#### **SCHEDULE 14A** Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934

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- **Preliminary Proxy Statement**
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- Definitive Proxy Statement
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# MiMedx Group, Inc. (Name of Registrant as Specified in Its Charter)

**Prescience Point Capital Management LLC Prescience Partners, LP Prescience Point Special Opportunity LP Prescience Capital, LLC Eiad Asbahi** Alfred G. Merriweather **Charlotte E. Sibley** William F. Spengler (Name of Person(s) Filing Proxy Statement, if other than the Registrant) Payment of Filing Fee (check the appropriate box):

- $\square$  No fee required.
- □ Fee computed on table below per Exchange Act Rule 14a-6(i)(4) and 0-11.
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  - 3) Filing Party:
  - 4) Date Filed:

On April 16, 2021, Prescience Point Capital Management LLC ("<u>Prescience</u>") issued a press release (the "<u>Press Release</u>") announcing its intention to nominate Eiad Asbahi, Alfred G. Merriweather, Charlotte E. Sibley and William F. Spengler (the "<u>Nominees</u>") for election at the 2021 annual meeting of shareholders of MiMedx Group, Inc. (the "<u>Company</u>") and containing a letter to shareholders of the Company. A copy of the Press Release, which includes the shareholder letter, is filed herewith as <u>Exhibit 1</u>. The Press Release contains a link to a report prepared by Prescience, which is filed herewith as <u>Exhibit 2</u>, and a JP Morgan Healthcare Conference presentation, which is filed herewith as <u>Exhibit 3</u>. The Press Release was also sent via email to certain shareholders of the Company.

Information regarding the Participants (as defined in <u>Exhibit 4</u>) in any future solicitation of proxies regarding the Company is filed herewith as <u>Exhibit 4</u>. In addition, Prescience filed a Schedule 13D/A on April 16, 2021 containing additional information regarding Prescience Partner, LP's intention to present certain proposals and nominate the Nominees for election at the Company's 2021 annual meeting of shareholders, the relevant text of which is attached herewith as <u>Exhibit 5</u>.

From time to time, the Participants may make posts to their social media channels on Twitter and LinkedIn, the texts of which are attached herewith as <u>Exhibit 6</u>.

#### Prescience Point Capital Management to Nominate Four Highly Qualified Director Candidates to MiMedx Board at 2021 Annual Meeting

#### Sends Letter to Fellow MiMedx Shareholders Citing Board's Failure to Maximize Shareholder Value

BATON ROUGE, La., April 16, 2021 /PRNewswire/ -- Prescience Point Capital Management, together with its affiliates ("Prescience Point"), a research-focused, catalyst-driven investment firm, announced today the nomination of four highly qualified director candidates to the Board of Directors (the "Board") of MiMedx Group, Inc. (NASDAQ: MDXG) ("MiMedx" or the "Company"). Prescience Point, a beneficial owner of approximately 8.1% of the outstanding shares of MiMedx, believes that the best path forward for unlocking shareholder value is the addition of Mr. Eiad Asbahi, Mr. Alfred G. Merriweather, Ms. Charlotte E. Sibley, and Mr. William F. Spengler to the Board at the upcoming Annual Meeting of Shareholders (the "Annual Meeting"), scheduled to be held on May 27, 2021.

"We continue to believe that MiMedx is deeply undervalued, due in large part to the Company's failure to effectively communicate the value of Amniofix to the investment community" said Eiad Asbahi, Founder and Managing Partner of Prescience Point. "Furthermore, under the current Board's oversight, power has become concentrated in the hands of one entity, rendering the Board incapable of unlocking the Company's substantial value for all shareholders."

"To realize the promise of MiMedx for all shareholders, the Company needs – first and foremost – a reconstituted Board that will help direct the Company to craft a more compelling story for investors and who will advocate for the best interests of ALL shareholders, not a select few," Mr. Asbahi added.

Prescience Point also announced that it has issued an open letter to MiMedx shareholders, the full text of which follows below:

#### Dear Fellow MiMedx Shareholders,

Prescience Point Capital Management, together with its affiliates ("Prescience Point"), currently owns approximately 8.1% of the outstanding shares of MiMedx Group, Inc. ("MDXG" or the "Company"), making us one of the Company's largest shareholders. We continue to believe that MDXG is deeply undervalued. However, under the current Board's oversight, we believe that power has become concentrated in the hands of one entity, EW Healthcare Partners ("EW"), rendering the Board incapable of unlocking the Company's substantial value for all shareholders.

As a significant, long-term owner of MDXG, we have helped create immense value for all shareholders through our activism efforts. Most notably, since 2018, we believe that we have played a vital role in helping MDXG to not only survive the financial and reputational fallout created by its accounting scandal – but also to transform itself into a much stronger company that is better positioned for sustained success.

Since then, shareholders have seen an increase in MDXG's share price from roughly \$3.00 per share just prior to the start of our activist efforts, to \$12.30 per share at yesterday's close. Even still, this valuation remains, in our view, far below the more than \$30.00<sup>[i]</sup> per share that we believe the Company should be worth right now, based on the enormous potential of its Amniofix injectable product.

To realize the promise of MDXG for all shareholders, we believe that the Company needs – first and foremost – a Board of Directors that is fully committed to continuing the process of unlocking value that Prescience Point began nearly two and a half years ago. That is why we have nominated a slate of four highly qualified candidates for election to the Company's Board of Directors (the "Board") at the Annual Meeting of Shareholders (the "Annual Meeting"), scheduled to be held on May 27, 2021. Our nominees will represent the interests of <u>ALL</u> MiMedx shareholders, not a select few. We urge all shareholders to ensure their voice can be heard in this upcoming Board election by ensuring their shares have not been lent out by their broker to other parties.

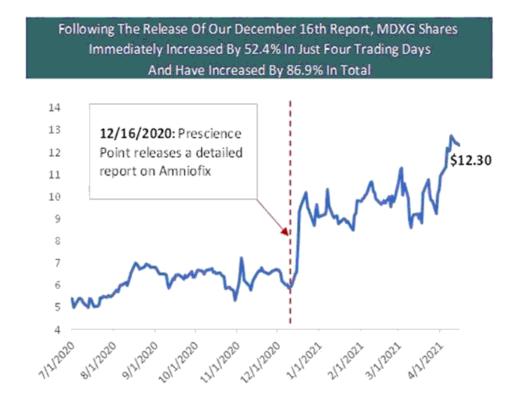
#### The Potential of a Game-Changing Product Remains Hidden, Resulting In Chronic Undervaluation

Prescience Point has remained a significant shareholder of MDXG in large part because of the immense promise of Amniofix. As detailed in our December 16, 2020 report, our research overwhelmingly indicates, and we strongly believe, that Amniofix will be a game-changing, multi-billion dollar treatment for knee osteoarthritis ("knee OA") and other musculoskeletal ailments.

Unfortunately, it is our belief that MDXG's management and Board have consistently failed to effectively convey the potential of this product to the investment community. For the past two years, in letters and private conversations, we have repeatedly urged management and the Board to be more vocal and transparent about Amniofix. Yet, despite repeated assurances to us by management that things would change, it seems that nothing has, resulting in the chronic undervaluation of MDXG equity.

