

**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): November 20, 2020**

**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.

**Item 7.01 Regulation FD Disclosure**

MiMedx Group, Inc. (the “*Company*” or the “*Registrant*”) will host its annual meeting at 10:00 a.m. Eastern time on November 20, 2020. Timothy R. Wright, Chief Executive Officer, will present an overview of the Company. Rohit Kashyap, Ph.D., Executive Vice President and Chief Commercial Officer, and Robert B. Stein, M.D., Ph.D., Executive Vice President, Research and Development, are scheduled to present an overview of the Company’s commercial and R&D initiatives, including an update on estimated, potential market sizes of future expected products intended to treat knee osteoarthritis pain. A copy of the presentation materials to be used during the presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein. Such materials will also be available on the Company’s website at [www.mimedx.com](http://www.mimedx.com).

All information in the presentation materials speak as of the date thereof, and MiMedx does not assume any obligation to update such information in the future. In addition, MiMedx disclaims any inference regarding the materiality of such information which otherwise may arise as a result of its furnishing such information under Item 7.01 of this Current Report on Form 8-K. Information contained on the Company’s website is not incorporated by reference into this Current Report on Form 8-K. The information in the preceding paragraph, as well as Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section. It may only be incorporated by reference into another filing under the Exchange Act or Securities Act of 1933 if such subsequent filing specifically references Section 7.01 of this Current Report on Form 8-K.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
99.1	<a href="#">Slide presentation dated November 20, 2020.</a>
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: November 20, 2020

By: /s/ Peter M. Carlson

Peter M. Carlson  
Chief Financial Officer

WELCOME TO

**MiMedx**

**2020 ANNUAL  
SHAREHOLDERS MEETING  
NOVEMBER 20, 2020**

MAKING A DIFFERENCE FOR PATIENTS  
A LEADER IN ADVANCED WOUND CARE

WELCOME BACK  
TO NASDAQ

**MiMedx**

MDXG-11/4/2020

MDXG NasdaqListed

 **Nasdaq**

# IMPORTANT CAUTIONARY STATEMENT

This presentation contains forward-looking statements. Investors are cautioned against placing undue reliance on these statements.

All statements relating to events or results that may occur in the future are forward-looking statements, including, without limitation, statements regarding the following:

- the regulatory pathway for our products, including our existing and planned investigative new drug application and pre-market approval requirements, the timing, design and success of our clinical trials and pursuit of biologic license applications ("BLAs") and other regulatory approvals for certain products;
- our expectations regarding our ability to continue marketing our micronized products and certain other products during and following the end of the period of enforcement discretion announced by the United States Food and Drug Administration ("FDA");
- expectations regarding future revenue growth, including product innovations, expansion into additional domestic and international markets, our product pipeline and the potential to increase our product offerings, and future research and development expenses;
- ongoing and future effects arising from the COVID-19 pandemic and the Company's plans to adhere to governmental recommendations with respect thereto;
- our expectations regarding market opportunities, expected growth in certain markets, and demographic and market trends; and
- our expectations regarding our ability to resolve certain legal matters.

Forward-looking statements generally can be identified by words such as "expect," "will," "change," "intend," "seek," "target," "future," "plan," "continue," "potential," "possible," "could," "estimate," "may," "anticipate," "to be" and similar expressions.

These statements are based on numerous assumptions and involve known and unknown risks, uncertainties and other factors that could significantly affect the Company's operations and may cause the Company's actual actions, results, financial condition, performance or achievements to differ materially. Factors that may cause such a difference include, without limitation, those discussed under the heading "Risk Factors" in our most recent Form 10-Q and in our Form 10-K for the year ended December 31, 2019.

Unless required by law, the Company does not intend, and undertakes no obligation, to update or publicly release any revision to any forward-looking statements, whether as a result of the receipt of new information, the occurrence of subsequent events, a change in circumstances or otherwise. Each forward-looking statement contained herein is specifically qualified in its entirety by the aforementioned factors.

# MEETING AGENDA

- 1 Introductions
- 2 Annual Meeting Matters
- 3 Company Highlights
- 4 Commercial
- 5 Research & Development
- 6 Question & Answer Session

# ANNUAL MEETING MATTERS

# ANNUAL MEETING AGENDA

**1 QUORUM**

**2 DESCRIPTION OF BUSINESS ITEMS:**

- a. Election of Two Class I Directors
- b. Approval of Amendment to Charter to Increase the Number of Authorized Shares of Common Stock
- c. Approval of Amendments to the Company's 2016 Equity and Cash Incentive Plan

