



MIMEDX Outlines Long-Term Value Creation Strategy at Virtual Investor Day

December 7, 2021

Company to Share Probability Values from its Knee Osteoarthritis (KOA) Study; Analyses Conducted Support Confidence in Initiation of Confirmatory Phase 3 Trials in 2022

Commercial Business Strategy Demonstrates Sustainable Double-digit Growth Potential in Multiple Underpenetrated Markets

MIMEDX Increases 2021 Adjusted Net Sales Outlook to between \$253 Million and \$258 Million

LINK: [Virtual Investor Day Begins at 9:00 A.M. ET](#)

MARIETTA, Ga., Dec. 07, 2021 (GLOBE NEWSWIRE) -- MiMedx Group, Inc. (Nasdaq: MDXG) ("MIMEDX" or "the Company"), a transformational placental biologics company, will provide new details about near- and long-term growth opportunities for its multimodal placental tissue platform at today's virtual Investor Day, which begins at 9:00 a.m. ET. The Investor Day will provide updates by Company leadership, third-party experts and key opinion leaders on the musculoskeletal late-stage pipeline and robust commercial business.

Timothy R. Wright, MIMEDX Chief Executive Officer, commented, "The leadership team is excited to share reasons behind our confidence in the Company's plans to design and execute a Phase 3 clinical trial program that will support approval and commercialization of our KOA candidate as a potential blockbuster biologic opportunity. The underlying mechanism of action and proprietary tissue engineering of MIMEDX dehydrated Human Amnion Chorion Membrane (dHACM) provides an extensive range of transformative platform potential and organic product innovation opportunities across multiple underpenetrated markets. Our commercial business is growing, with strong double-digit growth potential driven by global expansion initiatives and our dedication to product innovation. Our leadership team is talented, experienced in drug development and commercialization, tissue engineering, and resolute in our commitment to advancing the scientific rigor within the industry and bringing innovative solutions to physicians and patients in need across the world."

Key Insights to Be Shared at MIMEDX 2021 Investor Day Include:

KOA Clinical Program

- **Additional analyses from and next steps for the KOA clinical program**
 - Third-party biostatisticians validated the statistically significant and clinically meaningful improvement in Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Pain at three and six months, respectively ($p=0.032$ and $p=0.009$), WOMAC Function ($p=0.046$ and $p=0.009$), and WOMAC Total ($p=0.038$ and $p=0.008$) for the Pre-Interim Analysis Cohort of 190 patients.
 - Root-cause analysis has determined that the potency of the investigational product faded as it aged, which resulted in the study's failure to meet its primary endpoints. An intense examination of study results identified this factor as the primary difference in clinical responses observed between the Pre-Interim Analysis Cohort of 190 patients and the Post-Interim Analysis Cohort of 256 patients.
 - MIMEDX proprietary biochemical and biological tests detected this reduced potency, related to age of the investigational product used in the Phase 2B KOA study. The Company is confident in its manufacturing processes and proprietary tissue engineering know-how and has a clear path forward.
- Based on the clinically meaningful and statistically significant data from the Pre-Interim Analysis Cohort of 190 patients in the Phase 2B trial, published retrospective data, extensive real-world clinical use, and ongoing scientific mechanism of action research, the Company believes that future planned KOA trials have an increased probability of success, benefitted by the learnings gained from the exploratory Phase 2B KOA clinical trial.
- Commencing in 2022, MIMEDX expects to initiate Phase 3 trials for its KOA candidate, with a Biologics License Application (BLA) filing anticipated in late 2025, and will work closely with the U.S. Food & Drug Administration (FDA) in advancing these trials.

Robust Commercial Growth Potential

- MIMEDX anticipates achieving sustainable growth of 11-14% across its vibrant commercial portfolio. This above-market growth rate comprises:
 - An increase in its Advanced Wound Care business, driven by broadened product access across multiple

underpenetrated markets, along with commercial excellence initiatives.

- An increase in its Surgical Recovery business, driven by market development, product innovation and increased clinical and economic evidence.
 - An increase in its international markets, driven in part by its Japanese commercial strategy.
- The Company also has a robust near-term product pipeline, with two new product launches anticipated in the first half of 2022.

Outlook for 2021

The Company now expects that adjusted net sales for fiscal year 2021 will be between \$253 million to \$258 million, above the previously provided outlook of \$245 million to \$255 million. The revised 2021 outlook includes \$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.

Investor Day speakers and topics include:

Company Updates

- Timothy R. Wright, Chief Executive Officer, MIMEDX
- Peter M. Carlson, EVP, Chief Financial Officer, MIMEDX

Musculoskeletal Pipeline

KOA Key Findings & Path Forward

- Robert B. Stein, M.D., Ph.D., EVP, Research and Development, MIMEDX
- Michelle Massee, AVP, Product Development, MIMEDX
- Thomas M. Mick, M.D., Medical Director, Clinical Development, MIMEDX
- Vibeke Strand, M.D., Stanford University School of Medicine
- Kris J. Alden, M.D., Ph.D., Orthopaedic Surgeon, Hip, Knee & Shoulder Reconstruction

Commercial Business

Growth Strategy & Market Opportunity

- Rohit Kashyap, Ph.D., EVP, Chief Commercial Officer, MIMEDX
- John Harper, Ph.D., SVP, Research & Product Development, Chief Technology Officer, MIMEDX
- William H. Tettelbach, M.D., Principal Medical Officer, Head of Medical Affairs, MIMEDX
- Bidhan B. Das, M.D., Colon, Rectal & General Surgeon
- Caroline Clarke, M.D., Plastic, Reconstructive & Cosmetic Surgeon
- Jonathan Labovitz, D.P.M., Western University of Health Sciences

Registration Details

A live webcast will be available on the Events page of the Investors section of the Company's website at www.mimedx.com at the time of the event. To register for the webcast, participants must use access code 'MDXG.' Participants will have the opportunity to submit written questions to MIMEDX presenters via the webcast. A replay of the webcast will be available on the Company's website.

Important Cautionary Statement

This press release includes forward-looking statements. Statements regarding: (i) future sales or sales growth; (ii) the status, timing, causes and expected results of the Company's clinical trials and planned regulatory submissions, and our expectations regarding the timing of any trial or regulatory submission and eventual BLA approvals; (iii) the results of future scientific studies; and (iv) the effectiveness of amniotic tissue as a therapy for any particular indication or condition. 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 a transformational placental biologics company, developing and distributing placental tissue allografts with patent-protected, proprietary processes for multiple sectors of healthcare. As a pioneer in placental tissue engineering, we have both a commercial 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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