

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): September 13, 2021

MIMEDX GROUP, INC.

(Exact name of registrant as specified in charter)

Florida
(State or other jurisdiction
of incorporation)

001-35887
(Commission
File Number)

26-2792552
(IRS Employer
Identification No.)

1775 West Oak Commons Ct., NE, Marietta GA 30062
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (770) 651-9100

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	MDXG	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Important Cautionary Statement

This report includes forward-looking statements. 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. Such forward-looking statements include statements regarding: (i) future sales or sales growth; (ii) the Company's plans to review and conduct additional analyses of the clinical trial data from its plantar fasciitis, Achilles tendonitis, and knee osteoarthritis clinical trials and expectations regarding the results of such analyses, including expectations regarding safety and efficacy, and the value of safety data from the trials and these analyses; the Company's expectations regarding its mdHACM product's potential use as a safe and effective treatment option, and that it may be an effective treatment for persons battling inflammatory conditions; the Company's plans for completing 12-month safety visit follow-up and its timing; plans for meetings with the FDA, and planned biologics license application (BLA) submissions to the FDA, and their timing; plans for future clinical trials, including the Company's decision to pursue or not pursue, and their timing; (iii) estimates of potential market size for the Company's future products; (iv) plans for expansion outside of the U.S., or the potential to expand the Company's portfolio of products through licensing transactions or additional clinical research; the effectiveness of amniotic tissue as a therapy for any particular indication or condition; (v) expected spending on research and development in 2021; (vi) the Company's long-term strategy for value creation, the status of its pipeline products, expectations for future products, and expectations for future growth;

Additional forward-looking statements may be identified by words such as "believe," "expect," "may," "plan," "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 results of a clinical trial or trials may not demonstrate that the product is safe or effective, or may have little or no statistical value; the Company may change its plans due to unforeseen circumstances, and delay or alter the timeline for future trials, analyses, or public announcements; the timing of any meeting with the FDA depends on many factors and is outside of the Company's control, and the results from any meeting are uncertain; a BLA submission requires a number of prerequisites, including favorable study results and statistical support, and completion of a satisfactory FDA inspection of the Company's manufacturing facility or facilities; plans for future clinical trials depend on the results of pending clinical trials, discussion with the FDA, and other factors; and conducting clinical trials is a time-consuming, expensive, and uncertain process; (iii) the future market for the Company's products can depend on regulatory approval of such products, which might not occur at all or when expected, and is based in part on assumptions regarding the number of patients who elect less acute and more acute treatment than the Company's products, market acceptance of the Company's products, and adequate reimbursement for such therapies; (iv) the process of obtaining regulatory clearances or approvals to market a biological product or medical device from the FDA or similar regulatory authorities outside of the U.S. is costly and time consuming, and such clearances or approvals may not be granted on a timely basis, or at all, and the ability to obtain the rights to market additional, suitable products depends on negotiations with third parties which may not be forthcoming; (v) 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 (vi) expected spending can depend in part on the results of pending clinical trials;

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.

Item 7.01 Regulation FD.

On September 13, 2021, MIMEDX Group, Inc. (the "Company"), issued a press release announcing the top-line results from two late-stage musculoskeletal clinical trials of the Company's micronized dehydrated Human Amnion Chorion Membrane (mdHACM): a Phase 2B clinical trial for the treatment of Knee Osteoarthritis (KOA) and a Phase 3 clinical trial for the treatment of Plantar Fasciitis (PF). A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein for reference.

On September 13, 2021, Timothy R. Wright, MIMEDX Chief Executive Officer, Peter M. Carlson, MIMEDX Chief Financial Officer, and Robert B. Stein, M.D. Ph.D, MIMEDX Executive Vice President, Research and Development are expected to present at the H.C. Wainwright 23rd Annual Global Investment Conference beginning at 9:00 AM Eastern time. A copy of the presentation materials they will use are attached hereto as Exhibit 99.2 and are incorporated herein for reference. The presentation materials shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section and shall only be incorporated by reference into another filing under the Exchange Act or Securities Act of 1933 if such subsequent filing specifically references this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Press Release September 13, 2021.
99.2	Slide Presentation dated September 13, 2021.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

SIGNATURES

Pursuant to the requirements of the Exchange Act, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MIMEDX GROUP, INC.

Date: September 13, 2021

By: /s/ Peter M. Carlson
Peter M. Carlson
Chief Financial Officer

MIMEDX Reports Top-line Data from Two Late-Stage Musculoskeletal Trials with Proprietary Amniotic Tissue Technology

Phase 2B Knee Osteoarthritis (KOA) Study Top-line Interim Results Demonstrate Varied Efficacy Signals between Patient Cohorts

Company to Pursue Phase 3 KOA Confirmatory Studies

Initial Review of Phase 3 Plantar Fasciitis Trial Data Does Not Support a Biologics License Application (BLA) Filing at This Time, Pending Further Analysis

MARIETTA, Ga., September, 13, 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 top-line results from two late-stage musculoskeletal clinical trials of the Company's micronized dehydrated Human Amnion Chorion Membrane (mdHACM): a Phase 2B clinical trial for the treatment of Knee Osteoarthritis (KOA) and a Phase 3 clinical trial for the treatment of Plantar Fasciitis (PF).

Top-line results from an interim analysis of the six-month efficacy data for the Phase 2B clinical trial for KOA did not meet primary endpoints, but did reveal varied efficacy signals between patient cohorts evaluated pre- and post- a blinded interim analysis performed in mid-2019, prompting the Company to plan for confirmatory efficacy studies for the KOA indication. The Phase 3 PF study did not meet its primary endpoint, and the Company will not pursue a BLA for this indication at this time. Throughout both studies, the mdHACM product was found safe and well-tolerated.

Timothy R. Wright, MIMEDX Chief Executive Officer, commented, "These data, once examined thoroughly and reviewed with the U.S. Food and Drug Administration (FDA), will help guide our path forward, and merit additional clinical analysis as we pursue novel therapeutic solutions for patients with significant unmet needs. As a pioneer in amniotic tissue technology, our investigational studies further the science and our understanding of what is possible, and enable us to consider next-generation treatments for these painful and debilitating conditions. There is considerable market demand for safe and effective alternatives to reduce pain, improve function, and modify disease, and the potential positive signal within the KOA trial provides opportunity to build on these learnings and pursue additional studies. We look forward to further discussions with the FDA under the Regenerative Medicine Advanced Therapy (RMAT) process, and reviewing our next steps for continued clinical study of PURION® Processed mdHACM as a platform for regenerative medicine."