**3 OPENING OF POLLS FOR VOTING**

**4 CLOSING OF POLLS**

**5 REPORT ON RESULTS OF VOTE**

**6 ADJOURNMENT**

**7 COMPANY PRESENTATION**

**8 QUESTION & ANSWER SESSION**

# COMPANY HIGHLIGHTS

# PATIENTS ARE WHY WE ARE HERE.



ALVIN



PHYLLIS



NICK

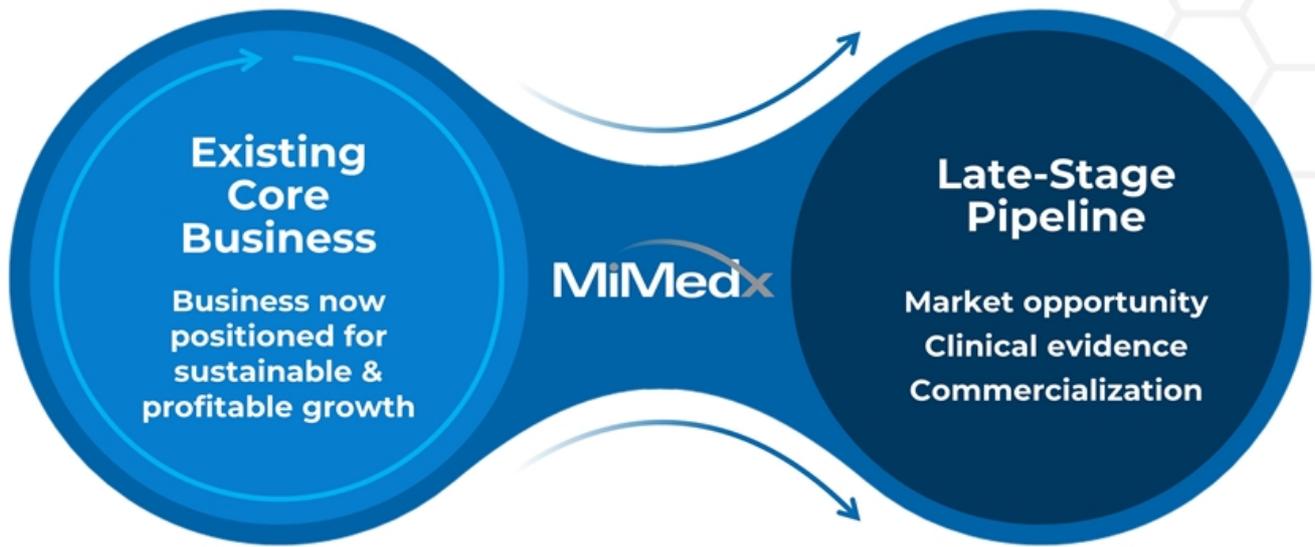


RUTH

“ WE HAVE AN OPPORTUNITY AND RESPONSIBILITY TO MAKE A DIFFERENCE FOR THESE PATIENTS. AND IN DOING SO, GROW A SUCCESSFUL AND MEANINGFUL HEALTHCARE COMPANY.”

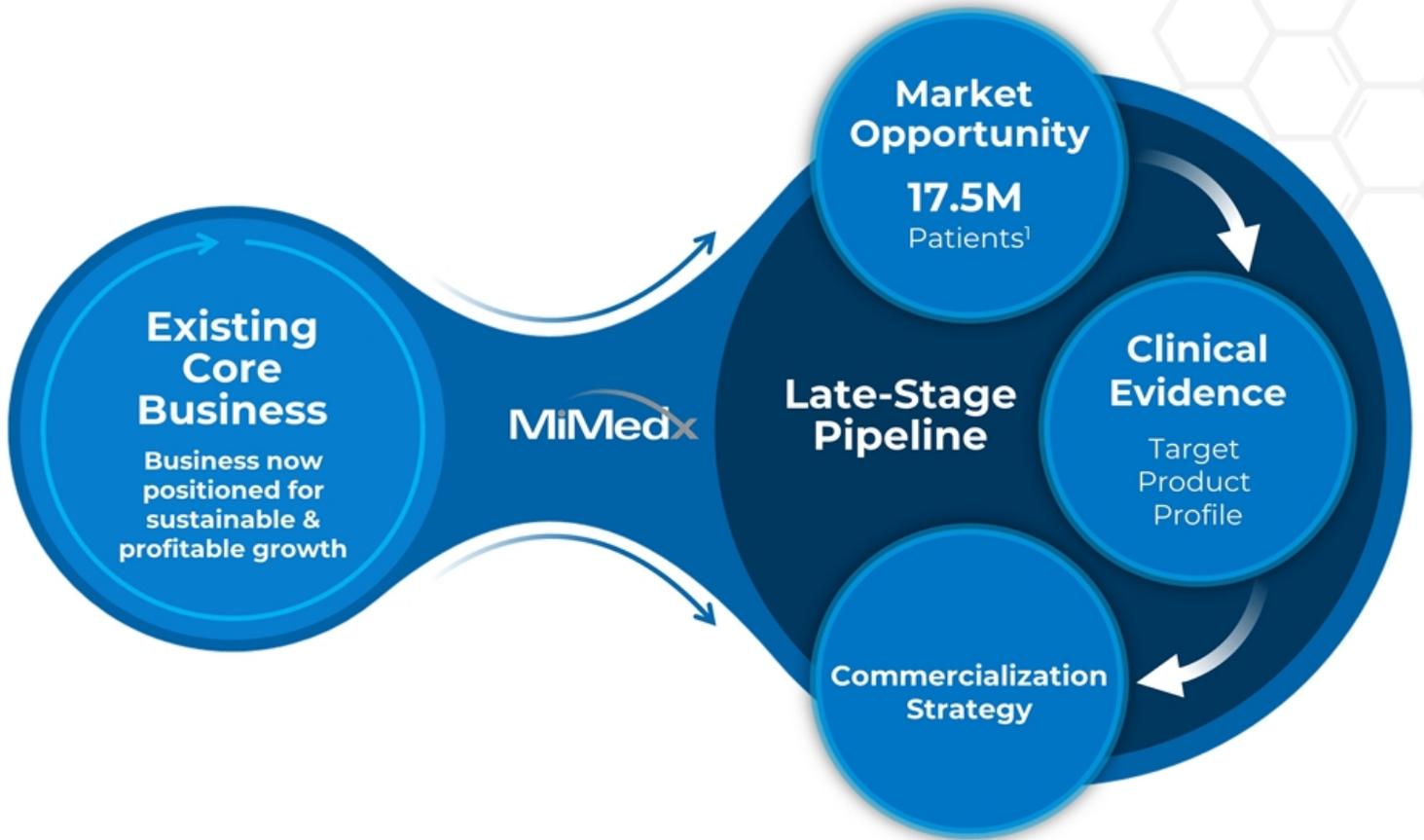
**TIMOTHY R. WRIGHT**  
CHIEF EXECUTIVE OFFICER

# MIMEDX IS A PIONEER IN PLACENTAL BIOLOGICS



**Leading Brands in Existing Core Business Position  
Company to Capitalize on Late-stage Pipeline**

# MIMEDX IS A PIONEER IN PLACENTAL BIOLOGICS



(1) Global Data Knee Reconstruction Data Model United States 2020

# INCREASING OPTIMISM IN KNEE OA OPPORTUNITY

Informed by low dropout rate,  
additional dosing potential in  
Phase 2B clinical trial, and evolving  
competitive landscape