Shareholders should be concerned by the Company's puzzling reluctance to provide meaningful information about Amniofix when communicating with investors. To the extent MDXG has released information, the data has been overly conservative and incomplete, and severely downplayed the product's potential, amounting in our view to misrepresentation. Look no further than the JP Morgan Healthcare Conference presentation, where the Company estimates the addressable market for Amniofix at just 1-1.5 million knee OA patients, despite the fact that there are almost 20 million knee OA patients in the US alone. Given blunders such as these, it is not surprising that almost every time the Company has spoken publicly about its business during the past two years, its share price has subsequently <u>declined</u>.

In contrast to the Company's failure to effectively tell its story to investors, consider the market's enthusiastic reaction to our December report on Amniofix. Prior to the publication of our report, the market was assigning little-to-no value to Amniofix, and MDXG shares were languishing in the \$5 to \$6 range. Immediately following our report's release, MDXG shares increased by 52% in the span of just four trading days, from \$6.58 on December 15, 2020 to \$10.03 on December 21<sup>st</sup>, 2020, in what we believe to be a clear indictment of management's inability to communicate the Company's potential for value-creation. This upward momentum has continued in 2021, and MDXG shares are currently trading at \$12.30.



#### Board and Management Decisions Have Destroyed Shareholder Value

Additionally, the current management and Board have made what we view to be baffling strategic decisions which have destroyed significant shareholder value. In July of last year, despite our objections and offer to help it raise capital at a more opportune time, the Company raised \$150 million of hugely dilutive capital from private equity firms EW and Hayfin Capital Management in the form of \$100 million of convertible preferred stock and a \$50 million term loan. Given the fact that, at the time, MDXG shares were trading at just \$5.40 and the Company had almost \$50 million of cash on its balance sheet, we believe this capital raise was excessive, ill-timed and, frankly, completely unnecessary. Even worse, the preferred shares were issued with a strike price of just \$3.85, which was almost 30% lower than the share price at that time! We cannot recall ever seeing another convertible deal consummated at such a deep discount.

We are also troubled by management's comments during recent investor conferences that it intends to actively pursue M&A opportunities in the wound care space. Given that the value of Amniofix greatly exceeds that of the wound care business, we believe this strategy is misdirected as it reflects a misunderstanding of the value drivers of the business and would be highly value destructive. In order to finance such a strategy, the Company would likely have to issue yet more shares, which would effectively transfer much of the value of Amniofix from existing shareholders to new shareholders.

To engage in such M&A "empire building," which is characteristic of a private equity "playbook," would be extremely distracting to the Company and further destructive of shareholder value.

#### MDXG Has Lost Significant Market Share to Organogenesis

MDXG's financial performance has also been disappointing. The Company reported an 11% year-over-year <u>decline</u> in sales in FY 2020 and has guided for a ~10% increase in sales in FY 2021. By contrast, Organogenesis ("ORGO") reported a 30% year-over-year <u>increase</u> in sales in FY 2020 and has guided for a 20% increase in sales in FY 2021. Said more simply, MDXG has lost and continues to lose significant market share to ORGO. Not surprisingly, ORGO's share price has dramatically outperformed that of MDXG and is up more than 600% over the past 12 months.

#### Recent Board Addition Gives EW Healthcare an Outsized Influence Over the Company

We are deeply troubled by the Board's recent decision to add a former EW affiliate, Dr. Phyllis Gardner, to its ranks. This addition was made shortly after we had expressed our desire to the Company to work cooperatively in reconstituting the Board with new members who would advocate for the best interests of <u>all</u> shareholders. Rather than engaging productively with us to achieve this goal, the Board instead responded by further entrenching its interests and those of EW, while stripping shareholders of the opportunity for true representation.

With Dr. Gardner's addition, 33% (three out of nine) of the seats on the Board are now held by current or former affiliates of EW, which far exceeds EW's percentage ownership in the Company. As a private equity firm, EW's interests may not align with those of public shareholders. For example, based on our conversations with Martin P. Sutter and William A. Hawkins III, EW representatives on the Board, we believe that EW is likely the driving force behind the Company's value-destructive pursuit of acquisitions in the wound care space. The entire MDXG Board must be held accountable for allowing EW to build such an outsized influence over the Company's direction.

It has become abundantly clear to us that MDXG needs additional representatives on the Board who will advocate for the best interests of <u>ALL</u> shareholders and who can direct the Company to craft a more compelling narrative about Amniofix for the investment community and court potential strategic partners. If the current course is not changed, and the Board is not reconstituted, we believe EW will continue to pack the Board. Thus, MDXG will <u>not reach its full</u> potential and its shares will continue to fail to reflect the true value of the business.

We did engage the Company in an effort to reach a consensual solution, and are disappointed that members of management and the Board refused our reasonable request for meaningful Board representation that better reflects the interests of public shareholders. As a result, we are compelled to take the step of nominating a new slate of candidates for election to the Board. Our four highly-qualified, diverse and independent nominees, including one representative from Prescience Point, are committed to rigorous oversight of the Company's management, operations, business strategy, and value-creation process. Importantly, our three non-Prescience nominees collectively have decades of experience as executives and directors of well-performing biopharma companies, many of which were eventually sold on their watch. We have provided detailed biographies of each of our nominees below.

#### **Biographies of Prescience Point's Nominees (in alphabetical order):**

#### Eiad Asbahi

Mr. Eiad Asbahi is currently the managing member of Prescience Point Capital Management, LLC, which he founded in 2009. Prior to founding Prescience Point, Mr. Asbahi was a consultant with the investment firm Kinderhook Partners from 2008 to 2009. At Kinderhook, Mr. Asbahi focused exclusively on analyzing small-cap equities, identifying undervalued companies with exceptional growth prospects or impending catalysts to unlock intrinsic value. Before his time at Kinderhook, Mr. Asbahi served as a consultant at Cohanzick Management in 2008, analyzing companies across the capital structure, with a focus on high yield and distressed debt, capital arbitrage and special situation equities. Mr. Asbahi began his career as an analyst with Sand Spring Capital in 2004, where he worked until 2008. He received a B.S. in Microbiology from Louisiana State University, summa cum laude, his MBA from Louisiana State University in 2006, graduating at the top of his class, and is a Chartered Financial Analyst (CFA®) holder.

#### Alfred G. Merriweather

Mr. Alfred G. Merriweather is currently a retired financial executive. Since January 2021, he has served as director, chair of the Board and chair of the Audit Committee of Cadex Genomics, Corp., a privately held molecular diagnostic company. Mr. Merriweather has spent over thirty years in chief financial officer roles in a number of life science and medical technology companies. Most recently, from 2017 to 2019, he was the CFO of Adamas Pharmaceuticals, Inc., a publicly traded pharmaceutical company focused on neurologic disorders. Prior to his employment by Adamas, Mr. Merriweather served as CFO of RainDance Technologies, Inc., a life science tools company, from 2013 to 2017. Mr. Merriweather has also served as CFO to several other device, tools, and diagnostic companies. These include clinical lab companies such as Verinata Health, Inc., Celera Corporation and Monogram BioSciences, Inc., as well as the medical device companies Laserscope and Symphonix Devices Inc. He began his career with Price Waterhouse as a chartered accountant in London, England and San Jose, California, and received his B.A. in Economics from the University of Cambridge in 1975.