Top-line Interim Results: Phase 2B Knee Osteoarthritis (KOA)

The Phase 2B KOA trial formally ends in October 2021. An interim review of the 446 patients enrolled in the clinical trial showed that the study did not meet its two primary efficacy endpoints of a statistically significant change in the Visual Analog Scale (VAS) for Pain or in the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index. The top-line data indicate a potential positive clinical efficacy signal, but did not indicate a statistical difference between patients in the product treatment

group and the placebo group, with all scores improving for both groups. Significant differences were observed between patients enrolled prior to the study's initial blinded interim analysis (the Pre-Interim Analysis Cohort), and those patients enrolled following the initial blinded interim analysis (the Post-Interim Analysis Cohort). Patients in the treatment group in the Pre-Interim Analysis Cohort demonstrated a greater improvement in WOMAC-Total, WOMAC-Pain and WOMAC-Function scores, with statistically significant separation between treatment and placebo-treated patients at both the three-month and six-month endpoints. The patients in the Post-Interim Analysis Cohort showed a positive response to both treatment and placebo. Additional analyses are planned to explore these differences.

Results for VAS did not indicate statistically significant differences between treatment and placebo-treated patients, or between the Pre-Interim Analysis Cohort and the Post-Interim Analysis Cohort at either the three-month or six-month endpoint, with a strong improvement in VAS observed across both cohorts.

Robert B. Stein, M.D., Ph.D., MIMEDX Executive Vice President, Research and Development, said, "The top-line interim results from the overall KOA study population are somewhat surprising given prior clinical experience and retrospective studies, and further examination will be required to determine the potential factors that may have contributed to the observed differences. The Phase 2B KOA trial provided important insights into our approach for the design of our future Phase 3 studies that could further elucidate the potential impact of mdHACM on the underlying disease process and cartilaginous tissues. In parallel, we are continuing to invest in research initiatives that broaden our understanding of the product's mechanism of action, disease modification potential, and long-term therapeutic utility."

The Company plans to meet with the FDA to thoroughly review the findings and determine the appropriate path forward toward the initiation of Phase 3 clinical trials in KOA. Based on the current analysis of the interim results for the Phase 2B clinical trial, the Company now believes that two Phase 3 studies in KOA will be required to file a BLA and intends to provide an update for the timing of the filing, previously tentatively planned for late-2024 or early-2025, following review and discussion with the FDA.

Top-line Results: Phase 3 Plantar Fasciitis (PF)

The Phase 3 PF study did not meet its primary endpoints. The product and placebo groups both improved during the treatment period, and demonstrated reduced VAS Pain and improved Foot Function Index-Revised (FFI-R) scores, without statistically significant separation between treatment groups. The Company plans on a complete review of the full study data, but does not intend to pursue a BLA filing for PF at this time, instead focusing resources on advancing confirmatory Phase 3 studies for KOA.

Both the Phase 2B KOA clinical trial and the Phase 3 PF clinical trial demonstrate strong safety results with no significant Adverse Events or Serious Adverse Events. The Company plans to review the full study results from both trials with investors at a future R&D Day, planned for later this year.

Mr. Wright added, "While the Plantar Fasciitis study results are disappointing, we continue to analyze these trial data from this trial to glean insights that may benefit our overall clinical pipeline. On behalf of

MIMEDX, I extend our gratitude to all the patients, families, and physicians who participated in these important and informative trials.”

About the [Intra-articular Micronized dHACM Versus Saline in the Treatment of Osteoarthritis of the Knee Trial](#)

This study was a Phase 2B prospective, double-blinded, randomized controlled trial of PURION® Processed micronized dehydrated Human Amnion/Chorion Membrane (mdHACM) Injection, as compared to saline placebo injection in the treatment of osteoarthritis of the knee. Trial enrollment included 466 patients between the ages of 21 to 80 years, with a diagnosis of osteoarthritis defined as grade 1 to 3 on the Kellgren Lawrence grading scale and a Visual Analog Scale (VAS) for Pain score greater than 45. Due to a lower-than-expected number of study participant dropouts (3% in both arms) and with an adequate number of patients meeting the required time in study to assess the primary endpoint, the final number randomized was 446 patients.

The primary efficacy endpoints included change from baseline in VAS at 90 days and change from baseline in Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index at 90 days; the primary safety endpoint was incidence of related Adverse Events (AEs), Serious Adverse Events (SAEs), and Unanticipated Adverse Events at 365 days. Secondary endpoints included: change from baseline in VAS at 180 days and change from baseline in WOMAC at 180 days. The WOMAC Index has become a standard study metric in KOA studies, and its use has been extensively validated. The 12-month safety visit follow up as requested by FDA is scheduled to be completed in October 2021.

About the [Micronized dHACM Injectable for the Treatment of Plantar Fasciitis Trial](#)

This study was a Phase 3 prospective, double-blinded, randomized controlled trial of a single injection of 40 mg of PURION® Processed micronized dehydrated Human Amnion/Chorion Membrane (mdHACM) into the plantar fascia, as compared to saline placebo injection in the treatment of plantar fasciitis. The trial enrolled 277 patients between the ages of 21 and 79 years, with an investigator-confirmed diagnosis of plantar fasciitis for greater than or equal to one month (30 days) and less than or equal to 18 months. Patients were required to have a Visual Analog Scale (VAS) Pain score of greater than or equal to 45 mm at randomization and to have received conservative treatment for greater than or equal to 1 month (30 days), including any of the following modalities: Rest, Ice, Compression, Elevation (RICE); stretching exercises; NSAIDs; or orthotics. The primary endpoints were change in VAS for Pain at 90 days and incidence of related adverse events at 180 days, serious adverse events and unanticipated events during the first 12 months post-injection. Secondary endpoints included self-reported responses to the Foot Function Index – Revised (FFI-R) at 90 days.

Important Cautionary Statement

This press release includes forward-looking statements. Statements regarding: (i) plans to conduct additional analyses of the clinical trial data and expectations regarding the results of such analyses, including expectations regarding safety and efficacy, and the value of safety data from the trials and these analyses; (ii) the Company's expectations regarding mdHACM's potential use as a safe and effective treatment option, and that it may be an effective treatment for persons battling inflammatory conditions; (iii) the Company's plans for completing 12-month safety visit follow-up and its timing; (iv) plans for meetings with the FDA, and planned BLA submissions to the FDA, and their timing; and (v) plans for future clinical trials, including the Company's decision to pursue or not pursue, and their



timing; are forward looking statements. Additional forward-looking statements may be identified by words such as "believe," "expect," "may," "plan," "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) the results of a clinical trial or trials may not demonstrate that the product is safe or effective, or may have little or no statistical value; (ii) the Company may change its plans due to unforeseen circumstances, and delay or alter the timeline for future trials, analyses, or public announcements; (iii) the timing of any meeting with the FDA depends on many factors and is outside of the Company's control, and the results from any meeting are uncertain; (iv) a BLA submission requires a number of prerequisites, including favorable study results and statistical support, and completion of a satisfactory FDA inspection of the Company's manufacturing facility or facilities; (v) plans for future clinical trials depend on the results of pending clinical trials, discussion with the FDA, and other factors; and (vi) conducting clinical trials is a time-consuming, expensive, and uncertain process. 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.