**~1M-1.5M**

**>17.5 million**

U.S. KOA patients  
(growing 2% per year)<sup>1</sup>

**8.8 million**

intra-articular injections across  
**4.4 million** patients<sup>2,3</sup>

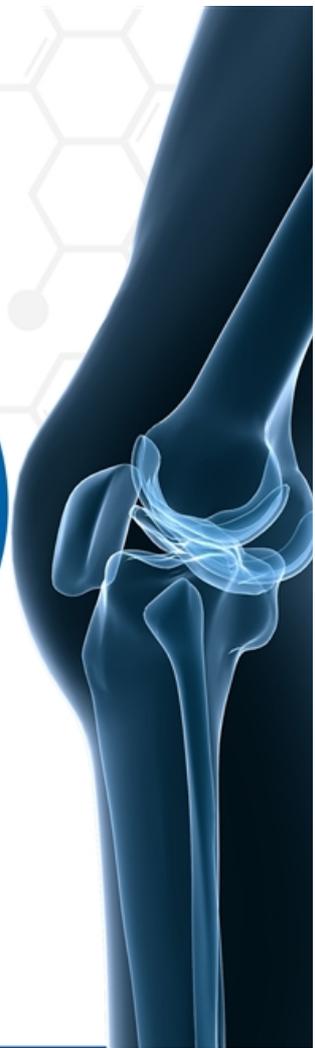
#### Current Treatments

- Corticosteroid injections
- Viscosupplementation (e.g. Hyaluronic Acid)
- Platelet Rich Plasma (PRP)
- Emerging therapies

**~300K-800K**

Potential candidates for  
injectable amnion/ chorion<sup>4</sup>

Offers **non-surgical** treatment option to  
**reduce pain & improve function**



# THREE PRIMARY DOMAINS OF VALUE CREATION

**Core business investment drives sustainable growth and creates competitive advantage**



COMMERCIAL

# FOUR KEY DRIVERS TO ACHIEVE CORE GROWTH

## Existing Core Business

### ENHANCE PORTFOLIO VALUE

**Maximize** core business

**Enhance** sales force productivity and commercial analytics

**Highlight** clinical and economic value

1

### EXPAND THE MARKET

**Drive disease state awareness** across care continuum

**Publish** additional data

Expand into **additional wound applications**

2

## Portfolio Expansion

### TARGET NEW BUSINESS

Continue **product innovation**

Explore additional **priority markets**

Identify **wound care adjacencies**

3

### PURSUE INTERNATIONAL EXPANSION

**Advance** market assessments and analytics

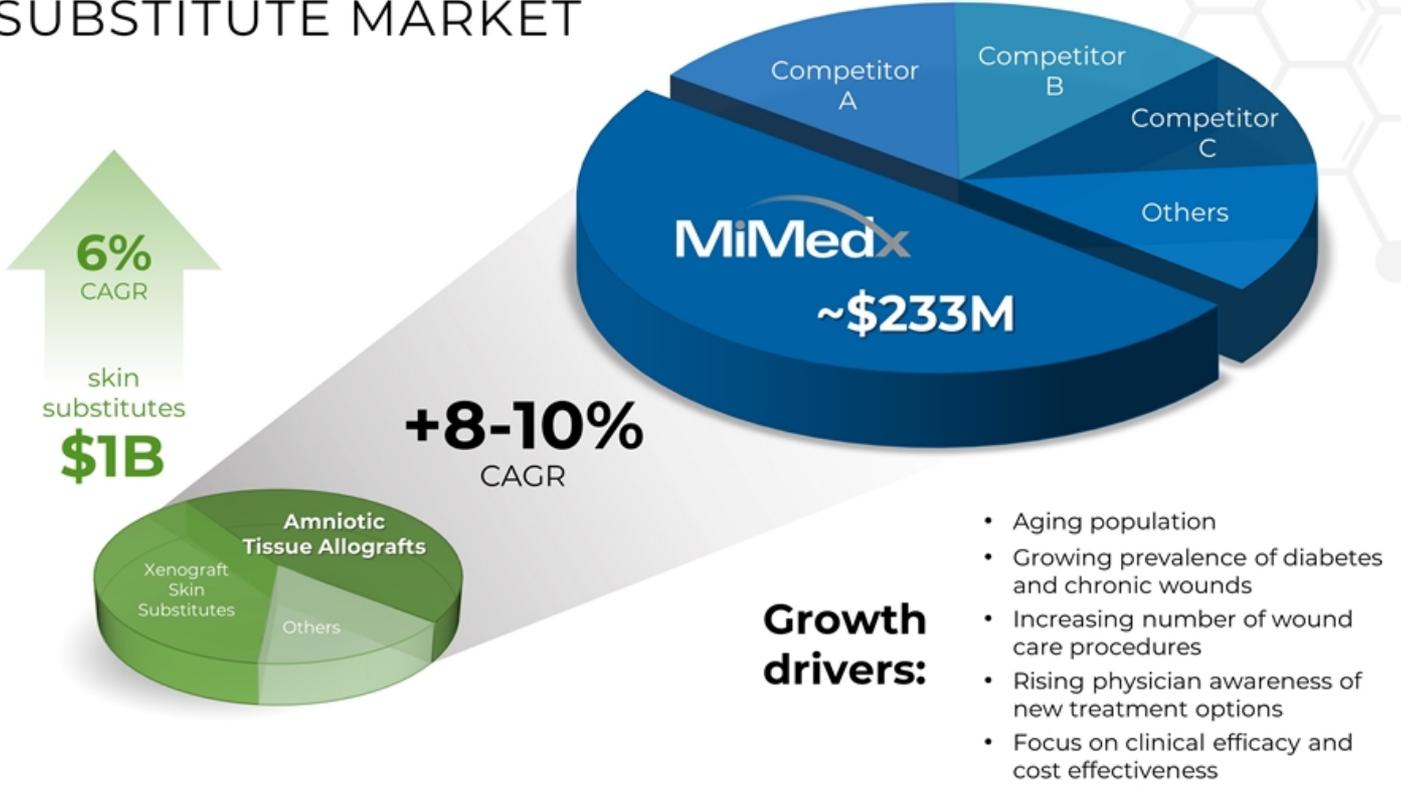
**Leverage** clinical and regulatory expertise

