MiMedx Announces First Quarter 2021 Financial and Operating Results

April 28, 2021

First Quarter Net Sales of $60.0 Million

Advancing Innovative Late-Stage Musculoskeletal Pipeline with Data Readouts Expected in Q3 2021

Company to Host Conference Call on April 29, 2021 at 8:30 AM ET

MARIETTA, Ga., April 28, 2021 (GLOBE NEWSWIRE) -- MiMedx Group, Inc. (Nasdaq: MDXG) ("MiMedx" or the "Company"), an industry leader in utilizing amniotic tissue as a platform for regenerative medicine, today announced the filing of its first quarter 2021 Form 10-Q for the period ended March 31, 2021.

Timothy R. Wright, MiMedx Chief Executive Officer, commented, "The first quarter marked significant progress in advancing our clinical programs, including planned investments in additional preclinical evidence to support both our pipeline and core business. One of our top priorities this year is to continue the acceleration of our late-stage clinical programs, and we look forward to announcing top-line results from our three Investigational New Drug (IND) studies in Plantar Fasciitis, Achilles Tendonitis, and Knee Osteoarthritis later this summer. On the commercial front, I am pleased to report that we are on track with the continued recruitment of highly-skilled field personnel to grow our core business. Looking ahead, we remain committed to executing our long-term, strategic initiatives that are designed to deliver meaningful value to all our stakeholders, and are steadfast in our mission to improve people's health and lives through evidence-based regenerative technologies that make healing possible."

First Quarter 2021 and Recent Operating Highlights:

- Completed last patients' final clinical visits in two Phase 3 studies of AmnioFix® Injectable (micronized dehydrated Human Amnion Chorion Membrane (mdHACM)) as a potential treatment for Plantar Fasciitis and Achilles Tendonitis
- Announced completion of all clinical effectiveness endpoint visits in a Phase 2B study of mdHACM as a potential treatment for Knee Osteoarthritis
- Added Dirk Stevens, Ph.D., an accomplished regulatory leader with more than 35 years of strategic leadership experience in quality management and regulatory compliance, as Senior Vice President, Quality Assurance and Regulatory Affairs
- Awarded a Group Purchasing Agreement for the Company's amniotic tissue portfolio from Premier® Inc.'s Synergizing for Unparalleled Results in Procurement and Strategic Sourcing (SURPASS™) purchasing program
- Received notification from the U.S. Food and Drug Administration (FDA) that the Company's IND for the use of AmnioFix® Injectable (mdHACM) in Chronic Cutaneous Ulcers was accepted as filed
- Appointed Phyllis Gardner, M.D., a professor of medicine at the Stanford University School of Medicine and distinguished business leader, to the Company's Board of Directors
- Received notification of expanded coverage by a large national commercial payor for EpiCord® as a medically necessary option in the treatment of Diabetic Foot Ulcers

Key First Quarter 2021 Financial Metrics

- Net sales of $60.0 million for first quarter 2021, compared to $61.7 million for the year prior
- Adjusted net sales[1], which excludes impacts of the change in the Company's methods for recognizing revenue, of $59.7 million for first quarter 2021, compared to $57.2 million for the prior year period
- Net loss of $8.4 million, reflecting $7.2 million of investigation, restatement and related expenses, for first quarter 2021, compared to a net loss of $4.8 million for the prior year period
- Adjusted EBITDA[2] of $4.7 million for first quarter 2021, compared to $3.1 million for the prior year period

	Quarter Ended March 31, (in thousands)	
	2021	**2020**
Net sales	$ 59,967	$ 61,736
Adjusted net sales[1]	59,669	57,241
Net loss	(8,382)	(4,821)

EBITDA[2]		(5,452)		(11,961)
Adjusted EBITDA[2]		4,732		3,114
Net loss per common share - basic	$	(0.09)	$	(0.04)
Net loss per common share - diluted	$	(0.09)	$	(0.04)

1. Adjusted Net Sales is a non-GAAP financial measure. See “Reconciliation of GAAP Net Sales to Adjusted Net Sales and Reconciliation of GAAP Net Income to EBITDA and Adjusted EBITDA” for a reconciliation of Adjusted Net Sales to Net Sales, located in “Selected Unaudited Financial Information” of this release.
2. EBITDA and Adjusted EBITDA are non-GAAP financial measures. See “Reconciliation of GAAP Net Sales to Adjusted Net Sales and Reconciliation of GAAP Net Income to EBITDA and Adjusted EBITDA” for a reconciliation of EBITDA and Adjusted EBITDA to Net loss, located in “Selected Unaudited Financial Information” of this release.