Contact:

Jack Howarth
Investor Relations
404-360-5681
jhowarth@mimedx.com

Contact:

Corporate Communications
Hilary Dixon
404-323-4779
hdixon@mimedx.com



ADVANCING REGENERATIVE
MEDICINE TREATMENT THROUGH
PLACENTAL SCIENCE

Investor Presentation

September 2021

DISCLAIMER & CAUTIONARY STATEMENTS

This presentation includes forward-looking statements. 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. Such forward-looking statements include statements regarding:

- future sales or sales growth;
- the Company's plans to review and conduct additional analyses of the clinical trial data from its plantar fasciitis, Achilles tendonitis, and knee osteoarthritis clinical trials and expectations regarding the results of such analyses, including expectations regarding safety and efficacy, and the value of safety data from the trials and these analyses; the Company's expectations regarding its mdHACM product's potential use as a safe and effective treatment option, and that it may be an effective treatment for persons battling inflammatory conditions; the Company's plans for completing 12-month safety visit follow-up and its timing; plans for meetings with the FDA, and planned biologics license application (BLA) submissions to the FDA, and their timing; plans for future clinical trials, including the Company's decision to pursue or not pursue, and their timing;
- estimates of potential market size for the Company's future products;
- plans for expansion outside of the U.S., or the potential to expand the Company's portfolio of products through licensing transactions or additional clinical research; the effectiveness of amniotic tissue as a therapy for any particular indication or condition;
- expected spending on research and development in 2021;
- the Company's long-term strategy for value creation, the status of its pipeline products, expectations for future products, and expectations for future growth;

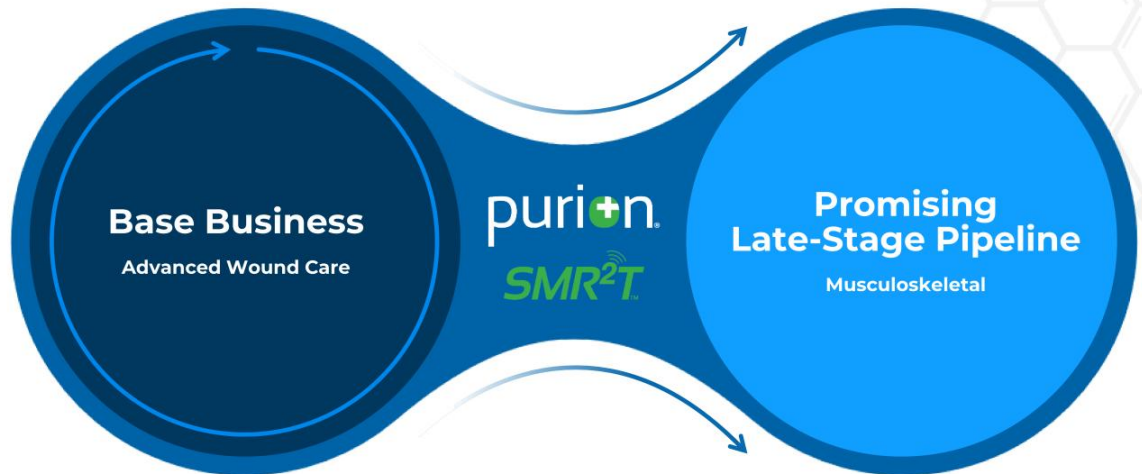
DISCLAIMER & CAUTIONARY STATEMENTS

Additional forward-looking statements may be identified by words such as "believe," "expect," "may," "plan," "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:

- future sales are uncertain and are affected by competition, access to customers, patient access to healthcare providers, and many other factors;
- the results of a clinical trial or trials may not demonstrate that the product is safe or effective, or may have little or no statistical value; the Company may change its plans due to unforeseen circumstances, and delay or alter the timeline for future trials, analyses, or public announcements; the timing of any meeting with the FDA depends on many factors and is outside of the Company's control, and the results from any meeting are uncertain; a BLA submission requires a number of prerequisites, including favorable study results and statistical support, and completion of a satisfactory FDA inspection of the Company's manufacturing facility or facilities; plans for future clinical trials depend on the results of pending clinical trials, discussion with the FDA, and other factors; and conducting clinical trials is a time-consuming, expensive, and uncertain process;
- the future market for the Company's products can depend on regulatory approval of such products, which might not occur at all or when expected, and is based in part on assumptions regarding the number of patients who elect less acute and more acute treatment than the Company's products, market acceptance of the Company's products, and adequate reimbursement for such therapies;
- the process of obtaining regulatory clearances or approvals to market a biological product or medical device from the FDA or similar regulatory authorities outside of the U.S. is costly and time consuming, and such clearances or approvals may not be granted on a timely basis, or at all, and the ability to obtain the rights to market additional, suitable products depends on negotiations with third parties which may not be forthcoming;
- 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
- expected spending can depend in part on the results of pending clinical trials;

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.

INDUSTRY LEADER IN UTILIZING AMNIOTIC
TISSUE AS A PLATFORM FOR REGENERATIVE
MEDICINE



**Distinct drivers of significant shareholder value with
current and future growth potential**

PLAN TO PROGRESS KOA PROGRAM TO PHASE 3 CONFIRMATORY EFFICACY STUDIES

- **Phase 2B Knee Osteoarthritis (KOA) study top-line interim results demonstrate varied efficacy signals between patient cohorts**
 - Top-line results from an interim analysis of six-month efficacy data did not meet primary endpoints
 - Pre-Interim Analysis Cohort treatment group demonstrated a greater improvement in WOMAC-Total, WOMAC-Pain and WOMAC-Function scores, with statistically significant separation between treatment and placebo-treated patients at both the three-month and six-month endpoints
 - VAS and WOMAC scores improved for both groups
- **Product was found safe and well-tolerated**

STATISTICAL DIFFERENCES BETWEEN PATIENTS TREATED WITH mdHACM AND WITH PLACEBO

Assessment	TOTAL TRIAL (446 PATIENTS)	Pre-Interim Analysis (190 patients)	Post-Interim Analysis (256 patients)
VAS	Not significant	Not significant	Not significant
WOMAC – Total	Not significant	Significant	Not significant
WOMAC – Pain	Not significant	Significant	Not significant
WOMAC – Function	Not significant	Significant	Not significant

5

mdHACM = micronized dehydrated Human Amnion Chorion Membrane; VAS = Visual Analog Scale ; WOMAC = Western Ontario and McMaster Universities Osteoarthritis Index; Table summarizes elements of the Phase 2B KOA clinical trial results, highlighting a statistically significant difference between patients in the product treatment group and the placebo group, and where there was no such statistically significant difference. It should be noted that overall, VAS and WOMAC scores improved for both groups in this clinical trial. The top line results between pre- and post-interim analysis require further examination of potential factors that may have contributed to the observed differences.