**Invest** in prioritized new markets

4

# AMNIOTIC TISSUE: LARGEST & FASTEST GROWING SEGMENT OF SKIN/DERMAL SUBSTITUTE MARKET

## U.S. Amniotic Tissue Market



# MAXIMIZING OPPORTUNITIES IN OUR CORE BUSINESS

## Existing Core Business



**Increase Market Opportunity**

**1**



**Capture Disproportionate Share**

**2**



**Invest to Enhance Commercial Excellence Model**

**3**

# 1 INCREASE MARKET OPPORTUNITY



## STRATEGIES

## TACTICS

**Raise Patient Awareness**

Direct-to-patient initiatives

**Enhance Provider Engagement**

Quality medical education  
for 1,500+ HCPs

**Leverage New Products**

Leverage treatment options  
throughout care continuum



# 2 CAPTURE DISPROPORTIONATE SHARE



## STRATEGIES

## TACTICS

### Communicate Product Differentiation

- Proprietary process
- More than 2 million allografts



### Build Provider Confidence

- AHRQ data<sup>1,2</sup>
- Generate health economic data

Reimbursement coverage, U.S.  
**300M+**  
lives

### Build Payor Confidence

- Prove value to total cost of care
- Expand coverage to additional areas of use

(1) Agency for Healthcare Research and Quality (AHRQ); (2) Skin Substitutes for Treating Chronic Wounds Technical Brief, Technology Assessment Program; Agency for Healthcare Research and Quality, Feb 2, 2020

# 3 INVEST TO ENHANCE COMMERCIAL EXCELLENCE MODEL



## STRATEGIES

## TACTICS

### CUSTOMER ECOSYSTEM

4,000+  
accounts

2,500+  
physicians

Q3 2020 Revenue (TTM)



**Identify, Target, Educate**

### Build Analytics and Customer Segmentation

- Target high value customers
- Education programs that drive awareness & utilization

**Demand Generation**

### Expand Sales Team by 10%+

- Near-term investment in structure and scale
- Improve productivity by targeting and training

**Fulfillment**

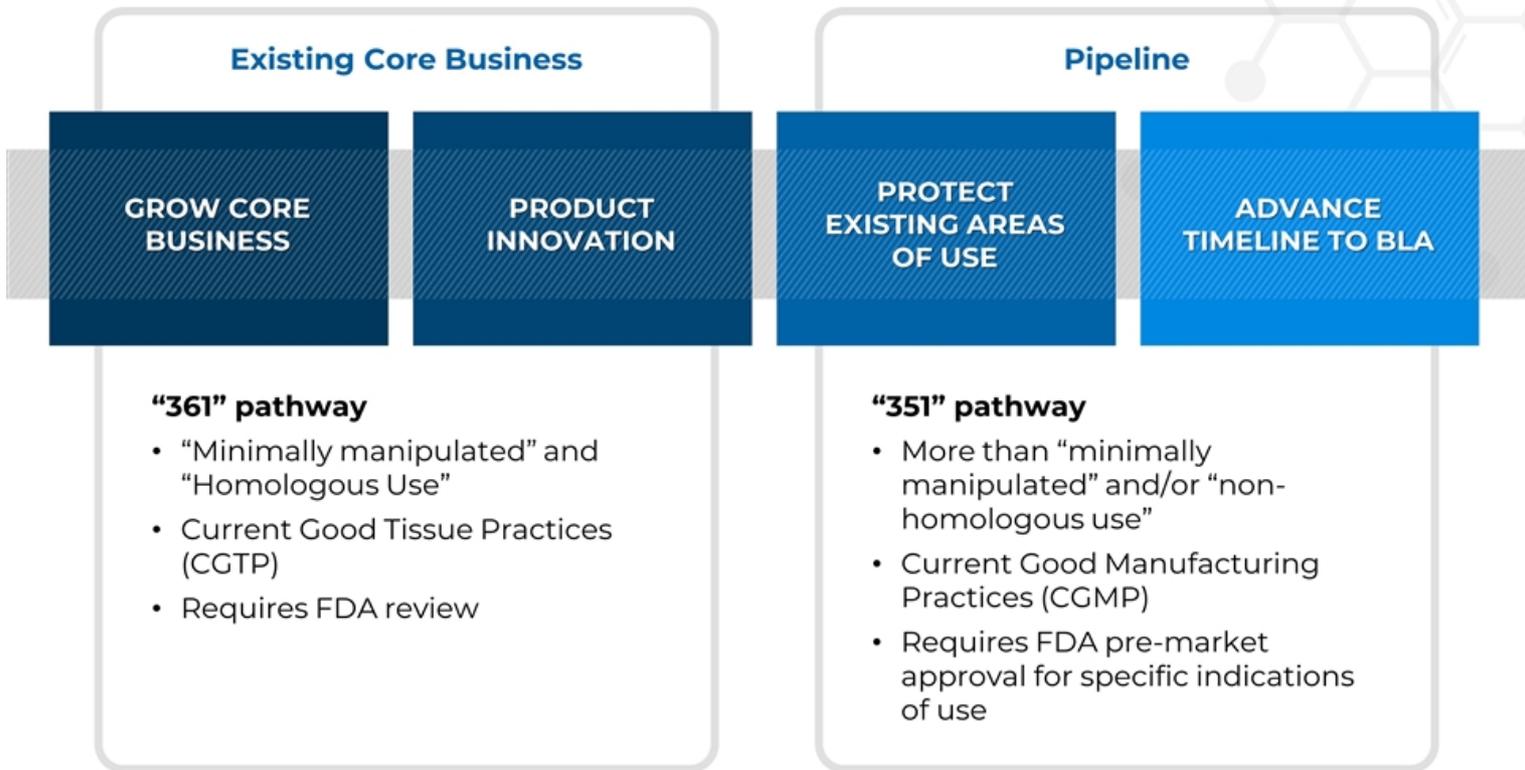
### Promote Value-added support

- Insurance verification teams process >50,000 patients/yr
- Reimbursement education to improve customer efficiency

