MIMEDX Announces Third Quarter 2021 Operating and Financial Results

November 2, 2021

Third Quarter Net Sales of $63.1 Million Versus $64.3 Million in 3Q20

Adjusted Net Sales of $62.8 Million Include a 13% Increase in Core Portfolio Sales Versus 3Q20

Year-to-Date Adjusted Net Sales Increase of 16% in Core Portfolio Sales Versus Prior Year Period Reflects Expansion in Surgical Applications

Company to Host Conference Call on November 3, 2021, at 8:30 AM ET

MARIETTA, Ga., Nov. 02, 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 third quarter 2021 Form 10-Q for the period ended September 30, 2021.

Timothy R. Wright, MIMEDX Chief Executive Officer, commented, "The growth in our core portfolio of tissue and cord products this quarter demonstrates consistent execution on multiple initiatives designed to reinforce and convey the differentiation, clinical evidence and economic value of our brands. We are expanding our presence in surgical applications with our AMNIOFIX® brand and continuing to gain traction with our EPICORD® Expandable product line, which enables customers to address a broader range of lower extremity wounds in a cost-effective way. The success in our base business fuels our investments in clinical operations, medical education, and product development initiatives including portfolio innovation and expansion, ultimately driving better outcomes for patients in need of advanced, evidence-based treatment options."

Mr. Wright continued, "Since announcing the top-line data from our late-stage musculoskeletal clinical trials in mid-September, we have been extensively reviewing the study results to determine the reasons behind the observed differences between patient cohorts in the Knee Osteoarthritis (KOA) trial. As part of our statistical analysis plan, third-party biostatisticians have validated the probability values (p-values) from the Phase 2B KOA study and substantiated both a statistically significant and clinically meaningful outcome in Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Total, WOMAC Pain, and WOMAC Function scores for the Pre-Interim Analysis Cohort of 190 patients, with p-values less than 0.05 at three months and less than 0.01 at six months. These positive efficacy signals, while limited to the Pre-Interim Analysis Cohort of 190 patients, provide us with important insights into our approach for our future Phase 3 studies, and we are confident in the therapeutic potential of micronized dehydrated Human Amnion Chorion Membrane (mdHACM). Our recent scientific publications continue to broaden our understanding of the product's mechanism of action, disease modification potential, and long-term utility as a platform for regenerative medicine. We look forward to reviewing these data and reasons for our continued optimism at our upcoming Investor Day on December 7, 2021, when we also plan to highlight our strategy for achieving sustainable growth across our immediate focus areas of acute and chronic wound care, surgical recovery, and international expansion."

Third Quarter 2021 and Recent Operating Highlights:

- Announced the publication of a peer-reviewed study in the *Journal of Wound Care* that described the observed impact of advanced treatment using skin substitute products for lower extremity diabetic foot ulcers, including significant reductions in amputations, emergency visits, and hospital readmissions.
- Filed a shelf registration statement with the Securities and Exchange Commission (SEC) that allows the Company to sell up to $350 million of various types of securities for a period of three years; the registration statement was subsequently declared effective by the SEC.
- Reported top-line data from two late-stage musculoskeletal trials in KOA and Plantar Fasciitis.
- Announced plans to host a virtual Investor Day on December 7, 2021.
- Announced the publication of two additional peer-reviewed studies in *Osteoarthritis and Cartilage Open* and *Biomedical Materials Research, Part B*. Both studies demonstrate *in vitro* bioactivity potential of mdHACM in preventing pathological processes underlying Osteoarthritis (OA) and Tendinopathy.

Key Third Quarter 2021 Financial Metrics

- Net sales of $63.1 million for third quarter 2021, compared to $64.3 million for the year prior
- Adjusted net sales[1], which excludes impacts of the change in the Company's methods for recognizing revenue, of $62.8 million for third quarter 2021, compared to $63.3 million for the prior year period
- Net loss of $2.3 million for third quarter 2021, compared to a net loss of $19.4 million for the prior year period
- Adjusted EBITDA[2] of $6.8 million for third quarter 2021, compared to $6.9 million for the prior year period

	Three Months Ended September 30, (in thousands)		**Nine Months Ended September 30,** (in thousands)	

	2021	2020	2021	2020
Net sales	$ 63,074	$ 64,303	$ 191,206	$ 179,686
Adjusted net sales[1]	62,771	63,264	190,292	172,446
Net loss	(2,339)	(19,417)	(12,500)	(32,704)
EBITDA[2]	41	(7,864)	(4,302)	(23,997)
Adjusted EBITDA[2]	6,761	6,939	14,331	20,294
Net loss per common share - basic	$ (0.04)	$ (0.48)	$ (0.15)	$ (0.60)
Net loss per common share - diluted	$ (0.04)	$ (0.48)	$ (0.15)	$ (0.60)

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 September 30, 2021, of $63.1 million, compared to $64.3 million for the three months ended September 30, 2020. Net sales for the three months ended September 30, 2021, includes revenue recognized on the Remaining Contracts (as defined below) of $0.3 million, compared to $1.0 million for the three months ended September 30, 2020.