MiMedx reported net sales for the three months ended March 31, 2021, of $60.0 million, a $1.8 million decrease compared to the three months ended March 31, 2020, in which the Company reported revenue of $61.7 million. Net sales for the three months ended March 31, 2021, includes revenue recognized on the remaining contracts of $0.3 million, compared to $4.5 million for the three months ended March 31, 2020.

Adjusted net sales for the three months ended March 31, 2021, which excludes cash collected on the remaining contracts outstanding at the time of the change in the Company's revenue recognition methodology, were $59.7 million compared to $57.2 million for the three months ended March 31, 2020. The increase in the first quarter includes the impact of sales from EpiCord® Expandable, which the Company launched in the third quarter of 2020, along with growth in its flagship EpiFix® sheet portfolio.

Gross profit margin for the three months ended March 31, 2021, was 83.9% compared to 83.8% for the three months ended March 31, 2020.

Selling, general and administrative expenses for the three months ended March 31, 2021, decreased $1.5 million, or 3.3%, to $45.4 million, compared to $46.9 million for the three months ended March 31, 2020. The decrease was driven primarily due to year-over-year decreases in travel expenses, as the government and Company imposed restrictions on travel in response to the COVID-19 pandemic. The Company anticipates that travel expenses will increase as the effects of the COVID-19 pandemic are mitigated.

Research and development expenses were $4.3 million for the three months ended March 31, 2021, compared to $2.7 million for the three months ended March 31, 2020. The increase was driven by higher consulting fees and additional head count to support the Company's clinical research efforts. In addition, the Company, as planned, increased its investments in preclinical studies, supportive of current and potential clinical study indications. MiMedx does expect these costs to increase over time as the Company plans to file INDs and continue working towards the filing of its Biologic License Applications (BLAs). The amount and timing of these expenses are partially dependent on whether interim results from the ongoing IND clinical trials merit further investment.

Investigation, restatement and related expenses for the three months ended March 31, 2021, were $7.2 million compared to $15.6 million for the three months ended March 31, 2020. The decrease was primarily driven by a decrease in expenses incurred related to the restatement of prior period financial information. The Company does not anticipate incurring any more costs related to the restatement of prior period financial information. Other decreases were driven by fewer expenses incurred relative to obligations to advance litigation defense costs to certain former members of management.

MiMedx expects to continue to incur some litigation costs moving forward, but expects a continued reduction in investigation, restatement, and related expenses, other than costs related to resolution of the securities class action matter, the amount and timing of which are highly uncertain. For additional details, see Note 13, “*Commitments and Contingencies,*” in the Unaudited Condensed Consolidated Financial Statements on Form 10-Q.

Net loss for three months ended March 31, 2021, was $8.4 million compared to a net loss of $4.8 million for the three months ended March 31, 2020.

Adjusted EBITDA for the three months ended March 31, 2021, was $4.7 million, or 7.9% of adjusted net sales, compared to $3.1 million, or 5.4% of adjusted net sales, for the three months ended March 31, 2020.

As of March 31, 2021, the Company had $84.7 million of cash and cash equivalents, compared to $95.8 million as of December 31, 2020.

Enforcement Discretion

In November 2017, the FDA developed the regenerative medicine policy framework to support innovations in regenerative medicine therapies, including human cells, tissues, and cellular and tissue-based products (HCT/Ps). As a result of the COVID-19 public health emergency, the FDA extended the enforcement discretion policy for certain HCT/Ps that do not raise reported safety concerns or potential significant safety concerns, from November 2020 to May 31, 2021. On April 21, 2021, the FDA reaffirmed that the period of Enforcement Discretion would not be extended and would therefore end on May 31, 2021. Combined sales of micronized and particulate products represented approximately 14% and 13% of the Company’s net sales, for the three months ended March 31, 2021, and the year ended December 31, 2020, respectively.

Mr. Wright, commented, “We have been watching and expecting this FDA development for some time and, in tandem, have been advancing our innovative late-stage pipeline. We remain committed to doing our part to evolve the science and technology that advances human health, and we unequivocally support the advancement of safe and effective treatment options for patients.”