# RESEARCH & DEVELOPMENT

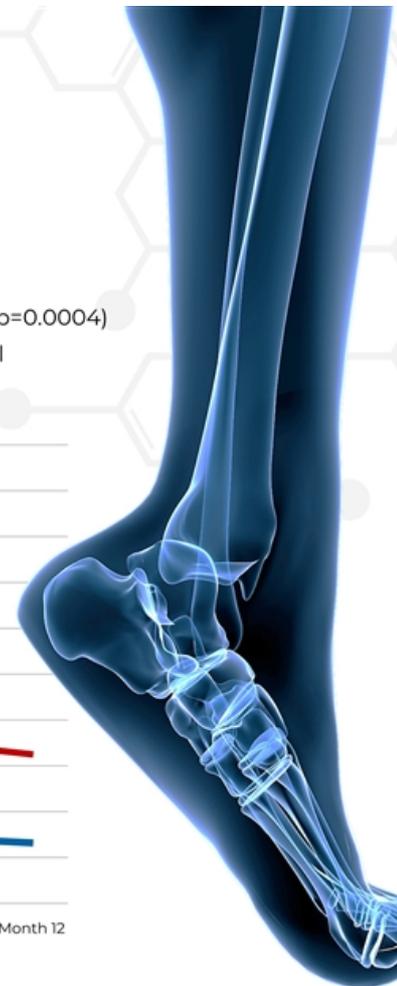
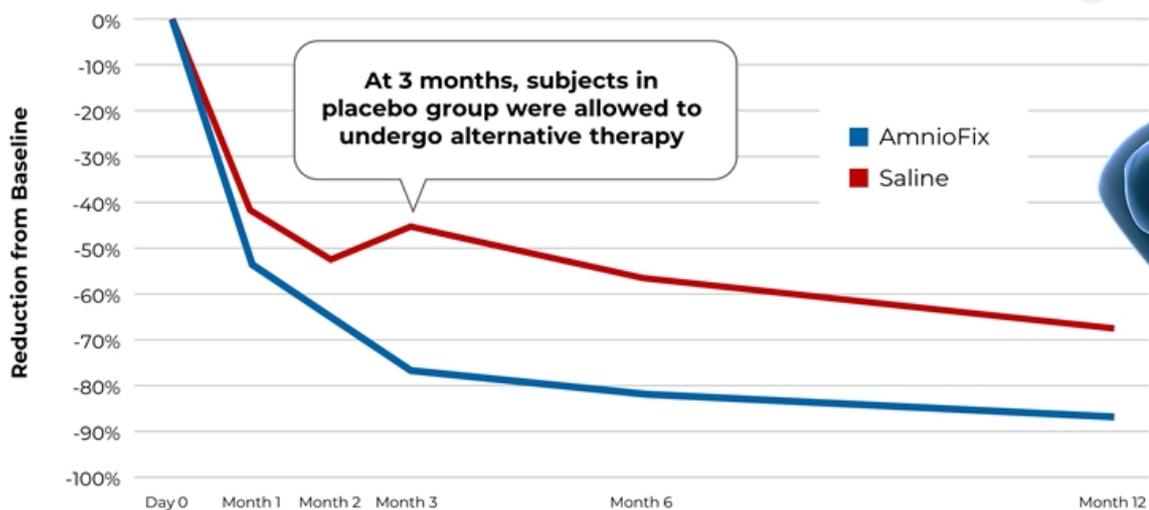
# R&D STRATEGIC IMPERATIVES

Regulatory Pathway Requires Different Development Approaches



# PHASE 2B STUDY DEMONSTRATES SIGNIFICANT BENEFIT

- **Primary Efficacy Endpoint:** reduction in VAS (visual analog scale) score for pain ( $p < 0.0001$ )
- **Secondary Efficacy Endpoint:** improvement in FFI-R (Foot Function Index-Revised) score ( $p = 0.0004$ )
- At 3-month follow-up visit, average reduction VAS score for pain was 76% vs. 45% for Control



# PLANTAR FASCIITIS (PF) CURRENT STATUS

## Phase 2B study completed

## Phase 3 study enrollment completed

- 277 patients in September 2020
- Last patient out in Q2 2021

## Potential timeline\*

- Meeting with FDA mid-2021
- BLA filing 1H 2022
- FDA approval and product launch 1H 2023

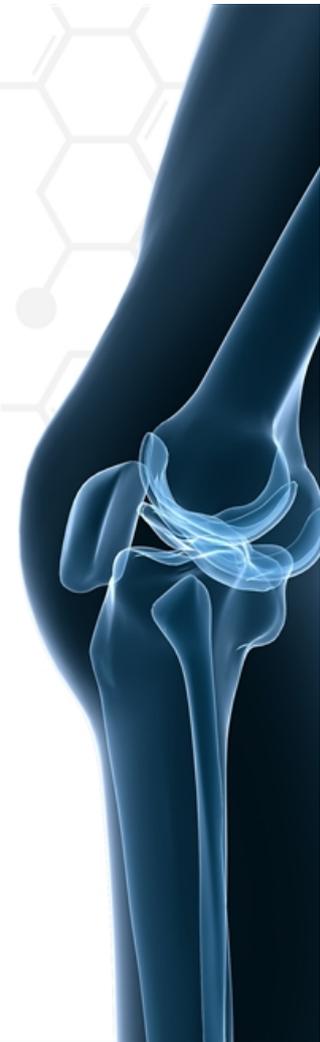
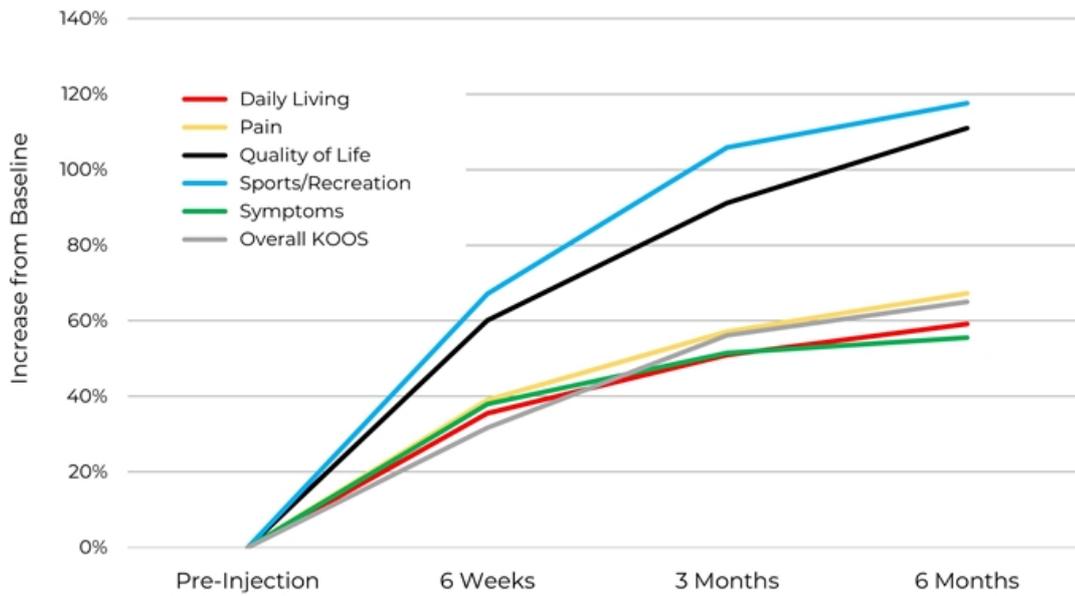
## PF Study Informs Safety, Efficacy and Other Future Indications