#### **Charlotte E. Sibley**

Ms. Charlotte E. Sibley is currently the President of Sibley Associates, LLC. Since 2018, she has also served on the board of directors of Advicenne, SA, a publicly-traded French specialty pharmaceutical company, where she was a member of the Remuneration Committee. Currently, Ms. Sibley is also a director and chair of the Compensation Committee of the Fort Hill Company, a position she has held since 2015. Ms. Sibley has over forty years of experience in the biopharmaceutical industry. Recently, she served on the board of directors of Taconic Biosciences, Inc., from 2013 to 2019 where she chaired the Nomination and Governance Committee. Prior to Taconic, Ms. Sibley was a director of the American Pacific Corporation from 2010 to 2014. Ms. Sibley began her career in the pharmaceutical industry as a market research manager for Pfizer in 1970, and held several managerial positions at companies such as Johnson & Johnson, the Medical Economics Company, and Bristol-Myers Squibb, and later held executive positions at Pfizer, Millennium Pharmaceuticals, and Shire plc. Ms. Sibley received her A.B. in French Language and Literature from Middlebury College in 1968 and her MBA from the University of Chicago Booth School of Business in 1970.

#### William F. Spengler

Mr. William F. Spengler is currently retired and working part time as a partner for Frederick Fox, LLC, an executive search firm, a position he has held since May 2020. Prior to his retirement, Mr. Spengler served on the board of directors of Endo International plc, a publicly traded pharmaceutical company, from 2008 to 2017. While on the board, Mr. Spengler was chair of the Audit Committee and a member of the Research & Development Committee. He has 14 years of experience as chief financial officer of multiple companies, including Smith & Wesson Brands Inc., MGI Pharma, Inc., and Guilford Pharmaceuticals, Inc., Earthshell Corporation, and Sweetheart Holdings. He also served as president of Chromadex from 2012 to 2015 and Osteo Implant Technologies from 2001 to 2003. Mr. Spengler began his career with Bristol-Myers Squibb, where he worked for fourteen years, before serving as vice president of finance in the International Group and later the Power Tools Group of Black and Decker, before moving to the Sweetheart Cup Company. Mr. Spengler received his MBA from the New York University Stern School of Business in 1980 and his B.A. in Economics from Yale University in 1977.

## We believe the addition of the above nominees to the Board is critical to help put MDXG on the right path to maximize value for all shareholders.

For updates and shareholder information, follow @PresciencePoint on Twitter or www.presciencepoint.com.

Sincerely,

Eiad Asbahi Prescience Point Capital Management, LLC

#### **CERTAIN INFORMATION CONCERNING THE PARTICIPANTS**

Prescience Investment Group, LLC d/b/a Prescience Point Capital Management LLC, Prescience Partners, LP, Prescience Point Special Opportunity LP, Prescience Capital, LLC, Eiad Asbahi, Alfred G. Merriweather, Charlotte E. Sibley and William F. Spengler (all of the foregoing, collectively the "Participants") intend to file with the Securities and Exchange Commission (the "SEC") a definitive proxy statement and accompanying form of GOLD proxy to be used in connection with the solicitation of proxies from the shareholders of MiMedx Group, Inc. (the "Company"). All shareholders of the Company are advised to read the definitive proxy statement and other documents related to the solicitation of proxies by the Participants when they become available, as they will contain important information, including additional information related to the Participants. The definitive proxy statement and an accompanying GOLD proxy card will be furnished to some or all of the Company's shareholders and will be, along with other relevant documents, available at no charge on the SEC website at http://www.sec.gov/.

Information about the Participants and a description of their direct or indirect interests by security holdings is contained in a Schedule 14A filed by the Participants with the Securities and Exchange Commission on April 16, 2021. This document is available free of charge from the source indicated above.

#### Disclaimer

This material does not constitute an offer to sell or a solicitation of an offer to buy any of the securities described herein in any state to any person. In addition, the discussions and opinions in this press release are for general information only, and are not intended to provide investment advice. All statements contained in this press release that are not clearly historical in nature or that necessarily depend on future events are "forward-looking statements," which are not guarantees of future performance or results, and the words "anticipate," "believe," "expect," "potential," "could," "opportunity," "estimate," and similar expressions are generally intended to identify forward-looking statements. The projected results and statements contained in this press release that are not historical facts are based on current expectations, speak only as of the date of this press release and involve risks that may cause the actual results to be materially different. Certain information included in this material is based on data obtained from sources considered to assist the recipient of this presentation in evaluating the matters described herein may be based on subjective assessments and assumptions and may use one among alternative methodologies that produce different results. Accordingly, any analyses should also not be viewed as factual and also should not be relied upon as an accurate prediction of future results. All figures are unaudited estimates and subject to revision without notice. Prescience Point disclaims any obligation to update the information herein and reserves the right to change any of its opinions expressed herein at any time as it deems appropriate. Past performance is not indicative of future results.

#### **About Prescience Point Capital Management**

Prescience Point Capital Management is a private investment manager that employs forensic investigative techniques to unearth significant mispricing in global markets. It specializes in extensive investigations of difficult-to-analyze public companies in order to uncover significant elements of the business that have been overlooked or ignored by others.

Prescience Point manages private funds on behalf of its clients and principals and takes positions both long and short in support of its research. Prescience Point invests across a broad set of equities that it believes have abnormally large disparities between what their underlying businesses are intrinsically worth and what their securities sell for. The firm was founded by investor Eiad Asbahi in 2009 and is headquartered in Baton Rouge, LA. Prescience Point Capital Management is a registered investment advisor with the State of Louisiana. Follow @PresciencePoint.

Investor Contacts Jason Alexander / Bruce Goldfarb Okapi Partners LLC 212-297-0720 info@okapipartners.com

Media Contacts Dukas Linden Public Relations 646-808-3665 prescience@dlpr.com

[i] Based on the sum-of-the-parts valuation analysis provided in Prescience Point's December 16, 2020 report.

SOURCE Prescience Point Capital Management



## MiMedx Group, Inc.

NASDAQ: MDXG

Raising Our Price Target To \$31 On New Findings That Indicate Amniofix Will Be A Blockbuster, Game-Changing Osteoarthritis Treatment

#### Prescience Point Research Opinions:

- Based on conservative assumptions, MDXG shares are worth \$3184, 4.8x the current share price
- Amniofix will be a blockbuster, game-changing treatment for knee osteoarthritis ("knee OA") and a variety of other musculoskeletal ailments
- MDXG's wound care sales will re-accelerate over the coming quarters

#### **Research Highlights:**

- MDXG has put its period of turmoil behind it. Over the past two years, the Company has refreshed
  its mgmt team and Board, strengthened its balance sheet by raising \$150m, settled with the SEC
  and DOJ for a modest amount, completed its financial restatement, and relisted on the NASDAQ
- The <u>wound care business is poised to re-accelerate</u> in FY 2L MDXG has begun hiring addth sales
  reps in anticipation of increased demand resulting from recent, positive developments which incl.
  the release of a new wound care product, gaining coverage from the largest US insurer, and several hospital contract wins
- Knee OA is a chronic, debilitating, and widespread condition affecting >20m people in the US alone
   There are few FDA-approved treatments for knee OA, and those treatments that exist NSAIDs, hyaluronic acid ("HA") injections.
- and corticosteroid injections have significant efficacy/safety drawbacks

