

# MIMEDX Outlines Key Strategic Milestones for 2022

January 10, 2022

MIMEDX Primed to Commence Pivotal Phase 3 Clinical Study Program of micronized dehydrated Human Amnion Chorion Membrane (mdHACM) in Knee Osteoarthritis (KOA), Targeting Potential Late-2026 Commercial Launch

Double-Digit Growth Objective in 2022 to be Driven by Treatment Transformation, Global Market Expansion and Ongoing Portfolio Innovation across Multimodal Placental Tissue Platform

Company to Present at 40<sup>th</sup> Annual J.P. Morgan Healthcare Conference on Wednesday, January 12 at 5:15 PM ET

MARIETTA, Ga., Jan. 10, 2022 (GLOBE NEWSWIRE) -- MiMedx Group, Inc. (Nasdaq: MDXG) ("MIMEDX" or "the Company"), a transformational placental biologics company, today provided a recap of key 2021 accomplishments and outlined strategic milestones planned for 2022. The Company expects strong, double-digit growth in 2022 to be driven by treatment transformation, including advancement into the Surgical Recovery market, global expansion with the launch of EPIFIX<sup>®</sup> in Japan anticipated for mid-2022 as a near-term catalyst, and portfolio innovation across its multimodal placental tissue platform. These innovations mark the Company's continued expansion into multiple therapeutic areas of significant unmet need.

Timothy R. Wright, MIMEDX Chief Executive Officer, commented, "2021 was a defining year for MIMEDX in which we advanced the therapeutic understanding of mdHACM as a potential blockbuster biologic. We believe that mdHACM has the potential to reduce pain and increase function in mild-to-moderate knee osteoarthritis, based in part on the clinically meaningful and statistically significant probability values (p-values) within the Pre-Interim Analysis Cohort of 190 patients in our Phase 2B KOA trial. We believe the findings from our Phase 2B trial have increased our probability of technical and regulatory success as we commence our Phase 3 KOA clinical study program this year. MIMEDX has pioneered an extensive body of scientific and clinical evidence and advanced our understanding of the underlying mechanism of action behind our proprietary PURION<sup>®</sup> tissue engineering. Our differentiated placental platform has the potential to transform medicine in large and high-growth markets with significant unmet needs, and more importantly, to improve people's health and lives."

Mr. Wright continued, "We believe that 2022 will be a transformational year for MIMEDX, and our vibrant commercial business positions us well for double-digit growth across multiple underpenetrated markets. We have the opportunity to change the practice of wound healing in Japan as we operationalize our commercial strategy for the mid-year launch of EPIFIX<sup>®</sup>, following expected reimbursement approval. We also plan to launch two new, organic products: AMNIOEFFECT<sup>TM</sup> and our Placental Collagen Matrix. The native and multimodal therapeutic properties of our PURIO® processed placental tissue provide a vast range of organic product innovations, and we believe we have the leadership team in place to invigorate our Product Vitality Index, accelerate expansion of our leading product portfolio, and achieve our above-market growth targets."

### 2021 Highlights

- Received regulatory approval of EPIFIX<sup>®</sup> in Japan
- Authored multiple peer-reviewed clinical, scientific and economic publications
- Filed additional U.S. Food and Drug Administration (FDA) Investigational New Drug (IND) applications
- Achieved double-digit top-line sales growth of continuing portfolio of products
- Expanded our sales force, putting the right people in the right places
- Furthered our scientific understanding of the significant therapeutic potential of mdHACM in KOA. The Company reviewed Phase 2B KOA clinical trial results, including p-values, additional study analyses, and the proposed path forward at its <a href="Investor Day">Investor Day</a> on December 7, 2021.

## 2022 Anticipated Milestones

- · Achieve annual growth target across the Company's vibrant commercial business
- Expand the Company's international footprint with the initial launch of EPIFIX ® in Japan
- · Commence Phase 3 KOA program, with two clinical trials
- Implement rigorous Current Good Manufacturing Practice (CGMP) standards throughout entire supply chain as a key market differentiator
- Continue to advance the scientific body of evidence substantiating clinical efficacy, economic viability and underlying

mechanism of action for our PURION® processed placental tissue platform through additional peer-reviewed publications, including rigorous scientific research and clinical studies

 Launch two new, organic products in the U.S.: AMNIOEFFECT™ and Placental Collagen Matrix, facilitating expansion into additional areas of significant unmet clinical need

#### 2022 Outlook

The Company provides the following financial outlook for 2022:

- Annual revenue growth of 11% to 14% in the Company's continuing portfolio of products
  - Base is 2021 Advanced Wound Care (AWC)/Section 361 Adjusted Net Sales (estimated to range from \$236 million to \$240 million)
  - o Contribution from individual drivers varies across quarters and years
  - Revenue Transition<sup>1</sup> impact complete in fourth guarter of 2021
  - We expect 2022 growth rates to be lowest in first quarter, increasing thereafter:
    - 1Q22: Mid-single digit percent growth
    - 2Q22: High-single digit percent growth
    - 3Q22: Mid- to high-teens percent growth
    - 4Q22: High-teens to twenty percent growth
- Research and Development (R&D) spend increasing from expected 2021 level of \$17 million to \$22 million
- Gross margins slightly lower due to competitive dynamics and product mix
- Expectations for growth assume full access to hospitals and health care provider facilities, as a continuation or escalation of access restrictions or lockdown orders resulting from the ongoing COVID-19 pandemic would adversely affect our results. These expectations additionally anticipate the mid-2022 launch of EPIFIX<sup>®</sup> in Japan, following expected reimbursement approval, and the 2022 launch of the Company's new AMNIOEFFECT™ and Placental Collagen Matrix product lines.
- 1. For a discussion of the revenue transition and the defined terms, refer to Item 8, Notes to the Consolidated Financial Statements in the MiMedx Group, Inc. Annual Report on Form 10-K for the years ended December 31, 2019 and 2020, and the respective Quarterly Reports on Form 10-Q for the noted quarterly periods.

#### J.P. Morgan Healthcare Conference Presentation

Timothy R. Wright, Chief Executive Officer, and Peter M. Carlson, Chief Financial Officer, will present virtually at the 40<sup>th</sup> Annual J.P. Morgan Healthcare Conference on Wednesday, January 12 at 5:15 PM Eastern Time.

Investors and other interested parties may access the live webcast on the Events page of the Investors section of the Company's website or by clicking here. A replay of the webcast will be available for 30 days on the Company's website at <a href="https://www.mimedx.com">www.mimedx.com</a> following the conclusion of the presentation.

### **Important Cautionary Statement**

This press release includes forward-looking statements. Statements regarding: (i) strategic milestones planned for 2022; (ii) our expected 2021 financial results and our 2022 financial outlook; (iii) our expectations regarding the timing of clinical trials; (iv) our expectations regarding the timing of new product launches; and (v) 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, planned regulatory submissions and regulatory approvals, 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) our access to hospitals and health care provider facilities could be restricted as a result of the ongoing COVID-19 pandemic; (v) the results of scientific research are uncertain and may have little or no value; (vi) our ability to sell our products in other countries depends on a number of factors including adequate

levels of reimbursement, regulatory approvals, market acceptance of novel therapies, and our ability to build and manage a direct sales force or third party distribution relationship; (vii) the effectiveness of amniotic tissue as a therapy for particular indications or conditions is the subject of further scientific and clinical studies; and (viii) 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 <a href="https://www.mimedx.com">www.mimedx.com</a>.

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