\* Timeline represents current plans and estimates only. Actual results and timing may differ materially. There can be no assurance that clinical trials are conducted or completed on schedule, that trial results are favorable, or that we obtain regulatory approval for our products and indications.

# RESULTS OF RETROSPECTIVE STUDY BY DR. KRIS ALDEN INDICATE SIGNIFICANT BENEFIT FROM mdHACM INJECTIONS

### KOOS Subscales (Mean % Increase) over Time



# KNEE OSTEOARTHRITIS (OA) CURRENT STATUS

## Phase 2B study ongoing

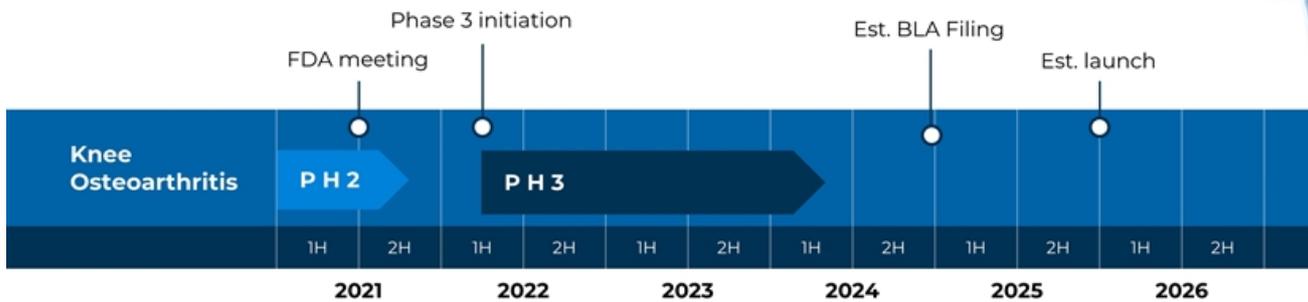
- Enrollment completed September 2020
  - Completed early, despite COVID-19 challenges
  - 447 patients enrolled
  - Drop-out rates lower than expected – 3% actual compared to 10% anticipated
- Last Patient Out for 6-month blinded observation in late 2021
- 6-month open-label extension allows all patients option to receive mdHACM

## Potential timeline\*

- Meeting with FDA in mid-2021
- Phase 3 initiation in first half 2022
- BLA filing 2H 2024 / 1H 2025
- FDA approval and product launch in 2H 2025 / 1H 2026