   Significant evidence indicates that Amniofix is a highly effective and safe treatment for knee OA which is <u>far superior to HA and</u>
- significant evidence indicates that annihilities a nighty effective and safe treatment for knee OA which is to superior to ha and conticosteroids, and that the product is highly likely to receive FDA approval and take significant share in the knee OA treatment market, leading to <u>multi-billions of dollars in potential peak revenue</u>.
- Studies suggest & several physicians that we spoke w/ believe that Amniofix is regenerative and can slowdown OA progression
   Preliminary results from MDXG's Phase 2b knee OA trial were very promising and showed a separation between the treatment and control group with a low dropout rate
- Independent knee OA studies of Amnoifix have shown very positive results. This includes a 100-person study which showed that Amniofix was very safe and highly effective with average quality of life and pain scores improving by TIX and 67%, respectively amplified effective and highly effective with average quality of life and pain scores improving by TIX and 67%, respectively
- Amniofix's efficacy can last for 9-12 months, while HA & corticosteroids last for just 4-6 months and 4-6 weeks, respectively
   Amniofix has reportedly been used on an off-label basis in >100,000 patients with zero severe adverse events reported
- The RMAT designation the FDA gave to Amniofix for the treatment of knee OA further increases Amniofix's already high chance
  of approval due to the often lower standard of evidence required for treatments with a fast track designation
- The RMAT designation also gives Amniofix the opportunity to receive <u>early FDA approval</u> after its Phase 2b knee OA trial
   The FDA's approval of Ziretta an extended-release corticosteroid despite mediocre clinical results indicates that the FDA
- The FUA's approval of ziretta an extended-reades concessiona despite medicere clinical results includes that the FUA' has lowered the standard of evidence required for knee OA treatments in general, even for those without an RMAT designation
   Amniofix has also shown overwhelmingly positive results for the treatment of a variety of musculoskeletal aliments beyond knee
- OA, including plantar fascilits, shoulder arthritis, and anide arthritis, and will likely receive approval for multiple indications
   Our conclusion that Armiofix will be a blockbuster treatment is supported by the fact that <u>3 of the top 5 selling drugs</u> in the US
- are for rheumatoid arthritis and psoriasis, which are conditions with similar disease burden characteristics as osteoarthritis, and is further supported by the lofty sales of HA injections despite their highly questionable efficacy
- Pre-revenue biotechs with comparable treatments to Amniofix have received lofty valuations early on in the clinical trial
  process. This includes Samumed which received a <u>\$128n valuation</u> while its lead indication for knee OA was in Phase 2 trials

HEREARCH REPORT EVERSIES SOLLY CUR OPENCIEL was Prescience Point Capital Monogement's mesorch opinions at your own risk. This is not investment advice nor should be construed as such. You should do your own mesorch and due digence before making any investment dealers with respect to the securities covered herein Formativiciating statement and projectore are interestly sacaptible to uncertainty and herein many risk (frame and writewer) the could cause and results of the method herein termination and writewer) the could cause and exercising position in Milledel stock and therefore stand to nealthe significant gains in the event that the price of such insurant increases. Press refer to our full decisioner located on the lost page of this report.

Date of Report 12/16/2020
SHARE PRICE \$5.58
52-WK HI / LOW \$2.95 / \$7.95
AVG DAILY VOL 591K
MARKET CAP \$901.6M

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#### Introduction

We are raising our price target for MiNedx Group ("MDXG" or the "Company") shares to \$3184 based on our research which overwhelmingly indicates that the Company's Amniofix injectable product will be a blockbuster, game-changing treatment for knee osteoarthritis ("knee OA") and other musculoskeletal aliments.

in the almost two years since we released our bullish initiation Report on MDXG, the Company has successfully resolved all of the key issues resulting from prior management's misdeeds. Thanks to these efforts, MDXG has managed to put its period of turmoil behind it and, in the process, has transformed itself into a much stronger company which is better positioned for sustained success. Specifically, MDXG has accomplished the following:

- Refreshed its management team and, with our help, refreshed its board of directors with highly reputable and accomplished executives
- Strengthened its balance sheet by raising \$150m of capital from outside investors
- · Successfully settled with the SEC and DOJ for a modest \$15m and \$8.5m, respectively
- Hired a new auditor, completed its financial restatement, and subsequently relisted on the NASDAQ
- Made considerable progress in updating its manufacturing processes to be compliant with the FDA's updated Current Good Manufacturing Practices (\*CGMP\*)
- Released a wound care product extension, gained coverage from the largest insurer in the US, and won several large hospital contracts, which should result in a <u>re-acceleration of growth in the wound</u> <u>oare business</u> over the coming quarters

With its troubles now behind it, we believe the future for MDXG is extremely bright. In addition to our bullish outlook for the wound care business, perhaps the biggest reason for our optimism is the Company's Amniofix injectable product which is ourrently in Phase 2b trials for knee OA, as well as Phase 3 trials for plantar fasciitis and Achilles tendonitis.

For the past six months, we have conducted in-depth due diligence to better understand Amniofix, including its market potential and chances of success. Our diligence included an extensive review of the knee OA and osteoarthritis market, an analysis of clinical data on Amniofix, an analysis of competing treatment options, and conversations with numerous physicians and patients who have used and been treated with the product. Here is what we found and why we believe Amniofix will be a blockbuster, game changing treatment for knee OA and other musculosketetal aliments:

- Knee OA is a chronic, debilitating, and widespread condition which affects more than 20m people in the US. Currently, there are few FDA approved treatments for knee OA and those that do exist – specifically, NSADs, hyaluronic acid ('HA') injections, and corticosteroid injections – all have considerable drawbacks in terms of efficacy and/or safety. For example, some studies have shown that HA injections are no better than placebo and that corticosteroids can actually accelerate the progression of knee OA
- Our research indicates that Amniofix is a <u>far more effective and safer treatment for knee OA than</u> <u>corticosteroids and HA</u> and will likely receive FDA approval. Amniofix has shown very positive efficacy

MiMedx Group (NASDAQ: MDXG)

results 1) in MDXG's Phase 2b knee OA trial where the interim data showed a separation between the treatment and control group with a low dropout rate, 2) in independent knee OA studies, including a recent 100-person study which showed that Amniofix improved quality of life and pain scores by an average of 11% and 67%, respectively, and 3) through off-label use by physicians and their knee OA patients, many of whom we spoke with. In addition to its overwhelmingly positive efficacy results, Amniofix also has a flawless safety record and has reportedly been used in >100,000 patients with <u>zero</u> severe adverse events.

