mann Group convertible note was \$13.4 million, or \$0.05 per share, for the three months ended June 30, 2021 compared to \$10.3 million, or \$0.05 per share, for the prior year period.

Six Months June 30, 2021

Total revenues were \$40.7 million for the six months ended June 30, 2021, an increase of \$9.4 million, or 30%, reflecting Afrezza net revenue of \$18.1 million and collaboration and services revenue of \$22.6 million. Afrezza net revenue increased 21% compared to \$15.0 million for the six months ended June 30, 2020, primarily as a result of higher prescription demand and the negative effects of the COVID-19 pandemic in the prior year period, a more favorable mix of Afrezza cartridges and price (including a lower gross-to-net deduction percentage of gross sales). Collaboration and services revenue for the six months ended June 30, 2021 increased \$6.3 million, or 38%, compared to the six months ended June 30, 2020, primarily due to the Company's collaboration with United Therapeutics.

Afrezza gross profit for the six months ended June 30, 2021 was \$9.3 million compared to \$7.1 million in the same period of 2020, a 31% increase that was driven primarily by higher Afrezza revenue. Cost of goods sold increased \$0.9 million compared to the same period in 2020, primarily due to a \$2.0 million fee for an amendment of the Company's insulin supply agreement, partially offset by \$0.8 million of costs associated with lower manufacturing cost per unit and the termination of the free goods program in December 2020, in addition to \$0.5 million of inventory write-offs in 2020. Gross margin for the six months ended June 30, 2021 was 52% compared to 48% for the same period in 2020. On a non-GAAP basis, which excludes the \$2.0 million insulin supply amendment fee, gross margin was 63% for the six months ended June 30, 2021 compared to 48% for the same period in 2020.

R&D expenses for the six months ended June 30, 2021 were \$4.8 million compared to \$3.2 million for the six months ended June 30, 2020. This increase of \$1.6 million, or 48%, was attributable to increased development activity related to our product pipeline.

SG&A expenses for the six months ended June 30, 2021 were \$37.5 million compared to \$28.0 million for the six months ended June 30, 2020, an increase of \$9.4 million, or 34%, as we expanded our investment behind Afrezza and lowered expenses in the prior year period when we voluntarily reduced compensation and field force activities in response to the onset of the COVID-19 pandemic. As we continued to re-engage our selling activities behind Afrezza, we increased promotional and marketing expenses by \$2.4 million and patient support services by \$0.9 million in the first half of 2021. Personnel expenses increased \$6.4 million due to the favorable impact of lower spending during the COVID-19 pandemic as well as increased headcount and stock compensation. The increased spending in SG&A in the first half of 2021 was partially offset by a reduction for the promotional cost for Thyquidity that was recognized as cost of revenue — collaboration and services in 2021.

For the six months ended June 30, 2021, the gain on foreign currency translation for insulin purchase commitments denominated in Euros was \$2.9 million compared to a \$0.1 million loss for the six months ended June 30, 2020. The fluctuation was due to the change in the U.S. dollar to Euro foreign exchange rate.

Interest expense on debt for the six months ended June 30, 2021 was \$9.6 million compared to \$4.7 million for the six months ended June 30, 2020. This increase of \$4.9 million was the result of a \$3.7 million milestone obligation achieved in the first quarter of 2021, interest on the \$230.0 million 2.5% senior convertible notes issued in the first quarter of 2021, partially offset by a decrease in interest due to the repayment of \$35.1 million of outstanding principal under the Mann Group non-convertible promissory note and the repayment of \$10.0 million outstanding principal under the MidCap credit facility in the second quarter of 2021. In addition, the Company reduced the interest rates on the outstanding principal balances under the MidCap credit facility and the Mann Group convertible note through amendments to the respective agreements in the second quarter of 2021.

Non-cash loss on extinguishment of debt for the six months ended June 30, 2021 was \$22.1 million as a result of the amendment to the Mann Group convertible note. The accounting for the \$22.1 million loss on extinguishment did not result in a change in the financial position of the Company.

The net loss for the six months ended June 30, 2021 was \$48.4 million, or \$0.20 per share, compared to a \$19.6 million net loss in the six months ended June 30, 2020, or \$0.09 per share. The increased net loss of \$28.9 million was primarily due to the non-cash loss on extinguishment of the Mann Group convertible note of \$22.1 million as well as an increase in SG&A expenses, cost of revenue – collaboration and services, and loss on purchase commitments, partially offset by an increase in Afrezza net revenues and revenues from collaboration and services. Non-GAAP net loss, adjusted to exclude the \$22.1 million non-cash loss on extinguishment of the Mann Group convertible note was \$26.3 million, or \$0.11 per share, for the six months ended June 30, 2021 compared to \$19.6 million, or \$0.09 per share, for the same period in the prior year.