Adjusted net sales for the three months ended September 30, 2021, which excludes cash collected on the remaining contracts outstanding at the time of the change in the Company's revenue recognition methodology, were $62.8 million compared to $63.3 million for the three months ended September 30, 2020, which included $8.2 million of revenue related to Section 351 products. Excluding sales of Section 351 products, adjusted net sales increased $7.2 million, or 13.1% over the prior year, reflecting growth in surgical applications with the Company's AMNIOFIX sheet portfolio, and in the EPICORD Expandable product line.

MIMEDX has two primary classes of products: (1) Advanced Wound Care, or Section 361, products, consisting of its tissue and cord sheet allograft products, and (2) Section 351 products, consisting of the Company’s micronized and particulate products, which prior to the end of the Food and Drug Administration's (FDA) period of Enforcement Discretion (as defined below) were used to treat a variety of patient needs, including both advanced wound care and musculoskeletal applications. Advanced Wound Care is further disaggregated between the Company’s Tissue/Other and Cord products. A summary of the Company's revenue, including revenue derived from its Section 351 products, is included in the table below (amounts in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Advanced Wound Care				
Tissue/Other	$ 56,035	$ 50,842	$ 156,012	$ 137,975
Cord	6,247	4,227	17,093	11,387
Total Advanced Wound Care	62,282	55,069	173,105	149,362
Section 351[1]	489	8,195	17,187	23,084
Other[2]	303	1,039	914	7,240
Total Net Sales	$ 63,074	$ 64,303	$ 191,206	$ 179,686

1. In connection with new guidance provided by the FDA in November 2017, the FDA chose to exercise enforcement discretion with respect to investigational new drug applications and pre-market approval requirements for certain products regulated as Human Cells, Tissues and Cellular and Tissue-Based Products (HCT/Ps) through May 31, 2021 (referred to as the period of Enforcement Discretion).
2. “Other” represents cash collections on the Remaining Contracts. Remaining Contracts are those contracts for which performance obligations have been satisfied as of September 30, 2019, but for which the criteria required for revenue recognition had not been met and would not be met until the ultimate collection of cash. For all practicable purposes, the Company is not able to allocate these revenues to different product groups.

Gross profit margin for the three months ended September 30, 2021, was 83.9% compared to 84.0% for the three months ended September 30, 2020.

Selling, general and administrative expenses for the three months ended September 30, 2021, were $46.3 million, compared to $48.0 million for the three months ended September 30, 2020. The decrease in selling, general and administrative expenses during the period was driven by lower professional fees on legal and other matters. These lower fees were partially offset by increases in travel expenses over the prior year period, when the Company implemented travel restrictions in the midst of the COVID-19 pandemic.

Research and development expenses were $4.4 million for the three months ended September 30, 2021, compared to $3.4 million for the three months ended September 30, 2020. The increase reflects higher personnel costs, driven by increases in headcount to support clinical research efforts. While the Company has increased its investments in clinical studies, it did not incur as much research and development expenses as anticipated, due to the delayed timing of clinical trials. Such costs are expected to increase as the Company plans and executes new trials, however the amount and timing of these expenses are partially dependent on whether the clinical trials merit further investment and other factors.

Investigation, restatement and related expenses for the three months ended September 30, 2021, were $3.2 million compared to $12.0 million for the three months ended September 30, 2020. During the three months ended September 30, 2020, MIMEDX incurred expenses toward the advancement of legal fees of certain former officers and directors of the Company. These expenses were not as significant during the same period in 2021. While the Company expects to continue to incur some litigation costs moving forward, a continued reduction in investigation, restatement and related expenses is anticipated, other than costs related to resolution of the securities class action matter, the amount and timing of which are highly uncertain.

Net loss for the three months ended September 30, 2021, was $2.3 million compared to a net loss of $19.4 million for the three months ended September 30, 2020.

Adjusted EBITDA for the three months ended September 30, 2021, was $6.8 million, or 10.8% of adjusted net sales, compared to $6.9 million, or 11.0% of adjusted net sales, for the three months ended September 30, 2020.

As of September 30, 2021, the Company had $90.6 million of cash and cash equivalents, compared to $95.8 million as of December 31, 2020.