- Studies suggest and several physicians that we spoke with believe that Amniofix has regenerative properties which can slowdown the progression of osteoarthritis. One physician who has treated hundreds of patients with Amniofix told us that he believes Amniofix can delay the need for a knee replacement by several years and has seen strong evidence of this in his patients. Given the substantial cost savings that Amniofix could provide for insurance companies by delaying or eliminating the need for costly surgery – a knee replacement costs between \$50K - \$55K – we believe that Amniofix could command a price of \$5K or higher per injection
- The RMAT designation that the FDA has granted to Amniofix for the treatment of knee OA further increases Amniofix's already high chance of approval due to the often lower standard of evidence that is required for treatments with a fast track designation. The RMAT designation also gives Amniofix the opportunity to receive <u>early FDA approval</u> after its Phase 2b knee OA trial, as the FDA can and often does approve fast track treatments following a successful Phase 2 trial
- Based on the very positive results that Amniofix has shown in treating a variety of musculoskeletal ailments, including plantar fasciitis, shoulder osteoarthritis, and ankle osteoarthritis, Amniofix will also likely receive approval for multiple indications beyond knee OA

Due to the massive market of patients with musculoskeletal aliments, and in particular knee OA, and Amniofix's promising results in both clinical studies and through off-label use, we believe that Amniofix will generate multibillions of dollars in annual sales. MDXG executives appear to be equally as optimistic as us. This includes CEO Tim Wright who told us during a conversation last year that he believes Amniofix's sales will eventually far eclipse that of its wound care business. This also includes R&D head Dr. Bob Stein who indicated to us during a recent conversation that he believed Amniofix's peak sales could amount to multi-billions of dollars.

Since the release of our initial report, MDXG shares have increased by 204.6% from \$2.16 to the current share price of \$8.58 as of December 15<sup>th</sup>. Despite this large run-up in share price, our sum-of-the-parts analysis shows that MDXG shares are still trading far below fair value.

Based on MDXG's pre-pandemic run-rate revenue of \$271.3m and assuming a 4.0x sales multiple, we value the wound care business at \$7.92 per share. Based on our estimate that Amniofix's peak sales will amount to \$4.38n, a peak sales multiple of 4x, and a very conservative 50% chance of FDA approval, and after discounting the resulting valuation to present value, we value Amniofix at \$23.92 per share. Our valuation for Amniofix is supported by the lofty valuations that pre-revenue blotechs with similar treatments for osteoarthritis have received. For example, Samuned was valued at an astounding \$128n while its lead indication for knee OA was only in Phase 2 clinical trials.

Adding it all up, our sum-of-the-parts analysis yields a valuation of \$31.84 per share for MDXG. This is 383.95 higher than the current share price of \$6.56. In addition to showing that MDXG shares are grossly undervalued, our sum-of-the-parts analysis also shows that the market is assigning little-to-no value to Amniofix. We estimate that the wound care business by itself is worth \$7.92 per share, which is 20.43 higher than MDXG's

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current share price. This means that investors who purchase MDXG shares today are buying the wound care business at a substantial discount and, on top of this, are receiving Amniofix, an asset that we believe is worth multi-billions of dollars, essentially for free.

We believe there is considerable upside to our \$31.84 price target given that this target is based on what we believe are very conservative assumptions. Specifically, our wound care valuation is based on MDXG's prepandemic run-rate revenue and does not give the Company any credit for future growth from its recent insurance and contract wins, as well as its newly released product extension, while our Anniofix valuation assumes i) no early FDA approval, 2) an only 50% chance of FDA approval, 3) just 20% market share for the knee OA indication, 4) a very conservative pricing of \$2,500 per injection for the knee OA indication, and 5) just \$200m of peak revenue from all other potential indications beyond knee OA.

There are a number of imminant catalysts which we believe will propel MDXG shares higher. The most notable of these catalysts include 1) selfside analysts resuming their coverage of MDXG, 2) a readout of the Phase 3 plantar fascilits trial results in early-to-mid-2021, and 3) a readout of the Phase 2b knee OA trial results in earlyto-mid-2021. We also believe that, if the Phase 2b knee OA trial results are positive, the Company is likely to receive a buyout offer given the considerable interest that larger biotechs have shown in the knee OA space.

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#### MDXG Has Completed A Positive Transformation And Is Well-Positioned For Sustained Success

Over the past two years, MDXG has worked diligently to correct the issues created by the misdeeds of prior management. In addition to cleaning up the messes of prior management, the Company has also made significant improvements to its operations and has made considerable progress in executing on several key growth initiatives. Thanks to these efforts, MDXG has emerged from its period of turnoil as a positively transformed company which is well-positioned for sustained success.

 The management team and board of directors has been refreshed with reputable, highly qualified individuals: Since the dismissal of its founder and former CEO Pete Petit and other former executives who worked alongside him, MDXG has, with our assistance, almost completely overhauled its management team and board of directors.

In May 2019, MDXG hired Tim Wright as its CEO, replacing interim CEO David Coles. Wright is an accomplished executive who was previously the head of business development at Teva Pharmaceuticals. In addition to Mr. Wright, the Company hired Pete Carlson as CFO, replacing interim CFO Ed Borkowski.

Since joining MDXG, Mr. Wright has managed to fill key executive positions at the Company with high caliber executives who have a decades-long track record of success in the healthcare space. The most notable of these new hires were Dr. Bob Stein as Executive VP of R&D and Dr. Rohit Kashyap as Chief Commercial Officer. Prior to joining MDXG, Dr. Stein had worked for more than 40 years in drug discovery and development at Merck, Bristol Meyers Squibb, Roche and Ligand Pharmaceuticals where he played a pivotal role in developing <u>multiple blackbuster drugs</u>, while Dr. Kashyap had worked for more than 20 years in the medical device industry which notably includes his time as global head of Acelity's commercial development team.

We believe Dr. Stein's deep knowledge and experience in drug development will prove instrumental in helping MDXG unlock the full value of its promising pipeline of late-stage clinical trials. Based on his success in leading Aceilty's global commercial efforts, we also believe that Dr. Kashyap will help the Company expand its wound care business into new indications and geographic markets. Overall, we couldn't be more pleased with the executives that Mr. Wright has helped recruit to the Company.

In addition to refreshing its management team, MDXG has substantially reconstituted its board of directors with several high-caliber board members who joined the Company in June 2019 following our successful activist campaign, and in July 2020 following EW Healthcare's investment in MDXG.

The most notable of these new board members include Dr. Kathleen Wilsey and William Hawkins III. Dr. Wilsey, who was appointed Chairwoman of MDXG, has had a long and successful career as a healthcare investor and entrepreneur and currently serves as Chairwoman of Sarepta Therapeutics, a \$138n gene therapy company, while Mr. Hawkins was the <u>former CEO of Meditronics</u>, the largest medical device company in the world.

Recent capital raise gives MDXG ample liquidity to continue operating without restrictions: On July 2<sup>nd</sup>, 2020, MDXG announced that it had raised \$150m of capital from outside investors, consisting of a \$90m equity investment by private equity firm EW Healthcare, and a \$10m equity investment and a \$50m term loan provided by Hayfin Capital Management.

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We believe the additional liquidity provided by this capital raise is hugely beneficial for MDXG. Due to the uncertainty and temporary decline in sales created by the COVID pandemic, there was some concern that the Company would have to temporarily dial back some of its angoing investments in various growth and operational initiatives. However, the recent capital infusion has removed this concern, and as a result, MDXG now has ample liquidity to continue improving its operations, pursuing growth opportunities, and funding its clinical trials without restriction.