PLAN TO PROGRESS KOA PROGRAM TO PHASE 3 CONFIRMATORY EFFICACY STUDIES

Knee Osteoarthritis:

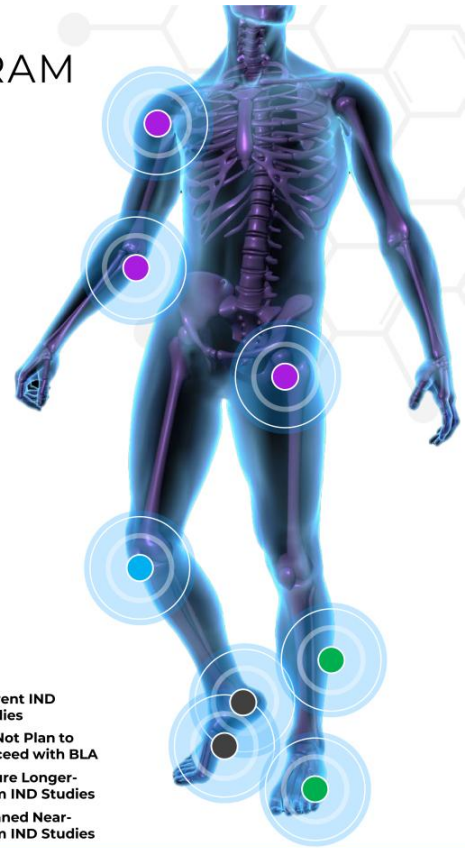
- Anticipate two Phase 3 KOA studies will be required to file a BLA
- 6-month open-label extension and safety readout anticipated in October 2021
- Plan to provide update for BLA timing following FDA review and discussion
- Continued R&D investment focused on:
 - Underlying disease process
 - Potential benefit to cartilaginous tissues
 - Advancing understanding of mdHACM mechanism of action

Plantar Fasciitis:

- Study did not meet its primary endpoints
- Do not plan to pursue a BLA filing for PF at this time

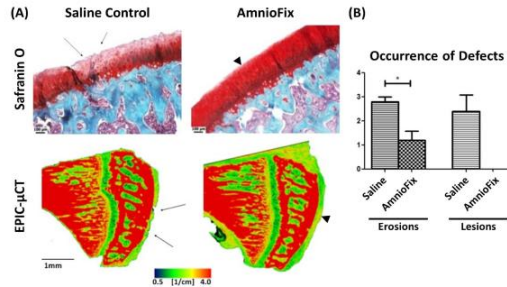
mdHACM treatment found safe and well-tolerated throughout both studies

- Current IND Studies
- Do Not Plan to Proceed with BLA
- Future Longer-Term IND Studies
- Planned Near-Term IND Studies



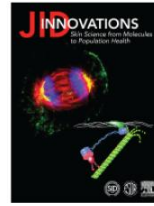
CONTINUED R&D INVESTMENT FOCUSED ON ADVANCING UNDERSTANDING OF mdHACM MECHANISM OF ACTION

Intra-articular Injection of Micronized Dehydrated Human Amnion/Chorion Membrane Attenuates Osteoarthritis Development¹



- mdHACM injections significantly reduced erosions and prevented lesion formation at day 21
- mdHACM rapidly sequestered in the synovial membrane following intra-articular injection and attenuates cartilage degradation in a rat OA model
- Data suggest that intra-articular delivery of mdHACM may have a therapeutic effect on OA development

Dehydrated Human Amniotic Membrane Modulates Canonical Wnt Signaling in Multiple Cell Types *In Vitro*²



- Data demonstrate ability of dHACM to regulate inherent molecular pathways
- Imply a possible mechanism of action for the prevention or treatment of pathological scar formation

Dehydrated Human Amniotic Membrane Inhibits Myofibroblast Contraction through the Regulation of the TGF β -SMAD Pathway *In Vitro*³

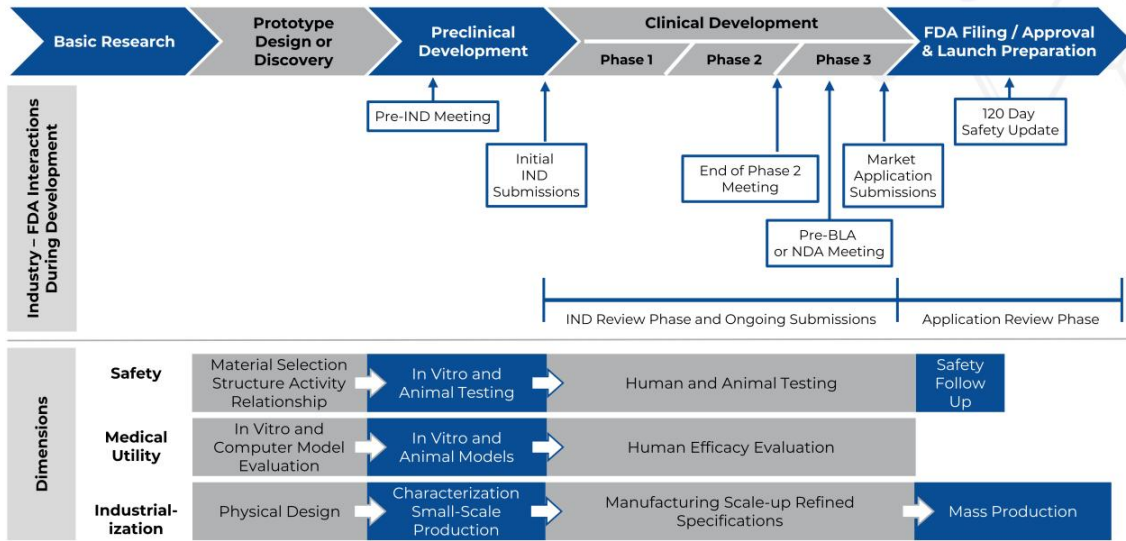


- mdHACM may regulate degenerative musculoskeletal diseases
- Highlights a potential molecular pathway targeted by the regulatory proteins contained within mdHACM to mitigate disease progression through Wnt signaling modulation