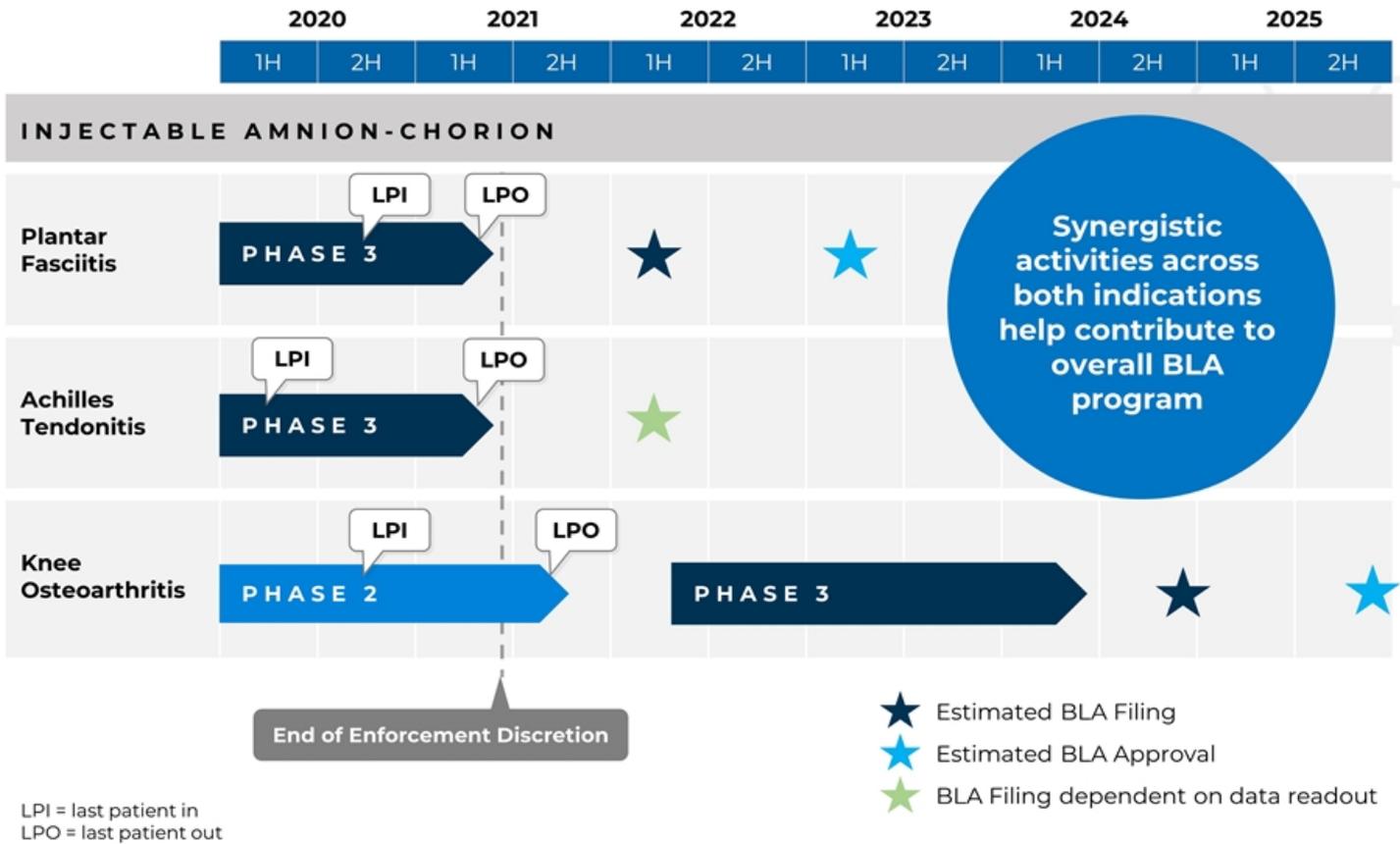
## Critical success factors

- Advantaged by CGMP readiness for Plantar Fasciitis BLA
- RMAT designation provides frequent dialogue with the FDA



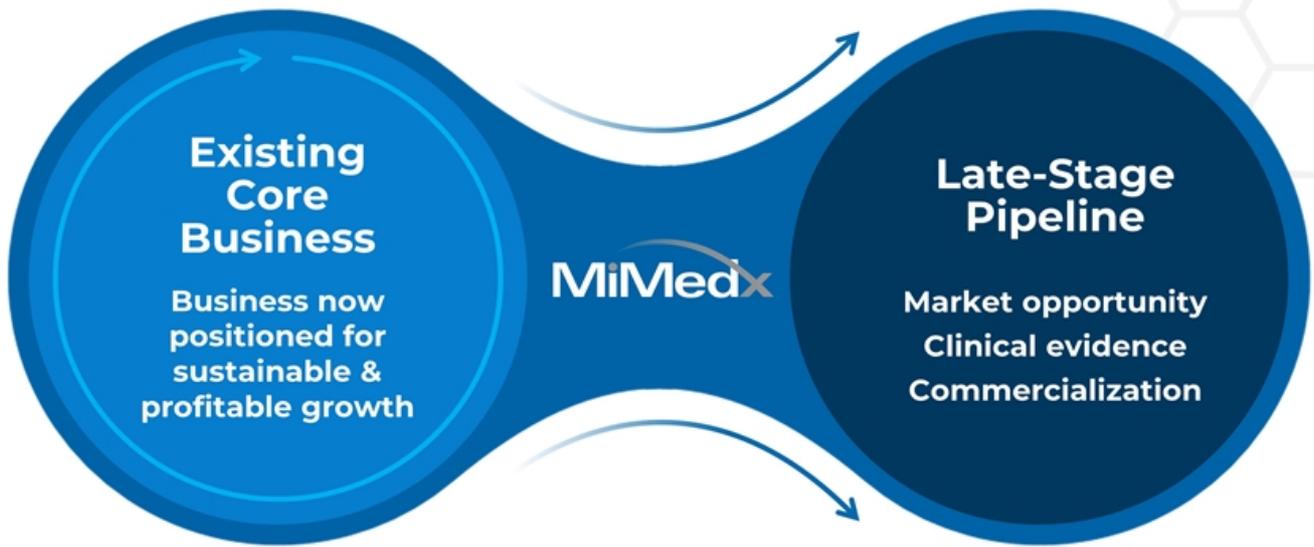
\* Timeline represents current plans and estimates only. Actual results and timing may differ materially. There can be no assurance that clinical trials are conducted or completed on schedule, that trial results are favorable, or that we obtain regulatory approval for our products and indications

# BLA APPROVAL REQUIRES CMC+CGMP+RCTs



CMC = Chemistry, Manufacturing and Controls; CGMP = Current Good Manufacturing Practices; RCT = Randomized Controlled Trial; According to recently updated FDA guidance, FDA generally intends to exercise enforcement discretion through May 31, 2021, with respect to the IND and the premarket approval requirements for certain HCT/PS, provided that use of the HCT/P does not raise reported safety concerns or potential significant safety concerns; Timeline represents current plans and estimates only. Actual results and timing may differ materially. There can be no assurance that clinical trials are conducted or completed on schedule, that trial results are favorable, or that we obtain regulatory approval for our products and indications

# MIMEDX IS A PIONEER IN PLACENTAL BIOLOGICS



**Core business investment drives sustainable growth and creates competitive advantage**

# QUESTION & ANSWER SESSION

# APPENDIX

# REGULATORY ENVIRONMENT OVERVIEW

	361	351
<b>Human Tissue</b> (i.e., placental tissue)	When minimally manipulated	When more than minimally manipulated
<b>Indication for use</b>	Homologous use*	As indicated by clinical trial
<b>Manufacturing process</b>	cGTP	cGMP
<b>FDA Oversight</b>	Regulated by the FDA for risk of disease transmission	Approved by the FDA for a specific indication for use

## Enforcement Discretion:

According to recently updated FDA guidance, FDA generally intends to exercise enforcement discretion through May 31, 2021, with respect to the IND and the premarket approval requirements for certain HCT/Ps, provided that use of the HCT/P does not raise reported safety concerns or potential significant safety concerns.

# PHASE 2B STUDY DEMONSTRATES SIGNIFICANT BENEFIT

## Plantar Fasciitis (PF)

### Phase 2b Study, AIPF004

147, subjects randomized, 100.68% complete enrollment

Total number of sites: 14

Study closed to enrollment, 12-month efficacy endpoint completed, study closeout visits completed

Final site monitoring visit completed August 14, 2018

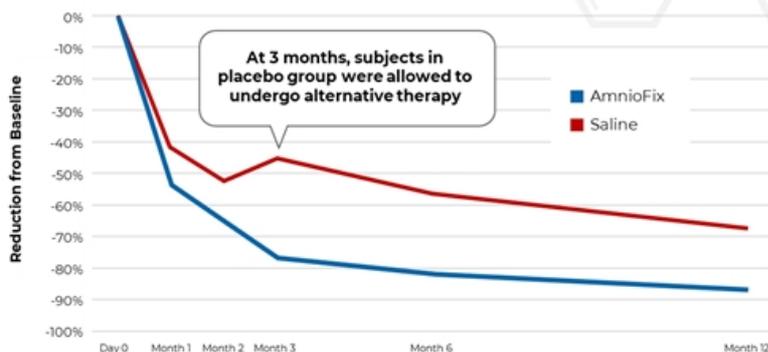
Timetable for Analysis and Clinical Study Report:

Clinical Study Report for Phase 2B Plantar Fasciitis trial in development. Final draft of data tables reviewed with statistics group and final analytical data tables received by Clinical. These have been sent to Rho. Completion of the Clinical Study Report initiated and hope to complete and audit HPA by Dec 2020.