The SEC and DOJ investigations, as well as the majority of the lawsuits against MDXG, were
successfully settled for a modest amount. Critics of the Company claimed that the SEC and DOJ
investigations would result in enormous fines and judgements, totaling in the hundreds-of-millions
of dollars, which would cripple MDXG. However, this prediction ultimately proved to be way off the
mark.

On November 26<sup>th</sup>, 2019, it was <u>announced</u> that MDXG had paid just \$15m to the SEC to settle the commission's investigation into alleged accounting fraud by the Company and its former executives:

The SEC's complaint, filed today in the Southern District of New York, charges all defendants with violating the antifraud, reporting, books and records, and internal control provisions of the federal securities laws. The SEC also charged Petit, Taylor, and Senken with lying to MiMedx's outside auditors. Without admitting or denying the allegations, MiMedx has agreed to a settlement and to pay a \$15 million penalty.

Then, on April 8<sup>th</sup>, 2020, it was <u>announced</u> that MDXG had paid a modest \$8.5m to the DOJ to settle an investigation into the accuracy of the Company's pricing disclosures to the US Department of Veterans Affairs ("VA"):

MiMedx Group\_today announced that it has finalized a settlement with the Department of Justice (the "DOJ"), resolving an investigation concerning the accuracy of commercial pricing disclosures to the United States Department of Veterans Affairs (the "VA")\_Without admitting the allegations the Company has agreed to pay \$6.5 million to the DOJ to resolve the matter.

In addition to settling the SEC and DOJ investigations, MDXG has settled the majority of its outstanding lawsuits – 12 of its 15 outstanding lawsuits to be exact – for a modest sum. For example, the Company <u>announcest</u> on October 22<sup>rd</sup>, 2020 that it had agreed to pay just \$3.5m to settle one of its outstanding shareholder lawsuits:

MiMedx Group, the embattled medical-instruments company in Marietta, has agreed to pay \$3.5 million to settle a kawsuit that alleges former executives' actions resulted in financial losses by its shareholders.

The recent relisting is highly positive for the equity: On November 3<sup>rd</sup>, 2020, MDXG announced that it
had finally received approval from the NASDAQ for its relisting application. Just two days later, the
Company's shares began trading on the exchange under the ticker "MDXG."

Beyond increased liquidity, being relisted on a major exchange will benefit MDXG and its shareholders in two ways which are highly positive for the equity. First, major institutional investors, most of whom are restricted from purchasing shares in stocks that trade over-the-counter, will once again be

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permitted to invest in MDXG. Second, now that its shares are relisted, sellside analysts can reinitiate their coverage of the Company which, in turn, will help to attract new investors to the stock.

 MDXG has re-engineered its manufacturing facilities to be CGMP-compliant, providing it with a significant competitive advantage: Since taking over, MDXG's new executive team has made significant investments in updating and re-engineering the Company's manufacturing processes. Thanks to these efforts, the Company expects to soon be compliant with the FDA's updated Current Good Manufacturing Practice ('CGMP') requirements, well ahead of its competitors in the wound care and therapeutic biologics space.

Achieving CGMP compliance will be beneficial for MDXG in two key ways. First, having a CGMPcompliant manufacturing facility will provide MDXG with a more favorable cost profile and higher quality controls across all of its product lines, giving the Company a significant advantage over competitors. Second, the FDA prohibits the marketing of micronized tissue products which are not manufactured in a CGMP-compliant facility, so achieving compliance marks an important step for the Company in the advancement of its ongoing clinical studies for Amniofix.

 Wound care sales are poised to accelerate following recent insurance coverage and customer wins, and the rollout of a new product extension: Since Tim Wright took over as CEO, MDXG has focused on leveraging the strength of its clinical data for Epifix as a means to expand insurance coverage for its products and secure more contracts from large hospital chains. Recent developments show that this strategy has begun to pay significant dividends.

On November 3<sup>rd</sup>, 2020, MDXG <u>announced</u> that the largest health insurance company in the US (i.e. UnitedHealthcare) would begin providing coverage for Epifix in the treatment of diabetic foot ulcers ("DFUs") effective December 1<sup>st</sup>. Importantly, they also disclosed that <u>Epifix was the only amniotic</u> membrane product to receive coverage from UnitedHealthcare.

Milledx Group\_today announced that the largest U.S. Commercial payor will now provide coverage for EpiFx®, the Company's flagship amnion/chorion membrane tissue product, as a proven and medically necessary option in the treatment of diabetic foot ulcers. The Company believes that EpiFix is the only amniotic membrane product to receive coverage under this payor's updated commercial medical policy\_Reimbursement coverage will become effective December 1.2020.

Then, just a couple days later during MDXG's 03 2020 earnings call on November 5<sup>th</sup>. Tim Wright revealed to investors that the Company had recently won several new wound care contracts:

We plan to leverage our commercial sales to operationalize the pull-through of the recent contract wins we've had and payer wins we've had...We have been very successful in contract wins

Management later clarified that these new contracts were with large hospital groups. A user on StockTwits claimed that one of these new contracts was with CHS, one of the largest hospital systems in the US.

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SMDXG my buddy works for MiMedx and said that a large hospital system,CHS, just gave MiMedx a sole access contract for their products.

This is good news because she said ORGO previously had the contract but now MiMedx has it for the next 4 years.

In addition to securing new insurance and contract wins, MDXG recently rolled out a new product extension. Specifically, on September 14<sup>th</sup>, 2020, the Company <u>announced</u> the release of its EpiCord Expandable allograft product. As detailed in the press release, this product expands MDXG's addressable market to include patients with larger, hard-to-heal wounds:

MiMedx Group\_today announced the launch of EpiCord Expandable, the latest advancement in its portfolio of products. At the care of this technology is EpiCord, which has demonstrated clinical efficacy in the treatment of diabetic foot ulcers. The patent-pending design of EpiCord Expandable allows the allograft to cover up to twice the surface area once expanded. This new placental tissue allograft provides healthcare professionals an additional option to support the advanced wound care needs of their patients with larger, chronic, and hard-to-heal wounds.

Due to the above positive developments, we expect MDXG's <u>wound care sales to accelerate</u> over the coming quarters. Our conclusion is supported by the fact that, during its most recent <u>comings call</u>. MDXG management disclosed that it intends to expand the size of its sales force in anticipation of increased demand for its products.

Unidentified Analyst Thank you so much for taking my question. In reference to the win with the large commercial carrier, you indicated that you intend to start to expand the salesforce...what (does) the expansion plans mean?

CFO Pete Carlson: having a large and growing sales force is an important part of our tasks... We do recognize the need to increase our field forces. So while we don't have the quantification and are not sharing that at this time. Rest assured that we are always focused on the resources we have in the field, distributing the product.

We also expect that MDXG's wound care sales will eventually get an additional boost once the current pandemic clears. Due to lockdowns across the country and fear of catching the coronavirus, many patients with diabetic ulcers and other advanced wounds have been unable to or reluctant to receive treatment. We believe this fear and the restrictions caused by the lockdowns will fully dissipate once the coronavirus vaccine is widely distributed and administered by mid-to-late 2021.