Outlook for 2021
The Company expects that adjusted net sales for fiscal year 2021 will be between $245 million to $255 million, including $16.7 million of Section 351 products sold in the United States for the six months ended June 30, 2021, prior to the end of the period of Enforcement Discretion. Adjusted net sales for fiscal year 2020 were $240.5 million, including $31.8 million of Section 351 products.

Conference Call and Webcast
MIMEDX will host a conference call and webcast to review its third quarter 2021 results on Wednesday, November 3, 2021, beginning at 8:30 a.m., Eastern Time. The call can be accessed using the following information:

Webcast: Click here

U.S. Investors: 877-407-6184
International Investors: 201-389-0877
Conference ID: 13723750

A replay of the webcast will be available for approximately 30 days on the Company's website at www.mimedx.com following the conclusion of the event.

Important Cautionary Statement
This press release includes forward-looking statements. Statements regarding: (i) future sales or sales growth; (ii) 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 and eventual BLA approvals; (iii) the timing of our disclosure of clinical trial results; (iv) the results of future scientific studies; (v) expectations regarding our ability to sell EPIFIX in other countries, (vi) the effectiveness of amniotic tissue as a therapy for any particular indication or condition, and (vii) future increases in research and development spending. 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) future sales are uncertain and are affected by competition, access to customers, patient access to healthcare providers, and many other factors; (ii) the status, timing, results 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 Current Good Manufacturing Practices (CGMP) and appropriate chemistry and manufacturing controls; (iii) the Company may change its plans due to unforeseen circumstances, or delays in analyzing and auditing results, and may delay or alter the timeline for future trials, analyses, or public announcements; (iv) the results of scientific research are uncertain and may have little or no value; (v) our ability to sell our products in other countries depends on a number of factors including adequate levels of reimbursement, market acceptance of novel therapies, and our ability to build and manage a direct sales force or third party distribution relationship; (vi) the effectiveness of amniotic tissue as a therapy for particular indications or conditions is the subject of further scientific and clinical studies; and (vii) we may alter the timing and amount of planned expenditures for research and development based on the results of clinical trials and other regulatory developments. 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.

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 base 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

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 90,607	$ 95,812
Accounts receivable, net	36,536	35,423
Inventory	11,196	10,361
Prepaid expenses	2,078	5,605
Income tax receivable	625	10,045
Other current assets	860	3,371
Total current assets	141,902	160,617
Property and equipment, net	9,856	11,437
Right of use asset	2,899	3,623
Goodwill	19,976	19,976
Intangible assets, net	5,620	6,004
Other assets	270	375
Total assets	$ 180,523	$ 202,032
LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 6,881	$ 8,765
Accrued compensation	19,475	18,467
Accrued expenses	13,692	30,460
Other current liabilities	1,698	1,470
Total current liabilities	41,746	59,162
Long term debt, net	48,015	47,697
Other liabilities	4,076	3,755
Total liabilities	93,837	110,614
Convertible preferred stock	92,494	91,568
Total stockholders' deficit	(5,808)	(150)
Total liabilities, convertible preferred stock, and stockholders' deficit	$ 180,523	$ 202,032

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net sales	$ 63,074	$ 64,303	$ 191,206	$ 179,686
Cost of sales	10,129	10,289	32,530	28,513
Gross profit	52,945	54,014	158,676	151,173
Operating expenses:				
Selling, general and administrative	46,289	48,046	145,291	132,316
Investigation, restatement and related	3,170	12,027	8,304	39,065

Research and development	4,368	3,372	12,770	8,281
Amortization of intangible assets	193	276	647	818
Operating loss	(1,075)	(9,707)	(8,336)	(29,307)
Other expense, net				
Loss on extinguishment of debt	—	(8,201)	—	(8,201)
Interest expense, net	(963)	(1,472)	(3,806)	(6,433)
Other income (expense), net	—	1	(3)	(2)
Loss before income tax provision	(2,038)	(19,379)	(12,145)	(43,943)
Income tax provision (expense) benefit	(301)	(38)	(355)	11,239
Net loss	$ (2,339)	$ (19,417)	$ (12,500)	$ (32,704)
Net loss available to common shareholders	$ (3,913)	$ (19,417)	$ (17,039)	$ (65,269)
Net loss per common share - basic	$ (0.04)	$ (0.48)	$ (0.15)	$ (0.60)
Net loss per common share - diluted	$ (0.04)	$ (0.48)	$ (0.15)	$ (0.60)
Weighted average common shares outstanding - basic	110,717,073	108,493,208	110,136,517	108,222,419
Weighted average common shares outstanding - diluted	110,717,073	108,493,208	110,136,517	108,222,419