THE BLA PROCESS IS LENGTHY AND REQUIRES CAREFUL PLANNING AND COORDINATION WITH THE FDA

MIMEDX has assembled the right Board and Management Team with the relevant clinical, scientific and regulatory expertise required to navigate the BLA pathway

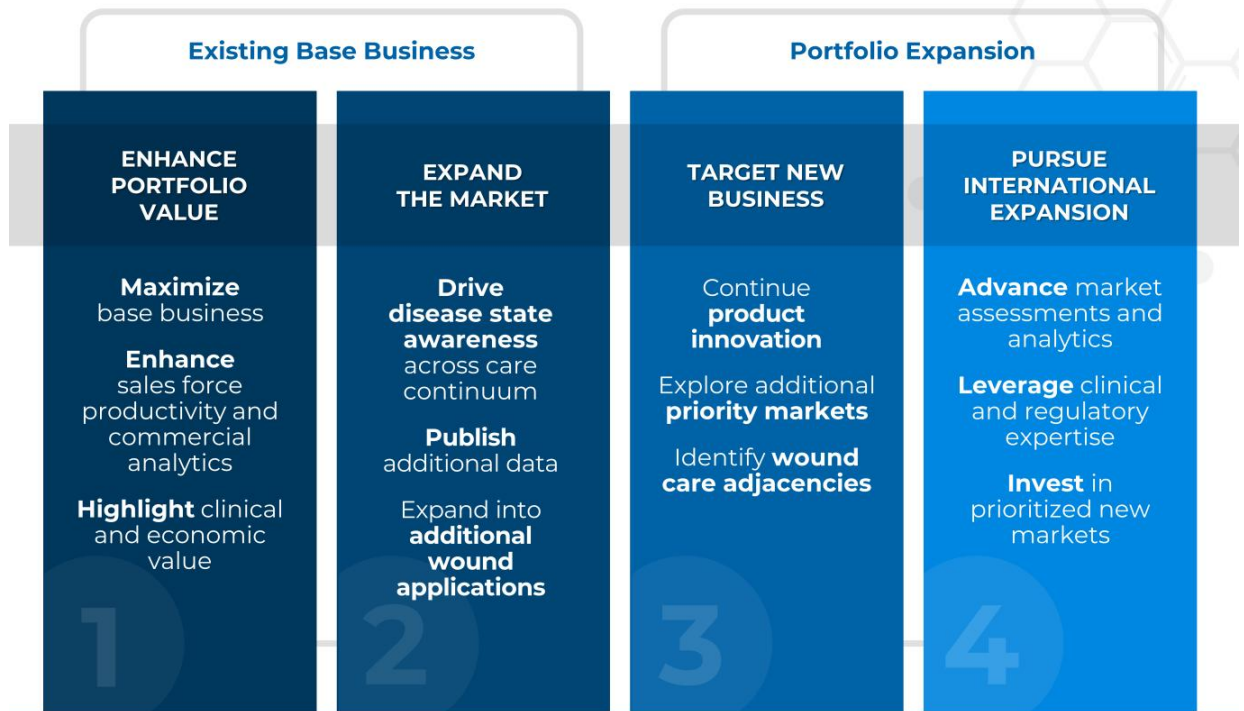
Industry – FDA Interactions During Development



8 The process of obtaining an approved BLA, including clinical trial development and execution as well as manufacturing processes, requires the expenditure of substantial time, effort and financial resources and may take years to complete. Clinical trials may not be successful or may return results that do not support approval. The FDA may not grant approval of our BLA on a timely basis, or at all, or we may decide not to pursue a BLA for certain products or indications, or may need to conduct additional trials for a given indication.

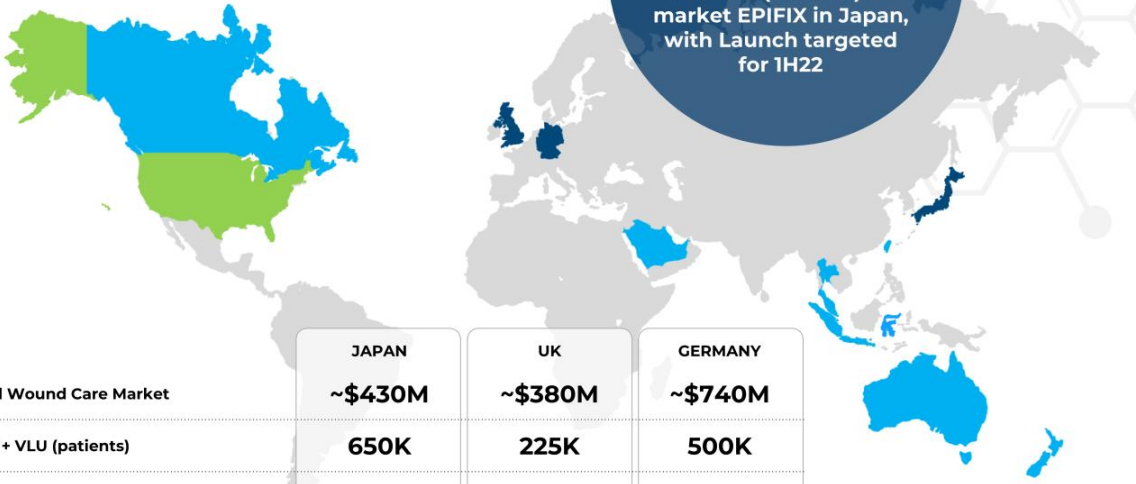


FOUR KEY DRIVERS TO ACHIEVE GROWTH IN BASE BUSINESS



TARGETED INVESTMENT FOR GEOGRAPHIC EXPANSION

Received Regulatory Approval by the Japanese Ministry of Health, Labour and Welfare (JMHLW) to market EPIFIX in Japan, with Launch targeted for 1H22



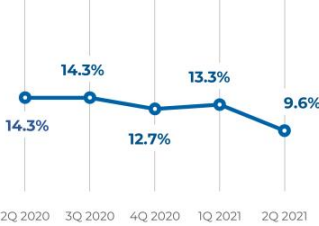
	JAPAN	UK	GERMANY
Total Wound Care Market	~\$430M	~\$380M	~\$740M
DFU + VLU (patients)	650K	225K	500K
MIMEDX Addressable Market (patients)	100K	35K	80K
Approval Status	Approved	Approved	Approved
Reimbursement Status	3-6 months post-approval*	In process	In process

- Current primary market
- 1-2 year expansion
- 2-3 year expansion

10 * Establishment of reimbursement pricing may take until mid-2022 to finalize, based on the JMHLW approval calendar.
 Source: Global Data Tissue Engineered-Skin Sub Data Model Wound Management Japan, Germany and UK Year 2020 - retrieved Sept 2020; Management estimates; MIMEDX Addressable Market represents assumed, eventual 15% penetration of the addressable market. Reaching this level is subject to numerous risks and uncertainties, including regulatory and market acceptance, and appropriate reimbursement. Investors are cautioned that actual results may differ materially.



