MannKind Corporation Reports 2021 Fourth Quarter and Full Year Financial Results

February 24, 2022

Conference Call to Begin Today at 5:00 p.m. (ET)

- *2021 Total Revenues of $75.4 million; +16% vs. 2020*
- *4Q 2021 Afrezza Net Revenue of $11.3 million; +13% vs. 4Q 2020*
- *$260.7 million of Cash, Cash Equivalents and Investments at December 31, 2021*
- *Commenced clofazimine Phase 1 clinical trial in 1Q 2022*
- *Tyvaso DPI review deadline extended to May 2022*

DANBURY, Conn. and WESTLAKE VILLAGE, Calif., Feb. 24, 2022 (GLOBE NEWSWIRE) -- **MannKind Corporation (Nasdaq: MNKD)** today reported financial results for the fourth quarter and full year ended December 31, 2021.

"We had a solid fourth quarter with Afrezza net revenue hitting a record $11.3 million and we ended the year with over $260 million in cash and investments on our balance sheet," said Michael Castagna, PharmD, Chief Executive Officer of MannKind Corporation. "Although the extension of the Tyvaso DPI review is frustrating, our manufacturing team remains focused on producing pre-launch supplies of Tyvaso DPI for our collaboration partner, United Therapeutics."

Fourth Quarter 2021 Results

Total revenues were $12.5 million for the fourth quarter of 2021, reflecting Afrezza net revenue of $11.3 million and collaborations and services revenue of $1.2 million. Afrezza net revenue increased 13% compared to $10.1 million in the fourth quarter of 2020 as a result of higher demand, a more favorable cartridge mix, price, and lower gross-to-net deductions. Collaborations and services revenue decreased $7.2 million compared to the fourth quarter of 2020 due to a decrease in revenue recognized from the initial License Agreement with United Therapeutics ("UT"), which was substantially completed in the third quarter of 2021. Revenue associated with the commercial production of Tyvaso DPI was deferred in the fourth quarter of 2021 and will be recognized over the period when commercial product is sold to UT.

Afrezza gross profit for the fourth quarter of 2021 was $7.0 million compared to $6.4 million in the same period of 2020, an increase of $0.6 million, or 10%, which was driven by an increase in Afrezza sales, partially offset by an increase in cost of goods sold. Cost of goods sold increased by $0.6 million, or 18%, compared to the same period in 2020, primarily due to a $2.0 million increase in inventory write-offs partially offset by $1.8 million in reduced manufacturing-related spending. Afrezza gross margin in the fourth quarter of 2021 was 62% compared to 64% for the same period in 2020.

Cost of revenue – collaborations and services increased by $4.5 million in the fourth quarter compared to 2020 due to increased pre-approval manufacturing activity for Tyvaso DPI.

Research and development ("R&D") expenses for the fourth quarter of 2021 were $3.9 million compared to $1.5 million for the fourth quarter of 2020. This $2.4 million increase was mainly related to pre-clinical development of inhaled clofazimine as well as the Afrezza pediatrics clinical study (INHALE-1).

Selling, general and administrative ("SG&A") expenses for the fourth quarter of 2021 were $22.7 million compared to $17.1 million for the fourth quarter of 2020. This $5.6 million increase was primarily attributable to higher Afrezza promotional expenses and patient support services as well as increased stock-based compensation.

For the fourth quarter of 2021, the gain on foreign currency translation (for insulin purchase commitments denominated in Euros) was $1.6 million compared to a loss of $4.0 million for the fourth quarter of 2020. The fluctuation was due to a change in the U.S. dollar to Euro foreign currency exchange rate.

Interest expense on financing liability was $1.4 million for the fourth quarter of 2021 and represented interest incurred on the sale lease-back transaction for our manufacturing facility in Danbury, CT.