Outlook for 2021

As a result of the end of the period of Enforcement Discretion on May 31, 2021, the Company now expects adjusted net sales for 2021 will be consistent with the prior year. This is in line with the expected impact previously disclosed in the Company's 2021 Outlook, within the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

Conference Call and Webcast

MiMedx will host a conference call and webcast to review its first quarter 2021 results on Thursday, April 29, 2021, beginning at 8:30 am, Eastern Time. The call can be accessed using the following information:

Webcast: https://edge.media-server.com/mmc/p/g7jeztsf
U.S. Investors: 877-359-9508
International Investors: 224-357-2393
Conference ID: 8590533

A replay of the webcast will be available for approximately thirty days on the Company's website at www.mimedx.com following the conclusion of the webcast.

Important Cautionary Statement
This press release includes forward-looking statements. Statements regarding: (i) planned responses to the end of enforcement discretion; (ii) planned engagement with the FDA regarding potential extension to enforcement discretion; (iii) future sales or sales growth; (iv) the status, timing, and expected results of the Company's clinical trials and planned regulatory submissions, and our expectations regarding our ability to potentially accelerate the timing of any trial or regulatory submission; (v) the Company's plans to review and analyze the results of its plantar fasciitis, Achilles tendonitis, and knee osteoarthritis clinical trials, and to announce top-line data from the plantar fasciitis, Achilles tendonitis, and knee osteoarthritis clinical trials in Q3 2021; (vi) plans for meetings with the FDA, and planned submissions to the FDA, and their timing; and (vii) the effectiveness of amniotic tissue as a therapy for any particular indication or condition; and (viii) estimates of potential addressable markets for our potential future products. Additional forward-looking statements may be identified by words such as "believe," "expect," "may," "plan," "goal," "outlook," "potential," "will," "preliminary," and similar expressions, and are based on management's current beliefs and expectations.

Forward-looking statements are subject to risks and uncertainties, and the Company cautions investors against placing undue reliance on such statements. Actual results may differ materially from those set forth in the forward-looking statements. Factors that could cause actual results to differ from expectations include: (i) notwithstanding the FDA's statement today, there remain a number of uncertainties regarding the application of the FDA's regulations to the Company's products and practices, and the Company may adjust its plans to comply with FDA's requirements; (ii) there can be no assurance that the FDA will further extend enforcement discretion to cover products that have a regulatory approval pending, nor can there be any assurance that the Company will even be able to engage with the FDA on the subject; (iii) the Company's estimate of the impact of enforcement discretion assumes that the Company is able to sell its products through May 31, 2021, and that the Company may continue to sell its cord products thereafter; (iv) the status, timing, and expected results of the Company's clinical trials and planned regulatory submissions, and our expectations regarding our ability to potentially accelerate the timing of any trial or regulatory submission depend on a number of factors including favorable trial results, patient access, and our ability to manufacture in accordance with CGMP and appropriate chemistry and manufacturing controls; (v) the Company may change its plans due to unforeseen circumstances, and delay or alter the timeline for future trials, analyses, or public announcements; (vi) generally any meeting with the FDA depends on successful clinical trial results and the availability of such a meeting and its timing is outside of the Company's control; (vii) the results of a clinical trial or trials may have little or no statistical value, or may fail to demonstrate that the product is safe or effective; and (viii) our estimates of potential addressable markets for our potential future products are merely estimates and will depend on market acceptance of our potential, future products. The Company describes additional risks and uncertainties in the Risk Factors section of its most recent annual report and quarterly reports filed with the Securities and Exchange Commission. Any forward-looking statements speak only as of the date of this press release and the Company assumes no obligation to update any forward-looking statement.

Important Information
The Company intends to file a definitive proxy statement and associated WHITE proxy card in connection with the solicitation of proxies for the 2021 Annual Meeting with the Securities and Exchange Commission (the "SEC"). Details concerning the nominees of the Company's board of directors for election at the 2021 Annual Meeting will be included in the proxy statement. BEFORE MAKING ANY VOTING DECISION, SHAREHOLDERS OF THE COMPANY ARE URGED TO READ ALL RELEVANT DOCUMENTS FILED WITH OR FURNISHED TO THE SEC, INCLUDING THE COMPANY'S DEFINITIVE PROXY STATEMENT AND ANY SUPPLEMENTS THERETO, BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. Investors and shareholders will be able to obtain a copy of the definitive proxy statement and other documents filed by the Company free of charge from the SEC's website at www.sec.gov. The Company's shareholders will also be able to obtain, without charge, a copy of the definitive proxy statement and other relevant filed documents from the "SEC Filings" section of the Company's website at www.mimedx.com.