FINANCIAL STRENGTH FORTIFIES SUSTAINABLE AND PROFITABLE GROWTH

<p>Adjusted Net Sales¹</p> <p>\$259M</p> <p>Advanced Wound Care (Section 361) \$225M</p> <p>Section 351 \$34M</p>	<p>Net Cash at 6/30/2021</p> <p>\$85M</p>	<p>Estimated 2021 Adjusted Net Sales</p> <p>\$245M-\$255M</p>												
<p>Adjusted Gross Margin¹</p> <p>83.3%</p>	<p>Adjusted EBITDA as % of Adjusted Net Sales²</p>  <table border="1"> <thead> <tr> <th>Quarter</th> <th>Adjusted EBITDA as % of Adjusted Net Sales</th> </tr> </thead> <tbody> <tr> <td>2Q 2020</td> <td>14.3%</td> </tr> <tr> <td>3Q 2020</td> <td>14.3%</td> </tr> <tr> <td>4Q 2020</td> <td>12.7%</td> </tr> <tr> <td>1Q 2021</td> <td>13.3%</td> </tr> <tr> <td>2Q 2021</td> <td>9.6%</td> </tr> </tbody> </table>	Quarter	Adjusted EBITDA as % of Adjusted Net Sales	2Q 2020	14.3%	3Q 2020	14.3%	4Q 2020	12.7%	1Q 2021	13.3%	2Q 2021	9.6%	<p>Estimated 2021 Adjusted Gross Margins</p> <p>83-85%</p> <p>(consistent with 2020)</p>
Quarter	Adjusted EBITDA as % of Adjusted Net Sales													
2Q 2020	14.3%													
3Q 2020	14.3%													
4Q 2020	12.7%													
1Q 2021	13.3%													
2Q 2021	9.6%													
<p>Net Loss¹</p> <p>\$46M</p> <p>Includes:</p> <ul style="list-style-type: none"> \$1.9M benefit from Revenue Transition \$8.2M loss on extinguishment of debt \$37.6M charge for Investigation, Restatement and Related Expenses 	<p>Adj. Free Cash Flow³</p> <p>\$19M</p>	<p>Estimated 2021 R&D Expense</p> <p>\$17M-\$22M</p>												

(1) Trailing twelve months period ended June 30, 2021. Adjusted Net Sales and Adjusted Gross Margin are non-GAAP measurements and exclude impact of Revenue Transition amounts; Refer to slide 14 for the respective GAAP amount and to slide 20 for more information. (2) Calculated on a trailing twelve-month basis for each period. Adjusted Net Sales and Adjusted EBITDA are non-GAAP measurements. Refer to slides 20 and 21 for more information and reconciliation to the nearest GAAP figure. (3) Adjusted Free Cash Flow is calculated as Adjusted EBITDA less capital expenditures and patent application costs; Refer to slide 21 for more information.

2021 OBJECTIVES SUPPORT CURRENT AND FUTURE GROWTH POTENTIAL

Commercial

- Top-line growth >10% (excludes impact of enforcement discretion)
- Sales force growth >10%
- Japan approval
- Pursue organic and inorganic growth opportunities

Operations

- CGMP compliance


R&D

- Interim data readouts (PF/KOA/AT)
 - Peer-reviewed clinical, scientific and economic publications
 - Accelerate late-stage pipeline
 - File additional INDs
-

APPENDIX

INDUSTRY LEADER IN UTILIZING AMNIOTIC TISSUE AS A PLATFORM FOR REGENERATIVE MEDICINE

Pioneer with leading brands and a late-stage pipeline

\$261.0M TTM 6/30/21 Net Sales ¹	83.3% Gross Margin ²	\$2.1B Market Cap ³	 <p>WELCOME BACK TO NASDAQ MiMedx MDXG - 11/4/2020 MDXG NasdaqListed</p>
2,000,000+ Allografts Distributed ⁴	~800 Employees ⁴	289 Field Sales Personnel ⁴	
30M (U.S.) with diabetes ⁵	\$6.2-\$18.7B Medicare cost of DFU/yr ⁷	EPIFIX® Purion SMR²T	Reimbursement coverage, U.S.: 300M+ lives
2.9M chronic wounds ⁶	\$60K/yr Cost of amputation care ⁸		
17.5M+ U.S. KOA patients ⁹	2M+ U.S. patients treated for PF annually ¹⁰	1,000+ patients studied under IND clinical programs ¹¹	10,000+ ft ² of ISO Class 7 clean room space

14 (1) Net sales for the TTM ended June 30, 2021, as reported in applicable SEC filing. (2) Represents GAAP gross margin for the TTM period ended June 30, 2021. (3) Based on closing stock price on September 10, 2021 and ~137 million fully diluted shares. (4) As of July 31, 2021. (5) Sen CK. Human Wounds and its Burden: An Updated Compendium of Estimates. Adv Wound Care (New Rochelle). 2019;8(2):39-48. doi:10.1089/wound.2019.0946. (6) Nussbaum SR, Carter MJ, Fife CE, Davanzo J, Haught R, Nusgart M, et al. An economic evaluation of the impact, cost, and Medicare policy implications of chronic nonhealing wounds. Value Health. 2018;21(1):27-32. (7) D. G. Armstrong, M.A. Szwedrowski, A.A. Armstrong, M. S. Conte, W. V. Padula, and S. A. Bus, "Five year mortality and direct costs of care for people with diabetic foot complications are comparable to cancer," Journal of Foot and Ankle Research, vol. 13, no. 1, BioMed Central Ltd., Mar. 24, 2020. doi: 10.1186/s13047-020-00383-2. (8) Global Data Knee Reconstruction Data Model United States 2020. (9) Tong KB, Furla J. Economic burden of plantar fasciitis treatment in the United States. Am J Orthop (Belle Mead NJ). 2010;39(5):227-231. (10) MIMEDX IND Clinical Trial Programs; Plantar Fasciitis Phase 2B-147; Plantar Fasciitis Phase 3-276; Knee Osteoarthritis Phase 2B-430+; Achilles Tendinitis Phase 3-158.