Interest expense on debt for the fourth quarter of 2021 was $2.8 million compared to $2.4 million for the fourth quarter of 2020. This increase of $0.4 million was the result of 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 expense on Mann Group promissory notes as a result of (i) the repayment of $35.1 million of outstanding principal under the Mann Group non-convertible note, (ii) the $10.0 million reduction of principal and interest on the Mann Group convertible note from a conversion to our common stock and (iii) a decrease of the interest rate from 7.00% to 2.50% on the remaining promissory note.

The net loss for the fourth quarter of 2021 was $28.1 million, or $0.11 per share, compared to $26.4 million in the fourth quarter of 2020, or $0.11 per share. The $1.7 million increase in the net loss was primarily due to a decrease in revenues from collaboration and services as well as increases in cost of revenue for collaborations and services and in SG&A expenses, partially offset by a gain on purchase commitment as well as the effect of the one-time acquisition of in-process R&D from QrumPharma in the fourth quarter of 2020.

Twelve Months Ended December 31, 2021

Total revenues were $75.4 million for the year ended December 31, 2021 reflecting Afrezza net revenue of $39.2 million and collaborations and services revenue of $36.3 million. Afrezza net revenue increased 21% compared to $32.3 million for the year ended December 31, 2020, primarily driven by higher demand, a more favorable cartridge mix, price, and lower gross-to-net deductions. Collaborations and services revenue increased

$3.5 million compared to 2020 due to additional development work associated with our collaboration with UT.

Afrezza gross profit was $22.3 million for the year ended December 31, 2021, an increase of $5.1 million, or 30%, compared to a gross profit of $17.2 million in the prior year, which was attributable to an increase in Afrezza sales, partially offset by an increase in cost of goods sold. Cost of goods sold increased by $1.8 million, or 12%, for the year ended December 31, 2021 compared to the prior year, primarily due to a $2.0 million fee for the amendment of the Insulin Supply Agreement, a $1.5 million increase in inventory write-offs, and a $1.0 million increase related to reduced manufacturing activities. The increase in cost of goods sold was partially offset by $2.3 million in reduced manufacturing-related spending, lower per-unit cost from increased manufacturing efficiencies and the termination of a free goods program in December 31, 2020.

R&D expenses for the year ended December 31, 2021 were $12.3 million compared to $6.2 million for the prior year. This $6.1 million increase was primarily attributable to costs incurred to develop our product pipeline and to begin the Afrezza pediatrics clinical study (INHALE-1).

SG&A expenses for the year ended December 31, 2021 were $77.4 million compared to $59.0 million for the prior year. This $18.4 million increase was primarily attributable to higher Afrezza promotional expenses, patient support services, increased headcount and stock-based compensation and our voluntary reduction in compensation in the prior year in response to the COVID-19 pandemic.

For the year ended December 31, 2021, the gain on foreign currency translation (for insulin purchase commitments denominated in Euros) was $6.6 million compared to a loss of $8.0 million for the prior year. The fluctuation was due to a change in the U.S. dollar to Euro foreign currency exchange rate.

Interest expense on financing liability was $1.4 million for the year ended December 31, 2021 and represented interest incurred on the sale lease-back transaction for our manufacturing facility in Danbury, CT.

Interest expense on debt for the year ended December 31, 2021 was $15.2 million compared to $9.5 million for the prior year. This $5.7 million increase was primarily due to interest expense on the $230.0 million 2.5% senior convertible notes as well as a $3.7 million milestone obligation that was achieved during the first quarter of 2021, partially offset by a decrease in interest expense on Mann Group promissory notes as a result of (i) the repayment of $35.1 million of outstanding principal under the Mann Group non-convertible note, (ii) the $10.0 million reduction of principal and interest on the Mann Group convertible note from a conversion to our common stock and (iii) a decrease of the interest rate from 7.00% to 2.50% on the remaining promissory note.