### Per Protocol Analysis: 135 subjects

- LOCF Pooled Site analysis dataset: Completed
- LOCF Original Site: Completed
- Observed Case Pooled Site: Completed
- Observed Case Original Site: Completed
- Clinical Study Report (CSR): Date to be revised
- Manuscript: estimated submission for publication Q1 2021

- Primary Efficacy Endpoint: reduction in VAS (visual analog scale) score for pain ( $p < 0.0001$ )
- Secondary Efficacy Endpoint: improvement in FFI-R (Foot Function Index-Revised) score ( $p = 0.0004$ )
- At 3-mo. follow-up visit, average reduction VAS score for pain was 76% vs. 45% for Control



### "End of Phase 2 Meeting" - MiMedx met with FDA in April 2017

- Face to Face Meeting
- Presented Interim (3 month) Phase 2B data
- Presented Phase 3 Protocol and discussed
- FDA had no comments about clinical study, Phase 3 Initiated
- Since Phase 2 data were "interim" this was not labeled a formal End of Phase meeting, but served that purpose.
- Next planned meeting as per regulations is Pre-BLA submission

# INJECTABLE DEHYDRATED HUMAN AMNION/CHORION MEMBRANE (dHACM) IN THE TREATMENT OF KNEE OSTEOARTHRITIS

Kris Alden, MD, PhD, Hinsdale Orthopaedics, Hinsdale, IL

## Retrospective study provided insight into potential for reducing pain and improving function

### Purpose

To present our clinical experience using micronized dHACM injection as a treatment for symptomatic knee OA.

### Methods

#### Study Design

- In a retrospective study design, data were abstracted from the electronic medical records of 82 OA patients and 100 knees injected with 100 mg dHACM by a single physician, over a 14-month period.
- Data collected included age, gender, adverse events and Knee Injury and Osteoarthritis Outcome Score (KOOS) scores routinely recorded at baseline and 6 weeks, and 3 and 6 months, post-treatment.

#### Treatment with Injectable dHACM

- Treatment consisted of an injection of 100 mg of dHACM, suspended in 3 ml of 0.9% sterile normal saline performed by the primary author.
- Prior to injection, local anesthesia was achieved by injection of 2 mls of 0.5% Marcaine in the subcutaneous tissue.
- The dHACM allograft was injected through a 22 gauge needle with ultrasound guidance.
- Patients were instructed to stop all NSAIDs post injection.

#### Knee injury and Osteoarthritis Outcome Score (KOOS)

- In the KOOS scale used in this evaluation, 0 represents the worst situation (extreme problems with item assessed), while 100 is an ideal situation (no problems with item assessed).
- Effectiveness of dHACM treatment was measured by serial KOOS scores at 6 weeks, and 3 and 6 months.
- An improvement in KOOS score of at least 10 points is considered to represent meaningful positive clinical change.

### Results

- Data from 82 patients with 100 treated knees were included for analysis. Of these 82 patients, the majority were female (51/82, 62%).
- Mean age at treatment was  $61.6 \pm 10.6$  years, median age of 58.0 years with an age range of 36-89 years.
- Overall mean KOOS score for the cohort was 40 at baseline, improving to 52, 62 and 65 at 6 weeks, 3 months and 6 months post-dHACM injection. (Table 1)
- Within 6 weeks of dHACM injection all areas of assessment in the KOOS sub-scale had an improvement of mean score by greater than 10 points signifying meaningful positive clinical change.
- By 6 months, differences of 24.8-30 points were observed in all sub-categories.
- Percent increases in KOOS scores were 32%, 56% and 65% respectively. (Table 2)
- The largest improvements at 6 months were in the quality of life and sports/recreation domains, 111% and 118% respectively.
- Pain scores improved by 67% at 6 months. All scores improved throughout the observation period.
- Short term pain or soreness around the knee post-injection was a common observation.
- No serious or ongoing, unresolved adverse events were observed in this cohort.

Table 1 Mean KOOS over time

KOOS subscale	Preinjection	6 wk	3 mo	6 mo
Daily living	48.6 ± 18.0	65.8 ± 18.0	73.3 ± 18.4	77.3 ± 18.5
Pain	43.5 ± 15.6	60.5 ± 17.5	68.4 ± 19.0	72.8 ± 18.3
Quality of life	27.0 ± 18.8	43.3 ± 19.8	51.7 ± 22.1	57.0 ± 22.5
Sports/Recreation	24.7 ± 21.2	41.3 ± 25.5	50.9 ± 26.7	53.8 ± 28.8
Symptoms	44.7 ± 18.3	61.7 ± 17.7	67.8 ± 19.3	69.5 ± 19.5
Overall KOOS	39.6 ± 14.2	52.2 ± 17.9	61.9 ± 19.4	65.4 ± 21.0

Abbreviation: KOOS, Knee Injury and Osteoarthritis Outcome Score.  
Note: Data presented as mean ± standard deviation.

Table 2 Mean percent increase over preinjection time point

KOOS subscale	Preinjection	6 wk	3 mo	6 mo
Daily living	0%	35%	51%	59%
Pain	0%	39%	57%	67%
Quality of life	0%	60%	91%	111%
Sports/Recreation	0%	67%	106%	118%
Symptoms	0%	38%	51%	55%
Overall KOOS	0%	32%	56%	65%

Abbreviation: KOOS, Knee Injury and Osteoarthritis Outcome Score.  
Note: Data presented as percentage.

### Conclusions

- To our knowledge, these data represents the largest single-physician experience with injectable amniotic tissue in the treatment of knee OA to date.
- In our experience, injectable dHACM appears to be a potentially useful treatment option for patients with knee OA.
- Further controlled studies are required to confirm these observations.