BASE BUSINESS HAS STABILIZED AND IS NOW POSITIONED FOR GROWTH

Net Sales (\$M)



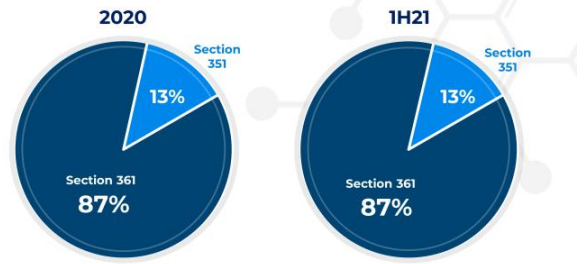
Adjusted Net Sales¹ (\$M)



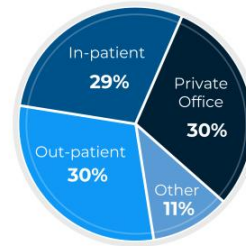
Advanced Wound Care/Section 361 Net Sales³



Section 361 vs. Section 351 Sales Breakdown^{2,3}



1H 2021 TTM Sales by Care Setting



(1) Adjusted net sales excludes impact of Revenue Transition amounts. Adjusted net sales is a non-GAAP measurement. Refer to slides 20 and 21 for more information and reconciliation to the nearest GAAP measure; (2) Section 361 includes Tissue + Cord sales. Section 351 includes Micronized + Particulate sales. (3) Non-GAAP. Please refer to slide 20 for a reconciliation to GAAP.

SUMMARY BALANCE SHEETS

(\$ millions)

	4Q19	1Q20	2Q20	3Q20	4Q20	1Q21	2Q21
Assets							
Cash and Cash Equivalents	69.1	53.5	48.2	109.6	95.8	84.7	85.0
Accounts Receivable, net	32.3	31.9	30.1	33.0	35.4	35.4	37.2
Inventory, net	9.1	9.2	10.6	11.0	10.4	11.6	10.1
Other Current Assets	12.7	21.2	18.7	17.9	19.0	18.3	15.4
Total Current Assets	123.2	115.9	107.6	171.5	160.6	150.0	147.7
Property and Equipment	12.3	11.8	10.8	10.3	11.4	11.0	10.3
Other Assets	31.6	31.2	32.5	31.5	30.0	29.8	29.1
Total Assets	167.2	158.9	150.9	213.3	202.0	190.8	187.1
Liabilities and Stockholders' Equity (Deficit)							
Current Liabilities	67.3	63.7	63.7	57.3	59.2	55.4	50.6
Long Term Debt, net	61.9	61.6	61.5	47.6	47.7	47.8	47.9
Other Liabilities	3.5	3.2	2.9	4.4	3.7	3.6	3.3
Total Liabilities	132.8	128.6	128.1	109.3	110.6	106.8	101.8
Convertible Preferred Stock	0.0	0.0	0.0	91.1	91.6	92.0	92.5
Stockholders' Equity (Deficit)	34.4	30.3	22.9	12.9	(0.2)	(8.0)	(7.2)
Total Liabilities and Stockholders' Equity (Deficit)	167.2	158.9	150.9	213.3	202.0	190.8	187.1

SUMMARY INCOME STATEMENTS

(\$ millions)	4Q19	1Q20	2Q20	3Q20	4Q20	1Q21	2Q21
Net Sales	76.4	61.7	53.6	64.3	68.5	60.0	68.2
Cost of Sales	12.7	10.0	8.2	10.3	10.8	9.7	12.8
Gross Profit	63.7	51.7	45.4	54.0	57.7	50.3	55.4
Research & Development	2.7	2.7	2.3	3.4	3.4	4.3	4.1
Selling, General, and Administrative	45.4	46.9	37.3	48.0	48.7	45.4	53.6
Investigation, Restatement, and Related	20.1	15.6	11.4	12.0	20.4	7.2	(2.1)
Amortization of Intangible Assets	0.3	0.3	0.3	0.3	0.3	0.2	0.2
Impairment of Intangible Assets	0.0	0.0	0.0	0.0	1.0	0.0	0.0
Operating Loss	(4.9)	(13.7)	(5.9)	(9.7)	(16.1)	(6.8)	(0.4)
Loss on extinguishment of debt	0.0	0.0	0.0	(8.2)	0.0	0.0	0.0
Interest Expense, net	(2.4)	(2.4)	(2.6)	(1.5)	(1.5)	(1.5)	(1.4)
Pretax Loss	(7.3)	(16.1)	(8.4)	(19.4)	(17.6)	(8.3)	(1.8)
Income Tax Provision (Expense) Benefit	(0.2)	11.3	0.0	0.0	1.0	(0.1)	0.0
Net Loss	(7.5)	(4.8)	(8.5)	(19.4)	(16.6)	(8.4)	(1.8)

SUMMARY CASH FLOW STATEMENTS

(\$ millions)	4Q19	1Q20	2Q20	3Q20	4Q20	1Q21	2Q21
Net Loss	(7.5)	(4.8)	(8.5)	(19.4)	(16.6)	(8.4)	(1.8)
Share-Based Compensation	2.9	3.3	4.4	3.7	3.9	3.2	4.1
Depreciation	1.6	1.5	1.4	1.5	1.3	1.2	1.3
Other Non-Cash Effects	1.2	1.2	1.3	9.5	1.7	1.1	0.9
Changes in Assets	(14.2)	(8.2)	2.9	(1.8)	(6.2)	0.1	1.9
Changes in Liabilities	(7.0)	(5.3)	(4.7)	1.9	5.5	(3.9)	(4.8)
Net Cash Flows (Used in) Provided By Operating Activities	(23.1)	(12.3)	(3.1)	(4.6)	(10.4)	(6.7)	1.6
Purchases of Property and Equipment	(0.7)	(1.0)	(0.4)	(0.7)	(2.2)	(1.9)	(0.4)
Patent Application Costs	(0.1)	(0.1)	(0.1)	0.0	(0.1)	(0.2)	(0.0)
Net Cash Flows Used in Investing Activities	(0.8)	(1.1)	(0.5)	(0.7)	(2.3)	(2.1)	(0.4)
Preferred Stock Net Proceeds	0.0	0.0	0.0	93.4	(0.8)	0.0	0.0
Proceeds from Term Loan	0.0	0.0	10.0	49.5	0.0	0.0	0.0
Repayment of Term Loan	(0.9)	(0.9)	(10.9)	(72.0)	0.0	0.0	0.0
Prepayment Premium on Term Loan	0.0	0.0	0.0	(1.4)	0.0	0.0	0.0
Deferred Financing Cost	0.0	0.0	0.0	(2.8)	(0.3)	0.0	0.0
Stock Repurchased for Tax Withholdings on Vesting of Restricted Stock	(0.2)	(1.5)	(0.8)	(0.1)	0.0	(3.2)	(1.4)
Proceeds from Exercise of Stock Options	0.0	0.3	0.0	0.1	0.0	0.9	0.5
Net Cash Flows (Used in) Provided By Financing Activities	(1.1)	(2.2)	(1.8)	66.7	(1.1)	(2.3)	(0.9)
Beginning Cash Balance	94.1	69.1	53.5	48.2	109.6	95.8	84.7
Change in Cash	(25.1)	(15.5)	(5.3)	61.4	(13.8)	(11.1)	0.3
Ending Cash Balance	69.1	53.5	48.2	109.6	95.8	84.7	85.0