Participants in the Solicitation
The Company, its directors, its director nominees and certain of its executive officers are participants in the solicitation of proxies from shareholders in respect of the 2021 Annual Meeting. Information regarding the names of the Company's directors and executive officers and certain other individuals and their respective interests in the Company by security holdings or otherwise is set forth in the Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2020, filed with the SEC on March 8, 2021, and the Company's definitive proxy statement for the 2020 annual meeting of the Company's shareholders, filed with the SEC on October 15, 2020. To the extent holdings of such participants in the Company's securities have changed since the amounts described in the proxy statement for the 2020 annual meeting of the Company's shareholders, such changes have been reflected on Initial Statements of Beneficial Ownership on Form 3 or Statements of Change in Ownership on Form 4 filed with the SEC. Additional information regarding the interests of these participants in any proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will also be included in the Company's proxy statement and other relevant materials to be filed with the SEC, if and when they become available. Details regarding the nominees of the Company's Board of Directors for election at the 2021 Annual Meeting will be included in the Company's proxy statement, when available.

About MiMedx
MiMedx is an industry leader in utilizing amniotic tissue as a platform for regenerative medicine, developing and distributing placental tissue allografts with patent-protected, proprietary processes for multiple sectors of healthcare. As a pioneer in placental biologics, we have both a core business, focused on addressing the needs of patients with acute and chronic non-healing wounds, and a promising late-stage pipeline targeted at decreasing pain and improving function for patients with degenerative musculoskeletal conditions. We derive our products from human placental tissues and process these tissues using our proprietary methods, including the PURION® process. We employ Current Good Tissue Practices, Current Good Manufacturing Practices, and terminal sterilization to produce our allografts. MiMedx has supplied over two million allografts, through both direct and consignment shipments. For additional information, please visit www.mimedx.com.

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Selected Unaudited Financial Information

MiMedx Group, Inc.
Condensed Consolidated Balance Sheets
(in thousands) Unaudited

	March 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 84,746	$ 95,812
Accounts receivable, net	35,420	35,423
Inventory	11,582	10,361
Prepaid expenses	4,695	5,605
Income tax receivable	9,991	10,045
Other current assets	3,530	3,371
Total current assets	149,964	160,617
Property and equipment, net	11,044	11,437
Right of use asset	3,567	3,623
Goodwill	19,976	19,976
Intangible assets, net	5,918	6,004
Other assets	344	375
Total assets	$ 190,813	$ 202,032
LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 6,925	$ 8,765
Accrued compensation	16,153	18,467
Accrued expenses	30,676	30,460
Other current liabilities	1,657	1,470
Total current liabilities	55,411	59,162
Long term debt, net	47,799	47,697
Other liabilities	3,624	3,755
Total liabilities	$ 106,834	$ 110,614
Convertible preferred stock Series B	$ 92,030	$ 91,568
Stockholders' deficit		
Preferred stock Series A	$ —	$ —
Common stock	113	113
Additional paid-in capital	156,733	158,610
Treasury stock	(5,091)	(7,449)
Accumulated deficit	(159,806)	(151,424)
Total stockholders' deficit	(8,051)	(150)
Total liabilities, convertible preferred stock, and stockholders' deficit	$ 190,813	$ 202,032

MiMedx Group, Inc.
Condensed Consolidated Statements of Operations
(in thousands) Unaudited

	Three months ended March 31,	
	2021	2020
Net sales	59,967	61,736
Cost of sales	9,641	10,025

Gross profit	50,326	51,711
Operating expenses:		
Selling, general and administrative	45,404	46,942
Investigation, restatement and related	7,196	15,592
Research and development	4,339	2,650
Amortization of intangible assets	239	271
Operating loss	(6,852)	(13,744)
Other expense, net		
Interest expense, net	(1,472)	(2,387)
Other income, net	—	6
Loss before income tax provision	(8,324)	(16,125)
Income tax provision (expense) benefit	(58)	11,304
Net loss	$ (8,382)	$ (4,821)
Net loss available to common stockholders	$ (9,850)	$ (4,821)
Net loss per common share - basic	$ (0.09)	$ (0.04)
Net loss per common share - diluted	$ (0.09)	$ (0.04)
Weighted average common shares outstanding - basic	109,401,383	107,538,509
Weighted average common shares outstanding - diluted	109,401,383	107,538,509

MiMedx Group, Inc.
Condensed Consolidated Statements of Cash Flows
(in thousands) Unaudited