Cash, cash equivalents, and investments at June 30, 2021 were \$201.4 million compared to \$67.0 million at December 31, 2020. The increase in cash, cash equivalents and investments was primarily due to the issuance of \$230.0 million of 2.5 % senior convertible notes in the first quarter of 2021.

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 compared in accordance with GAAP.

The following tables reconcile our gross margin financial measure to a non-GAAP presentation as adjusted for the nonrecurring amendment fee related to an amendment to our Insulin Supply Agreement.

(In thousands)	Three Months Ended June 30,			
	2021	2020	\$ Change	% Change
Net revenue — Afrezza	\$ 9,976	\$ 6,985	\$ 2,991	43 %
Less cost of goods sold	(4,411)	(3,677)	\$ (734)	20 %
GAAP gross profit — Afrezza	5,565	3,308	\$ 2,257	68 %
Exclude Amphastar amendment fee	2,000	—	\$ 2,000	*
Non-GAAP gross profit — Afrezza	\$ 7,565	\$ 3,308	\$ 4,257	129 %
Non-GAAP gross margin	76 %	47 %		

	Six Months Ended June 30,			
	2021	2020	\$ Change	% Change
Net revenue — Afrezza	\$ 18,075	\$ 14,985	\$ 3,090	21 %
Less cost of goods sold	(8,726)	(7,841)	\$ 885	11 %
GAAP gross profit — Afrezza	9,349	7,144	\$ 2,205	31 %
Exclude Amphastar amendment fee	2,000	—	\$ 2,000	*
Non-GAAP gross profit — Afrezza	\$ 11,349	\$ 7,144	\$ 4,205	59 %
Non-GAAP gross margin	63 %	48 %		

* Not meaningful

The following tables reconcile our financial measure for net loss and EPS as reported in our condensed consolidated statement of operations to a non-GAAP presentation as adjusted for the \$22.1 million non-cash loss on extinguishment of the Mann Group convertible note, which did not result in a change in our financial position.

(In thousands, except per share data)	Three Months Ended June 30,			
	2021	2020	\$ Change	% Change
GAAP to Non-GAAP Net Loss and EPS				
Net loss	\$ (35,523)	\$ (10,252)	\$ 25,271	246 %
Net loss per share - basic and diluted	\$ (0.14)	\$ (0.05)	\$ 0.09	180 %
Less non-cash loss on extinguishment of debt ⁽¹⁾	22,130	—	\$ 22,130	*
Non-GAAP net loss	\$ (13,393)	\$ (10,252)	\$ 3,141	31 %
Non-GAAP net loss per share - basic and diluted	\$ (0.05)	\$ (0.05)	\$ —	—%
Shares used to compute non-GAAP basic and diluted net loss per share	249,295	213,880	35,415	17 %

	Six Months Ended June 30,			
	2021	2020	\$ Change	% Change
GAAP to Non-GAAP Net Loss and EPS				
Net loss	\$ (48,439)	\$ (19,574)	\$ 28,865	147 %

Net loss per share - basic and diluted	\$ <u>(0.20)</u>	\$ <u>(0.09)</u>	\$	0.11	122 %
Less non-cash loss on extinguishment of debt ⁽¹⁾	<u>22,130</u>	<u>—</u>	\$	22,130	*
Non-GAAP net loss	\$ <u>(26,309)</u>	\$ <u>(19,574)</u>	\$	6,735	34 %
Non-GAAP net loss per share - basic and diluted	\$ <u>(0.11)</u>	\$ <u>(0.09)</u>	\$	0.02	22 %
Shares used to compute non-GAAP basic and diluted net loss per share	247,970	212,943		35,027	(16 %)

* Not meaningful

(1) There is no provision for income taxes associated with the non-cash loss on extinguishment of debt as a result of our full valuation allowance.

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 www.mannkindcorp.com under Events & Presentations. 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 was established in 1991 and is headquartered in Westlake Village, Calif., and has a manufacturing and R&D facility in Danbury, Conn. The Company also employs field sales and medical representatives across the U.S. Please visit www.mannkindcorp.com to learn more.

Forward-Looking Statements

Statements in this press release that are not statements of historical fact are forward-looking statements that involve risks and uncertainties. These statements include, without limitation, statements regarding the potential approval and commercial launch of Tyvaso DPI, MannKind's future commercial growth and pipeline advancement, and 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 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 risk that Tyvaso DPI may not be approved by the FDA on the timeline expected, or at all, risks associated with product commercialization, risks associated with developing product candidates, risks associated with MannKind's ability to manage its existing cash resources or raise additional cash resources, the impact of the COVID-19 pandemic, stock price volatility and other risks detailed in MannKind's filings with the Securities and Exchange Commission, including under the "Risk Factors" heading of its 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, each as filed with the Securities and Exchange Commission. 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 is an investigational combination product that is not approved for any use in any country. The Tyvaso DPI tradename is pending final FDA review. Tyvaso DPI is a trademark of United Therapeutics Corporation.