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#### The Market Is Grossly Undervaluing MDXG's Highly Promising Amniofix Injectable Product

Amniofix is MDXG's injectable allograft product which is composed of micronized amniotic tissue. The product has been used on an off-label basis for several years to treat knee OA, plantar fasciltis, Achilles tendonitis, ankle OA, shoulder OA, and many other joint diseases.

In 2013, the FDA notified MDXG that its Amniofix injectable product had been manipulated to an extent that it would need a biologics license ("BLA") from the FDA in order to continue to be marketed. In response, MDXG eventually initiated three separate clinical trials for Amniofix for the treatment of 1) knee OA (2) plantar fascilitis and 3) Achilles tendonitis. Despite all of the turmoil that has surrounded it over the past few years, the Company has made considerable progress in advancing these trials: Currently, the knee OA trial is nearing the end of Phase 2b, while both the plantar fascilitis and Achilles tendonitis trials are nearing the end of Phase 2.

For the past few months, we have conducted deep due-diligence to better understand Amniofix's future prospects and potential. Based on our overwhelmingly positive findings, we believe that Amniofix will be a blockbuster, game-changing treatment for knee OA and a variety of other musculoskeletal aliments. The key findings of our research, which are more thoroughly detailed in the sections below, include the following:

- Knee OA is a chronic, often debilitating, and widespread condition with insufficient treatment options: Knee OA is a chronic, often debilitating, and widespread condition which affects more than 20m people in the US alone. Despite this, there are very few FDA approved treatments for knee OA and those that do exist - specifically, NSAIDs, HA injections, and corticosteroid injections - all have considerable drawbacks in terms of efficacy and/or safety. For example, studies have shown that HA injections are no better than placebo and that corticosteroids can actually accelerate the progression of knee OA
- Anniofix has shown tremendous promise as a treatment for knee OA and in our view, will likely receive FDA approvat Our research indicates that Anniofix is a far more effective and aafer treatment for knee OA than corticosteroids and HA and will likely receive FDA approval. Anniofix has shown very positive efficacy results 1) in MDXG's Phase 2b knee OA trial where the interim data showed a separation between the treatment and control group with a low dropout rate, 2) in independent knee OA studies, including a recent 100-person study which showed that Anniofix improved quality of life and pain scores by an average of 11% and 67%, respectively, and 3) through off-label use by physicians and their knee OA patients, many of whom we spoke with. Additionally, Anniofix has a flowless safety record and has reportedly been used in >100,000 patients with zero severe adverse events. Lastly, our research also indicates that Anniofix has regenerative properties which could delay or even eliminate the need for a costly knee replacement and provide substantial cost savings for insurance companies
- RMAT designation further increases Anniofix's already high chance of FDA approval and could open the door to early approval: The RMAT designation that the FDA has granted to Anniofix for the treatment of knee OA further increases Anniofix's already high chance of approval due to the often lower standard of evidence that is required for treatments with a fast track designation. The RMAT designation also gives Anniofix a good chance of receiving <u>early approval</u> after its Phase 2b knee

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OA trial, as the FDA can and often does approve fast track treatments following a successful Phase 2 trial

- Anniofix has also shown promise as a platform treatment for various other musculoskeletal aliments: Based on considerable evidence, Anniofix will also likely receive approval for multiple indications beyond knee OA. This evidence includes the positive results that Anniofix has shown 1) in MDXG's Phase 2b plantar fascilits trial, 2) in treating a variety of musculoskeletal aliments in independent studies, and 3) through off-label use for a variety of musculoskeletal aliments
- We believe that Anniofix will generate multi-billions of dollars in annual sales: Using conservative market share and pricing assumptions, we estimate that Anniofix's peak sales from the knee OA indication alone will be multi-billions of dollars. We also believe that Anniofix's peak sales from other indications could amount to an additional several hundreds-of-millions to one billion dollars. Our bullish sales projections are supported by the multi-billions of dollars in annual sales that treatments for rheumatoid arthritis and psoriasis which have similar disease burden characteristics as osteoarthritis generate each year, as well as the lofty sales of HA injections despite their highly questionable efficacy

#### Knee OA Is A Chronic, Often Debilitating, And Widespread Condition With Insufficient Treatment Options

Knee OA is a joint disease characterized by the loss of articular knee cartilage. Knee OA is a chronic and degenerative condition, and is the most prevalent joint disease in the world, <u>affecting</u> more than 20m people in the US alone. Unfortunately, there is no known cure for knee OA, and there have been very few advances in its treatment for more than a decade.

Currently, there are just three primary pharmacological treatments for symptomatic knee OA – NSAIDs and pain relievers, corticosteroid injections, and HA injections. Unfortunately, each of these treatments has significant drawbacks in terms of efficacy and/or safety which greatly limits their usefulness in treating the disease.

NSAIDs are of limited effectiveness and have notable safety risks: NSAIDs are, by far, the most widely
used treatment for knee OA. While NSAIDs, which include Aspirin, Ibuprofen, and Naproxen, are
generally effective in reducing pain and swelling in patients with mild OA, it is less effective in
adequately reducing the symptoms of patients with more moderate-to-severe OA. Therefore, many
patients with more advanced knee OA often require and receive additional treatments beyond
NSAIDs.

In addition to having limited efficacy, NSAIDs also have well-documented risks of severe, adverse side effects, particularly with prolonged use. These potential adverse side effects include severe gastrointestinal issues such as ulcers, as well as cardiovascular issues such as strokes and heart attacks. Due to these risks, physicians often recommend that patients with knee OA only take NSAIDs over short periods of time on an as-needed basis.

 Conticosteroid injections are of questionable efficacy and can actually cause significant damage to the innee joint: Conticosteroid injections are widely administered to patients with moderate-to-severe knee OA who no longer receive sufficient symptom relief from physical therapy and NSAIDs. In a <u>study</u>

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published in May 2018, it was found that of the 1,065,175 patients with knee OA identified in the Humana database from 2007 to 2015, 405,101 or 38,0% of them had received a corticosteroid injection.

Despite the popularity of corticosteroids in treating knee OA, the evidence in support of their effectiveness has been decidedly mixed. In 2015, Cochrane published the results of a <u>meto-analysis</u> of data from 27 knee OA trials. Based on this analysis, the author of the study concluded that it was unclear whether corticosteroids had any positive effect on pain and physical function:

Whether there are clinically important benefits of intra-articular corticosteroids after one to six weeks remains unclear in view of the overall quality of the evidence, considerable heterogeneity between trials, and evidence of small-study effects. A single trial included in this review described adequate measures to minimise biases and did not find any benefit of intra-articular corticosteroids.

In 2017, the Journal of the American Medical Association ("JAMA") published the results of a "bombshell" study which showed that patients with knee OA who received a saline injection (placebo) reported no differences in pain relative to those who received a corticosteroid injection. An <u>article</u> posted on ClinicalCorrelations.org in April 2018 provided more details on the results of the study:

With regard to pain relief, the decrease in knee pain did not significantly differ across treatment groups: -12 units in the triamcinolone group vs -19 in the saline group (betweengroup mean difference, -0.84; 95% Cl, -18 to 0.29, P < J7). There was also no significant difference in patient reported stiffness and function.