	Years Ended March 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (8,382)	$ (4,821)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	3,244	3,349
Depreciation	1,161	1,506
Amortization of deferred financing costs and debt discount	415	668
Amortization of intangible assets	239	271
Non cash lease expenses	237	239
Accretion of asset retirement obligation	17	—
Loss on fixed asset disposal	236	—
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	3	395
Inventory	(1,221)	(143)
Prepaid expenses	910	1,430
Other assets	319	812
Accounts payable	(936)	1,046
Accrued compensation	(2,314)	(4,186)
Accrued expenses	(484)	(2,845)
Income taxes	54	(10,711)
Other liabilities	(177)	709
Net cash used in operating activities	(6,679)	(12,281)
Cash flows from investing activities:		
Purchases of property and equipment	(1,941)	(1,011)
Patent application costs	(153)	(75)
Principal payments from note receivable	15	—
Net cash flows used in investing activities	(2,079)	(1,086)
Cash flows from financing activities:		

Repayment of term loans	—	(937)
Principal payments on finance lease	(7)	—
Stock repurchased for tax withholdings on vesting of restricted stock	(3,216)	(1,538)
Proceeds from exercise of stock options	915	298
Net cash flows used in financing activities	(2,308)	(2,177)
Net change in cash	(11,066)	(15,544)
Cash and cash equivalents, beginning of year	95,812	69,069
Cash and cash equivalents, end of year	$ 84,746	$ 53,525

Reconciliation of GAAP Net Sales to Adjusted Net Sales and Reconciliation of GAAP Net Income to EBITDA and Adjusted EBITDA

In addition to our GAAP results, we provide certain non-GAAP metrics including Adjusted Net Sales, Earnings Before Interest, Taxes, Depreciation and Amortization ("EBITDA") and Adjusted EBITDA. We believe that the presentation of these measures provides important supplemental information to management and investors regarding our performance. These measurements are not a substitute for GAAP measurements. Company management uses these Non-GAAP measurements as aids in monitoring our ongoing financial performance from quarter-to-quarter and year-to-year on a regular basis and for benchmarking against comparable companies. Adjusted Net Sales is intended to allow one to understand the trend, if any, in sales and to facilitate comparison of sales amounts in periods that used different revenue recognition methods. EBITDA is intended to provide a measure of the Company's operating performance as it eliminates the effects of financing and capital expenditures. EBITDA consists of GAAP net loss excluding: (i) depreciation, (ii) amortization of intangibles, (iii) interest expense, net, and (iv) income tax provision (benefit). Adjusted EBITDA is intended to provide a normalized view of EBITDA and our broader business operations that we expect to experience on an ongoing basis by removing items that may be irregular, one-time, or non-recurring from EBITDA; most significantly those expenses related to the Audit Committee investigation and restatement. This enables us to identify underlying trends in our business that could otherwise be masked by such items. Adjusted EBITDA consists of GAAP net loss excluding: (i) depreciation, (ii) amortization of intangibles, (iii) interest expense, (iv) income tax provision (benefit), (v) costs incurred in connection with the Audit Committee investigation and restatement, (vi) the effect of the Company's change in revenue recognition pattern, and (vii) share-based compensation. A reconciliation of (i) Adjusted Net sales to GAAP Net Sales, (ii) GAAP Net Loss to EBITDA, and (iii) Adjusted EBITDA appears in the table below (in thousands).

	Three months Ended March 31,	
	2021	2020
Net sales	59,967	61,736
Effect of change in revenue recognition	(298)	(4,495)
Adjusted net sales	59,669	57,241

	Three months Ended March,	
	2021	2020
Net loss	$ (8,382)	$ (4,821)
Net margin	*(14.0 %)*	*(7.8%)*
Non-GAAP Adjustments:		
Depreciation expense	1,161	1,506
Amortization of intangible assets	239	271
Interest expense, net	1,472	2,387
Income tax provision (benefit) expense	58	(11,304)
EBITDA	$ (5,452)	$ (11,961)
EBITDA margin	*(9.1%)*	*(19.4%)*
Additional Non-GAAP Adjustments		
Costs incurred in connection with Audit Committee Investigation and Restatement	7,196	15,592
Effect of change in revenue recognition	(256)	(3,866)
Share-based compensation	3,244	3,349
Adjusted EBITDA	$ 4,732	$ 3,114
Adjusted EBITDA margin	*7.9 %*	*5.0 %*
Adjusted EBITDA, % of Adjusted Net Sales	*7.9 %*	*5.4 %*