The net loss for the year ended December 31, 2021 was $80.9 million, or $0.32 per share, compared to $57.2 million net loss for the year ended December 31, 2020, or $0.26 per share. The higher net loss was mainly attributable to the $22.1 million non-cash loss on extinguishment of the Mann Group convertible note net of a $4.9 million non-cash gain on extinguishment of the PPP loan, as well as an increase in SG&A expenses and in cost of revenue – collaboration and services, partially offset by an increase in Afrezza net revenues and revenues from collaboration and services, a gain on purchase commitment as well as the effect of the one-time acquisition of in-process R&D from QrumPharma in the prior year. On a non-GAAP basis, excluding the expense incurred for the loss on extinguishment of the Mann Group convertible note offset by the gain on extinguishment of the PPP loan, and the Amphastar amendment fee, the net loss for the year ended December 31, 2021 was $61.7 million, or $0.25 per share.

Cash, cash equivalents, restricted cash, and investments as of December 31, 2021 was $260.7 million compared to $67.2 million as of December 31, 2020. The increase was mainly due to the sale of senior convertible notes in the first quarter of 2021 for $230.0 million and the cash received from the sale-leaseback of our Danbury, CT manufacturing facility of approximately $100 million, offset by operating costs for 2021.

Non-GAAP Measures

To supplement our unaudited condensed consolidated financial statements presented under U.S. generally accepted accounting principles (GAAP), we are presenting certain non-GAAP financial measures. We are providing these non-GAAP financial measures to disclose additional information to facilitate the comparison of past and present operations, and they are among the indicators management uses as a basis for evaluating our financial performance. We believe that these non-GAAP financial measures, when considered together with our GAAP financial results, provide management and investors with an additional understanding of our business operating results, including underlying trends.

These non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable GAAP measures; should be read in conjunction with our unaudited condensed consolidated financial statements prepared in accordance with GAAP; have no standardized meaning prescribed by GAAP; and are not prepared under any comprehensive set of accounting rules or principles. In addition, from time to time in the future there may be other items that we may exclude for purposes of our non-GAAP financial measures; and we may in the future cease to exclude items that we have historically excluded for purposes of our non-GAAP financial measures. Likewise, we may determine to modify the nature of its adjustments to arrive at our non-GAAP financial measures. Because of the non-standardized definitions of non-GAAP financial measures, the non-GAAP financial measures as used by us in this report have limits in their usefulness to investors and may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies.

The following table reconciles 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.

	Twelve Months Ended December 31,	
	2021	**2020**
Net revenue — commercial product sales	$ 39,168	$ 32,324
Less cost of goods sold	(16,833)	(15,084)
GAAP gross profit — Afrezza	22,335	17,240
Exclude Amphastar amendment fee	2,000	—
Non-GAAP gross profit — Afrezza	$ 24,335	$ 17,240
Non-GAAP gross margin	62%	53%

The following table reconciles our financial measure for net loss and net loss per share as reported in our 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 net of the $4.9 million gain on extinguishment of the PPP loan for the year ended December 31, 2021, which did not result in a change in our financial position, as well as the $2.0 million Amphastar amendment fee.

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
GAAP to Non-GAAP Net Loss and EPS				
Net loss	$ (28,061)	$ (26,411)	$ (80,926)	$ (57,240)
GAAP net loss per share — basic and diluted	$ (0.11)	$ (0.11)	$ (0.32)	$ (0.26)
Less non-cash loss on extinguishment of debt, net	—	—	17,200	—
Less Amphastar amendment fee	—	—	2,000	—
Non-GAAP net loss	$ (28,061)	$ (26,411)	$ (61,726)	$ (57,240)
Non-GAAP net loss per share — basic and diluted	$ (0.11)	$ (0.11)	$ (0.25)	$ (0.26)

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 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 located in Danbury, Conn., and Westlake Village, Calif. The Company also employs field sales and medical representatives across the U.S. Please visit 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 MannKind's future commercial growth and pipeline advancement, and MannKind's ability to 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, 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 ("SEC"), including under the "Risk Factors" heading of its Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, as filed with the SEC on November 9, 2021, and under the "Risk Factors" heading of its Annual Report on Form 10-K for the year ended December 31, 2021, being filed with the SEC on February 24, 2022. 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.