Thyquidity is a trademark of Vertice Pharma.

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

	<u>June 30, 2021</u>	<u>December 31, 2020</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 62,522	\$ 67,005
Restricted cash	—	158
Short-term investments	99,970	—
Accounts receivable, net	6,305	4,218
Inventory	7,482	4,973
Prepaid expenses and other current assets	3,624	3,122
Total current assets	<u>179,903</u>	<u>79,476</u>
Property and equipment, net	28,139	25,867
Long-term investments	38,950	—
Other assets	5,799	3,265
Total assets	<u>\$ 252,791</u>	<u>\$ 108,608</u>

LIABILITIES AND STOCKHOLDERS' DEFICIT

Current liabilities:		
Accounts payable	\$ 7,486	\$ 5,582
Accrued expenses and other current liabilities	22,406	19,707
PPP loan — current	4,873	4,061
Deferred revenue — current	20,126	33,275
Recognized loss on purchase commitments — current	5,538	11,080
Total current liabilities	<u>60,429</u>	<u>73,705</u>
Senior convertible notes	223,217	—
MidCap credit facility	38,614	49,335
Mann Group promissory notes	18,425	63,027
Accrued interest —Mann Group promissory notes	169	4,150
PPP loan — long term	—	812
2024 convertible notes	—	5,000
Recognized loss on purchase commitments — long term	83,179	84,208
Operating lease liability	564	1,202
Deferred revenue — long term	1,589	1,662
Milestone rights liability	4,839	5,926
Deposits from customer	5,317	—
Total liabilities	<u>436,342</u>	<u>289,027</u>
Stockholders' deficit:		
Undesignated preferred stock, \$0.01 par value — 10,000,000 shares authorized; no shares issued or outstanding as of June 30, 2021 and December 31, 2020	—	—
Common stock, \$0.01 par value - 400,000,000 shares authorized, 249,617,550 and 242,117,089 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	2,496	2,421
Additional paid-in capital	2,911,535	2,866,303
Accumulated deficit	(3,097,582)	(3,049,143)
Total stockholders' deficit	<u>(183,551)</u>	<u>(180,419)</u>
Total liabilities and stockholders' deficit	<u>\$ 252,791</u>	<u>\$ 108,608</u>

MANKIND CORPORATION AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except per share data)

<u>Three Months Ended</u>		<u>Six Months Ended</u>	
<u>June 30,</u>		<u>June 30,</u>	
<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>

Revenues:				
Net revenue — commercial product sales	\$ 9,976	\$ 6,985	\$ 18,075	\$ 14,985
Revenue — collaborations and services	13,304	8,129	22,641	16,364
Total revenues	<u>23,280</u>	<u>15,114</u>	<u>40,716</u>	<u>31,349</u>
Expenses:				
Cost of goods sold	4,411	3,677	8,726	7,841
Cost of revenue — collaborations and services	5,515	1,983	8,810	5,345
Research and development	2,329	1,464	4,771	3,219
Selling, general and administrative	20,056	13,670	37,469	28,020
Asset impairment	—	368	—	1,889
Loss (gain) on foreign currency translation	903	1,867	(2,935)	71
Loss on purchase commitments	339	—	339	—
Total expenses	<u>33,553</u>	<u>23,029</u>	<u>57,180</u>	<u>46,385</u>
Loss from operations	<u>(10,273)</u>	<u>(7,915)</u>	<u>(16,464)</u>	<u>(15,036)</u>
Other (expense) income:				
Interest income	25	14	28	147
Interest expense on notes	(2,812)	(1,084)	(8,234)	(2,155)
Interest expense on Mann Group promissory notes	(368)	(1,281)	(1,398)	(2,540)
Loss on extinguishment of debt	(22,130)	—	(22,130)	—
Other income (expense)	35	14	(241)	10
Total other expense	<u>(25,250)</u>	<u>(2,337)</u>	<u>(31,975)</u>	<u>(4,538)</u>
Loss before provision for income taxes	<u>(35,523)</u>	<u>(10,252)</u>	<u>(48,439)</u>	<u>(19,574)</u>
Provision for income taxes	—	—	—	—
Net loss	<u>\$ (35,523)</u>	<u>\$ (10,252)</u>	<u>\$ (48,439)</u>	<u>\$ (19,574)</u>
Net loss per share - basic and diluted	<u>\$ (0.14)</u>	<u>\$ (0.05)</u>	<u>\$ (0.20)</u>	<u>\$ (0.09)</u>
Shares used to compute basic and diluted net loss per share	249,295	213,880	247,970	212,943

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Source: MannKind