MIMEDX Confirms Fourth Quarter and Full Year 2022 Net Sales Expectations, Comments on Evolving Medicare Reimbursement Landscape and Provides Corporate Updates

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Fourth quarter and full year 2022 net sales expected in the ranges of $73 million to $76 million and $266 million to $269 million, respectively

Provides commentary regarding the potential impact of recently published Medicare reimbursement proposals on its wound care products

MARIETTA, Ga., Jan. 09, 2023 (GLOBE NEWSWIRE) -- MiMedx Group, Inc. (Nasdaq: MDXG) ("MIMEDX" or the "Company"), a pioneer and leader in placental biologics, today provided the following updates about its business.

Reaffirms Fourth Quarter and Full Year 2022 Expectations

The Company announced that it expects its fourth quarter and full year 2022 net sales to be in the ranges of $73 million to $76 million and $266 million to $269 million, respectively, unchanged from the outlook provided during the Company's third quarter 2022 results conference call in November 2022.

Comments on Potential Exposure to Changes for Medicare Reimbursement of Skin Substitutes

Recently, several wide-ranging proposals have been published for public comment and are under consideration by the U.S. Centers for Medicare and Medicaid Services ("CMS"). In addition, three Medicare Administrative Contractors ("MACs") have recently published for public comment changes to their Local Coverage Determinations ("LCDs") that they are considering. If adopted, these proposals would significantly change Medicare policies governing the reimbursement of skin substitute products principally when used for wound treatment in the private physician office setting.

MIMEDX business in the private physician office setting accounted for approximately 28% of the Company's 2022 sales, of which roughly three-quarters were likely reimbursed by CMS. By product type, over 90% of its sales to this site-of-service are derived from sales of EPIFIX® (Q4186), with the remainder primarily coming from EPICORD® (Q4187) product sales.

While there remains uncertainty regarding the timing, form or extent to which these proposals may be adopted, if at all, MIMEDX has taken steps to mitigate its risks associated with these potential changes.

- With regard to the CMS proposals, MIMEDX continues to advocate for fair competition and cost control and has recommended CMS immediately publish all skin substitute products on the Medicare Part B Drug Average Sales Price file ("ASP list"). Currently, MIMEDX's entire product offering sold to this customer base is included on the ASP list.

- The LCDs in the proposals could adopt a new standard of clinical evidence required as a prerequisite to coverage. In addition, the proposals all require a confirmation that the products are regulated solely under Section 361 of the Public Health Service Act as a prerequisite to continued coverage. This confirmation can be demonstrated through receipt of a Tissue Reference Group ("TRG") letter or equivalent documentation from the U.S. Food & Drug Administration ("FDA"). In December of 2022, the Company received a TRG letter from the FDA confirming that EPIFIX meets the criteria for regulation solely under Section 361, and the Company is currently pursuing the required confirmation for its EPICORD product with the FDA.

- The proposed LCDs also include language that could lower the number of allowed applications of a product below what is commonly used in standard practice by physicians today, supported by clinical evidence, and reflected by LCDs currently in force with the MACs. The Company as well as industry stakeholders across the wound care industry do not support lowering the applications.

Commenting on the potential future Medicare reimbursement changes, MIMEDX interim Chief Executive Officer Todd Newton stated, "With significant focus from CMS on the reimbursement of skin substitute products such as ours, MIMEDX has worked to identify and mitigate these risks, based upon what we know about these proposed rules. We believe that with our current products on the ASP list, the receipt in December of the EPIFIX TRG letter and the body of evidence for the use of our products in clinical literature, we have mitigated much of the controllable risk to the continued reimbursement of our products. We have provided comments regarding these proposals to CMS and the MACs and expect to reiterate our views and concerns at the upcoming CMS Town Hall meeting scheduled for January 18, 2023. Our overriding objective is to ensure that well-intentioned policy changes do not have the unintended consequence of reducing the access to care of high-risk patient populations suffering from hard-to-heal wounds."

Additional Corporate Updates

In the fourth quarter, the Company continued steps to restructure its corporate costs. The associated headcount reductions are expected to reduce costs by approximately $5 million on an annualized basis. In addition, the Company completed a sales force realignment effort expected to improve sales productivity and the operating margin contribution of its Wound & Surgical business unit. Other updates in the fourth quarter included:

- Entered into a distribution partnership with Gunze Medical to support the launch of EPIFIX in Japan;

- Appointed Ricci S. Whitlow as Chief Operating Officer, a role that will head up responsibility for the Company's manufacturing, supply chain, procurement, quality, and regulatory functions; and
- Announced worldwide exclusive license to Turn Therapeutics' proprietary antimicrobial technology platform, PermaFusion®.

"On our third quarter call, we discussed four key fundamentals that this business is executing on with a sense of urgency," stated Mr. Newton. "In a relatively short period of time, we have implemented and achieved a number of measures that we expect will position us to expand the reach of our products to a large and growing population of physicians and patients in the U.S. and also internationally, beginning with Japan. We expect these recent changes and accomplishments put us in position entering 2023 to continue to build a growing and profitable Wound & Surgical business with exciting and amplified R&D potential. Additionally, we expect to commence our next registrational study for the use of our mDHACM product in the treatment of knee osteoarthritis in early 2023."

The Company will provide additional commentary on its fourth quarter and full year 2022 results as well as its expectations for 2023 when it reports results, currently scheduled for March 1, 2023.

About MIMEDX

MIMEDX is a pioneer and leader in placental biologics, developing and distributing placental tissue allografts to help address unmet clinical needs in multiple sectors of healthcare, including the Advanced Wound Care market as well as in surgical recovery settings. MIMEDX is also focused on advancing a promising late-stage pipeline opportunity targeted at decreasing pain and improving function for patients with knee osteoarthritis. Our products are derived from human placental tissues and processed using our proprietary methods, including the Company's own 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.

MIMEDX Safe Harbor Statement

Some of the information and statements contained in this press release and certain oral statements made from time to time by representatives of MIMEDX constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that do not directly or exclusively relate to historical facts. Forward-looking statements include statements regarding: (i) our expectations for our net sales and other financial results for the fourth quarter and full year 2022; and (ii) our expectations regarding CMS and MAC reimbursement policies and the impact of CMS and MAC reimbursement policy proposals on our business and financial results in 2023 and beyond; (iii) our belief that we have mitigated much of the controllable risk to the continued reimbursement of our products; (iv) our expectation that our headcount reductions will reduce costs by approximately $5 million on an annualized basis and that our sales force realignment effort will improve sales productivity and the operating margin contribution of our Wound & Surgical business unit; (v) our belief that recent changes and our accomplishments put us in position entering 2023 to continue to build a growing and profitable Wound & Surgical business with exciting and amplified R&D potential; and (vi) our expectation that we will commence our next registrational study for the use of our mDHACM product in the treatment of knee osteoarthritis in early 2023. 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. These statements are based on numerous assumptions and involve known and unknown risks, uncertainties and other factors that could significantly affect our operations and may cause our actual actions, results, financial condition, performance or achievements to differ materially from any future actions, results, financial condition, performance or achievements expressed or implied by any such forward-looking statements. Factors that may cause such a difference include, without limitation, those discussed in the Risk Factors section of the Company's 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.

Contact
Matt Notarianni
Investor Relations
470-304-7291
mnotarianni@mimedx.com