REVENUE DETAIL



(\$ millions)	Quarter							Trailing 12 Months			
	4Q19	1Q20	2Q20	3Q20	4Q20	1Q21	2Q21	3Q20	4Q20	1Q21	2Q21
Advanced Wound Care / Section 361 ¹	56.2	48.5	45.8	55.1	59.3	51.5	59.3	205.6	208.7	211.7	225.2
Section 351 ¹	12.0	8.7	6.1	8.2	8.7	8.2	8.6	35.0	31.7	31.2	33.7
Adjusted Net Sales²	68.2	57.2	51.9	63.3	68.0	59.7	67.9	240.6	240.4	242.9	258.9
Revenue Transition Impact ³	8.2	4.5	1.7	1.0	0.5	0.3	0.3	15.4	7.7	3.5	2.1
Net Sales	\$ 76.4	\$ 61.7	\$ 53.6	\$ 64.3	\$ 68.5	\$ 60.0	\$68.2	\$256.0	\$248.1	\$246.4	\$261.0

(1) Section 361 includes Tissue + Cord sales. Section 351 includes Micronized + Particulate sales. Advanced Wound Care/Section 361 and Section 351 Sales are Non-GAAP metrics. These two metrics allow investors to better understand the trend in sales between the two different product groups. (2) Adjusted net sales excludes impact of Revenue Transition amounts. Adjusted net sales is a non-GAAP measurement. Our reported net sales, specifically those reported prior to and after the Transition, led to situations where we included revenue recognized on the cash basis and "as-shipped" basis in the same period. Management uses Adjusted Net Sales to provide comparative assessments and understand the trend in the Company's sales across periods, exclusive of effects related to the Company's transition to revenue recognition at the point of shipment. (3) Impact of revenue transition includes cash collected related to the remaining contracts. 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. Form 10-K for the years ended December 31, 2019 and 2020, and the respective Form 10-Qs for the noted quarterly periods.

NON-GAAP METRICS RECONCILIATION

(\$ millions)	4Q19	1Q20	2Q20	3Q20	4Q20	1Q21	2Q21
Net Sales – Reported	76.4	61.7	53.6	64.3	68.5	60.0	68.2
Less: Revenue Transition Impact ¹	(8.2)	(4.5)	(1.7)	(1.0)	(0.5)	(0.3)	(0.3)
Adjusted Net Sales	68.2	57.2	51.9	63.3	68.0	59.7	67.9
Gross Profit	63.7	51.7	45.4	54.0	57.7	50.3	55.4
Less: Revenue Transition Impact ¹	(7.1)	(3.9)	(1.5)	(0.9)	(0.4)	(0.2)	(0.3)
Adjusted Gross Profit	56.6	47.8	44.0	53.1	57.3	50.1	55.1
Adjusted Gross Margin	83.0%	83.6%	84.8%	83.9%	84.2%	83.9%	81.3%
Adjusted EBITDA	14.1	3.1	10.2	6.9	10.3	4.7	2.9
Less: Capital Expenditures	(0.7)	(1.0)	(0.4)	(0.7)	(2.2)	(1.9)	(0.4)
Less: Patent Application Costs	(0.1)	(0.1)	(0.1)	0.0	(0.1)	(0.2)	(0.0)
Adjusted Free Cash Flow	13.3	2.0	9.7	6.2	8.0	2.6	2.5

⁽¹⁾ Impact of revenue transition includes cash collected related to the remaining contracts. 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. Form 10-K for the years ended December 31, 2019 and 2020, and the respective Form 10-Qs for the noted quarterly periods.

ADJUSTED EBITDA RECONCILIATION

(\$ millions)	4Q19	1Q20	2Q20	3Q20	4Q20	1Q21	2Q21
Net Loss	(7.5)	(4.8)	(8.5)	(19.4)	(16.6)	(8.4)	(1.8)
Depreciation & Amortization	1.8	1.8	1.7	1.8	1.6	1.5	1.5
Interest Expense	2.4	2.4	2.6	1.5	1.5	1.5	1.4
Loss on Extinguishment of Debt	0.0	0.0	0.0	8.2	0.0	0.0	0.0
Income Tax	0.3	(11.3)	0.0	0.0	(1.0)	0.1	(0.0)
EBITDA	(3.0)	(12.0)	(4.2)	(7.9)	(14.5)	(5.5)	1.1
Investigation, Restatement & Related	20.1	15.6	11.4	12.0	20.4	7.2	(2.1)
Revenue Transition ¹	(5.9)	(3.9)	(1.5)	(0.9)	(0.4)	(0.2)	(0.3)
Impairment of intangible assets	0.0	0.0	0.0	0.0	1.0	0.0	0.0
Share-Based Compensation	2.9	3.3	4.4	3.7	3.9	3.2	4.1
Adjusted EBITDA²	14.1	3.1	10.2	6.9	10.4	4.7	2.8

Investigation, Restatement & Related:

- Audit Committee Investigation completed in 2Q19
- Restatement activities completed in 2Q20
- Going forward, remainder is legal costs for Company matters, resolution costs for Company matters, recoveries from insurance providers, and indemnification costs under agreements with former officers and directors

(1) Impact of revenue transition includes cash collected related to the remaining contracts. 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. Form 10-K for the years ended December 31, 2019 and 2020, and the respective Form 10-Qs for the noted quarterly periods. (2) 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, Restatement, and Related, (vii) the effect of the change in revenue recognition on net loss, (viii) Impairment of intangible assets, and (ix) share-based compensation.