AFREZZA is a registered trademark of MannKind Corporation.

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

	December 31,	
	2021	2020
	(In thousands except share and per share data)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 124,184	$ 67,005
Restricted cash	—	158

Short-term investments	79,932	—
Accounts receivable, net	4,994	4,218
Inventory	7,152	4,973
Prepaid expenses and other current assets	3,482	3,122
Total current assets	219,744	79,476
Property and equipment, net	36,612	25,867
Long-term investments	56,619	—
Other assets	8,186	3,265
Total assets	$ 321,161	$ 108,608
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 6,956	$ 5,582
Accrued expenses and other current liabilities	27,419	19,707
Financing liability — current	6,977	—
Paycheck Protection Program loan — current	—	4,061
Deferred revenue — current	827	33,275
Recognized loss on purchase commitments — current	6,170	11,080
Total current liabilities	48,349	73,705
Promissory notes	18,425	63,027
Accrued interest — promissory notes	404	4,150
Financing liability — long term	93,525	—
Long-term Midcap credit facility	38,833	49,335
Senior convertible notes	223,944	—
Recognized loss on purchase commitments — long term	76,659	84,208
Operating lease liability	1,040	1,202
Deferred revenue — long term	19,543	1,662
Milestone rights liability	4,838	5,926
2024 convertible notes	—	5,000
Paycheck Protection Program loan — long term	—	812
Deposits from customer	4,950	—
Total liabilities	530,510	289,027
Stockholders' deficit:		
Undesignated preferred stock, $0.01 par value — 10,000,000 shares authorized; no shares issued or outstanding at December 31, 2021 and 2020	—	—
Common stock, $0.01 par value — 400,000,000 shares authorized, 251,477,562 and 242,117,089 shares issued and outstanding at December 31, 2021 and 2020, respectively	2,515	2,421
Additional paid-in capital	2,918,205	2,866,303
Accumulated other comprehensive loss	—	—
Accumulated deficit	(3,130,069)	(3,049,143)
Total stockholders' deficit	(209,349)	(180,419)
Total liabilities and stockholders' deficit	$ 321,161	$ 108,608

MANNKIND CORPORATION AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
Revenues:				
Net revenue — commercial product sales	$ 11,340	$ 10,064	$ 39,168	$ 32,324
Revenue — collaborations and services	1,175	8,379	36,274	32,820
Total revenues	12,515	18,443	75,442	65,144
Expenses:				
Cost of goods sold	4,295	3,652	16,833	15,084
Cost of revenue — collaborations and services	7,139	2,631	22,024	9,557
Research and development	3,886	1,545	12,312	6,248
Acquired In-Process R&D	—	13,233	—	13,233
Selling, general and administrative	22,727	17,121	77,417	59,040

Impairment of assets	—	—	106	1,889
(Gain) loss on foreign currency translation	(1,564)	4,008	(6,567)	8,006
Loss on purchase commitments	—	—	339	—
Total expenses	36,483	42,190	122,464	113,057
Loss from operations	(23,968)	(23,747)	(47,022)	(47,913)
Other (expense) income:				
Interest income	48	2	112	167
Interest expense on financing liability	(1,373)	—	(1,373)	—
Interest expense on notes	(2,769)	(2,401)	(15,204)	(9,471)
Loss on extinguishment of debt	—	(264)	(17,200)	(264)
Other (expense) income	1	(1)	(239)	23
Total other expense	(4,093)	(2,664)	(33,904)	(9,545)
Loss before income tax expense	(28,061)	(26,411)	(80,926)	(57,458)
Benefit from income taxes	—	—	—	218
Net loss	$ (28,061)	$ (26,411)	$ (80,926)	$ (57,240)
Net loss per share — basic and diluted	$ (0.11)	$ (0.11)	$ (0.32)	$ (0.26)
Shares used to compute net loss per share — basic and diluted	251,083	234,575	249,244	222,585

Source: MannKind