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

	Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (12,500)	$ (32,704)
Adjustments to reconcile net loss to net cash flows provided by (used in) operating activities:		
Share-based compensation	11,115	11,452
Depreciation	3,390	4,494
Amortization of intangible assets	647	818
Amortization of deferred financing costs	943	1,811
Non-cash lease expenses	724	702
Accretion of asset retirement obligation	57	—
Loss on fixed asset disposal	236	—
Loss on extinguishment of debt	—	8,201
Increase (decrease) in cash resulting from changes in:		
Accounts receivable	(1,113)	(715)
Inventory	(835)	(1,919)
Prepaid expenses	3,527	5,177
Income taxes	9,420	(10,835)
Other assets	1,990	1,633
Accounts payable	(828)	339
Accrued compensation	2,085	(2,775)
Accrued expenses	(16,768)	(4,835)
Other liabilities	(840)	(840)
Net cash flows provided by (used in) operating activities	1,250	(19,996)
Cash flows from investing activities:		
Purchases of equipment	(2,893)	(2,073)
Principal payments from note receivable	75	—
Patent application costs	(263)	(209)
Net cash flows used in investing activities	(3,081)	(2,282)
Cash flows from financing activities:		
Proceeds from exercise of stock options	1,404	370
Stock repurchased for tax withholdings on vesting of restricted stock	(4,751)	(2,409)
Principal payments on finance lease	(27)	—

Deferred financing cost	—	(2,782)
Repayment of term loans	—	(83,872)
Proceeds from term loans	—	59,500
Proceeds from sale of Series B convertible preferred stock	—	100,000
Stock issuance costs	—	(6,564)
Prepayment premium on early repayment of term loan	—	(1,439)
Net cash flows (used in) provided by financing activities	(3,374)	62,804
Net change in cash	(5,205)	40,526
Cash and cash equivalents, beginning of period	95,812	69,069
Cash and cash equivalents, end of period	$ 90,607	$ 109,595

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, (iv) loss on extinguishment of debt, and (v) income tax provision. 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 certain non-cash items and items that may be irregular, one-time, or non-recurring from EBITDA; most significantly those expenses related to the investigation conducted by the Audit Committee (the "Audit Committee") of the Company's Board of Directors (the "Board") into prior-period matters relating to allegations regarding certain sales and distribution practices at the Company and certain other matters (the "Investigation" or the "Audit Committee Investigation"), the restatement of our consolidated financial statements previously filed in our Annual Report on Form 10-K for the year ended December 31, 2016, as well as selected unaudited condensed consolidated financial data as of and for the years ended December 31, 2015 (Restated) and 2014 (Restated), which reflected adjustments to our previously filed consolidated financial statements as of and for the years ended December 31, 2015 and 2014 (collectively, the "Restatement"), and related litigation. This also includes share-based compensation, which is predominantly settled in shares. 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) loss on extinguishment of debt, (v) income tax provision, (vi) costs incurred in connection with Audit Committee Investigation and Restatement, (vii) the effect of the change in revenue recognition on net loss, and (viii) share-based compensation.

A reconciliation of GAAP net sales to Adjusted Net Sales appears in the table below (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net sales	$ 63,074	$ 64,303	$ 191,206	$ 179,686
Effect of change in revenue recognition	303	1,039	914	7,240
Adjusted net sales	$ 62,771	$ 63,264	$ 190,292	$ 172,446

A reconciliation of GAAP net loss to EBITDA and Adjusted EBITDA appears in the table below (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss	$ (2,339)	$ (19,417)	$ (12,500)	$ (32,704)
Net margin	*(3.7) %*	*(30.2) %*	*(6.5) %*	*(18.2) %*
Non-GAAP Adjustments:				
Depreciation expense	923	1,566	3,390	4,494
Amortization of intangible assets	193	276	647	818
Interest expense, net	963	1,472	3,806	6,433
Loss on extinguishment of debt	—	8,201	—	8,201
Income tax provision expense (benefit)	301	38	355	(11,239)
EBITDA	41	(7,864)	(4,302)	(23,997)
EBITDA margin	*0.1 %*	*(12.2) %*	*(2.2) %*	*(13.4) %*
Additional Non-GAAP Adjustments				
Costs incurred in connection with Audit Committee Investigation and Restatement	3,170	12,027	8,304	39,065
Effect of change in revenue recognition	(261)	(893)	(786)	(6,226)
Share-based compensation	3,811	3,669	11,115	11,452
Adjusted EBITDA	$ 6,761	$ 6,939	$ 14,331	$ 20,294

Adjusted EBITDA margin	*10.7 %*	*10.8 %*	*7.5 %*	*11.3 %*
Adjusted EBITDA, % of Adjusted Net Sales	*10.8 %*	*11.0 %*	*7.5 %*	*11.8 %*