The American Academy of Orthopaedic Surgeons ("AAOS") has also expressed doubts over the effectiveness of corticosteroids. As detailed in their clinical practice <u>guideline</u>, the AAOS assigned a "unable to recommend for or against" recommendation for the use of corticosteroid injections in the treatment of knee OA due to a lack of compelling evidence in support of their use.

We are unable to recommend for or against the use of intraarticular (IA) conticosteroids for patients with symptomatic osteoarthritis of the knee...Our search found only four placebo comparison studies that met criteria and evaluated pain relief for a minimum treatment period of four weeks. One study found IA corticosteroids to be superior to placebo on WOMAC total subscale scores at four weeks. However, another study found IA corticosteroids injections inferior to hyakronic acid injections and a third study found IA corticosteroids inferior to needle lavage (tidal irrigation).

Perhaps even more troubling than the questionable efficacy of corticosteroids is the growing evidence that these injections can accelerate and worsen joint damage in a sizable portion of patients in an October 2019 article published by The Atlantic titled "A Warning From a Doctor Who Has Done Thousands of Steroid Injections for Arthritis," the author detailed the concerning results of a 2018 study conducted by physicians at Boston University which showed that 8% of patients who received corticosteroid injections had complications which worsened the health of their joints:

As a specialist in joint pain, Guermazi has done thousands of steroid injections over decades of work\_But now he has come to believe that the procedure is more dangerous than he knew. And he and a group of his Boston University colleagues are raising a warning flag for doctors and patients alike.

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In the journal Radiology this week, Guermazi and his colleagues at Boston University published a study of 459 patients at their hospital who got injections, in the hips or knees, in 2018. Of those patients, 8 percent had complications that worsened the state of their joints. In some cases, the arthritis actually sped up. Others developed small fractures under the cartilage or had complications that compromised the blood supply to bone. In the worst cases, patients had what Guermazi and his colleagues described as 'rapid joint destruction."

The findings of the 2017 JAMA study mentioned earlier echoed these findings and showed that, in addition to not providing any reduction in pain relative to saline injections, corticosteroid injections also resulted in greater cartilage volume loss:

There was greater cartiloge volume loss in the triamcinolone group than the saline group (-0.21 vs -010 mm cartilage thickness; between group difference -0.11 mm; 95% Cl, -0.20 to -0.03;  $P \in Dl$ ). There were no significant differences in the two groups in progression of cartilage denudation, bone marrow lesion, effusion volume, or trabecular morphology.

HA injections are of very questionable efficacy and are costly: Hyaluronic acid is similar to a naturally
occurring substrate in the joints which provides lubrication and shock absorption. Hyaluronic acid
injections, also known as HA injections, are typically given to knee OA patients after other treatments
such as physical therapy, NSAIDs and corticosteroid injections have failed.

The evidence in support of the use of HA injections is even weaker and spattier than that of corticosteroids. While HA injections are generally safe, their efficacy has been called into serious question by major healthcare bodies.

In 2013, the AAOS notably changed its recommendation for HA injections from "unable to recommend for or against" to "cannot recommend." In support, the AAOS <u>cited</u> an analysis of multiple clinical studies which showed that there was little clinical benefit from using HA injections:

Fourteen studies (three high-strength studies and 11 moderate-strength studies) assessed intraarticular hyaluronic acid (HA) injections... Meta-analysis in meaningfully important difference (MID) units showed that the over effect was less than 0.5 MID units, indicating a low likelihood that an appreciable number of patients achieved clinically important benefits in the outcomes (Guyatt et al).

As disclosed on its website, the Arthritis Foundation also currently <u>does not recommand</u> HA injections due to the lack of evidence that they work

Hyaluronic acid (HA). This acts like the fluid that lubricates your joints. While research is mixed on whether HA shots really help experts say they rarely cause harm. Pain relief may last up to 6 months for the knee or shoulder. ACR/AF guidelines do not recommend HA injections because proof that they work is limited. However, they say it should be up to the doctor and patient to discuss and decide.

Even physicians who actually use HA injections on their patients have serious doubts over the efficacy of this treatment. For example, during a roundtable discussion posted on <u>YouTube</u>, orthopedic doctors from respected medical institutions such as New York Langone Medical Center

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acknowledged that it is unclear whether and how much HA injections actually work. Particularly notable was their comments that patients with earlier stage knee OA tend to get much better results from HA injections than those with later stage disease, but that those patients with earlier stage knee OA who improved after receiving an HA injection likely would have gotten "better no matter what":

Richard Lorio, MD at New York Langone Medical Center: I only use hyaluronic acid when all else fails and they don't want surgery...

Andrew Spitzer, MD at Cedars-Sinai Orthopaedic Center: fil just sort of push back a little bit, because if you wait till the end game, the likelihood of efficacy is going to be less. There are certainly, uh, there are certainly studies that suggest that earlier on in the disease the efficacy is greater. So, if you wait until you really need a hail many, the hyaluronic acid many not provide that.

Richard Lorio, MD at New York Langone Medical Center: So, III push back a little bit there, earlier on in the disease most people get better no matter what you do. So that could be a selection bias issue.

To make matters worse, in addition to being of highly questionable efficacy, HA treatments are still very costly at around \$800 per injection. Given that the duration of relief for the small percentage of patients that do benefit from HA injections is only around 4 to 6 months, multiple injections a year are often needed, resulting in an annual cost significantly in excess of \$1,000 for these patients.

#### Amniofix Has Shown Tremendous Promise As A Treatment For Knee OA And Will Likely Receive FDA Approval

The lack of effective treatments for moderate-to-severe knee OA has resulted in a substantial cost burden to the US and global health system. Patients who are in the late stages of the disease often have no other option but to eventually undergo an expensive total knee replacement surgery which typically costs around \$50,000 to \$55,000. In 2014, an astounding \$2080 was spent in the US alone on knee and hip replacement surgeries, consisting of 723,000 knee replacements and 505,000 hip replacements. Therefore, it is clear that new treatments which better manage the symptoms of this disease and delay the need for costly surgery are sorely needed.

We believe that MDXG's Amniofix injectable product has the potential to help address this significant unmet need. The evidence in support of Amniofix is highly promising and strongly indicates that it is an effective and safe treatment for knee OA which is superior to both corticosteroid and HA injections. There is also evidence suggesting that Amniofix may have regenerative properties which could help to slowdown the progression of knee OA and osteoarthritis in general. Based on this overwhelmingly positive evidence, we believe that Amniofix will ultimately receive FDA approval, and that it has the potential to be a game-changing treatment for knee OA both in terms of patient outcomes and cost.

Positive preliminary results strongly indicate that MDXG's Phase 2b knee OA trial for Amniofix will be a
success: In March 2018, MDXG initiated its Phase 2b knee OA trial comparing the efficacy and safety
of its Amniofix injectable product relative to a placebo saline injection. The Company originally
planned to enroll 318 patients in this trial but later expanded it to 486 patients in order to increase the
chances of obtaining a clinically significant result.

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With this trial nearing completion, MDXG has recently provided some very encouraging updates to investors on the preliminary results. In July 2020, the Company disclosed in its <u>PF 2018 Super ID-K</u> that the preliminary data from its clinical trials, which includes its Phase 2b knee OA trial, showed a "separation between treatment and control groups," meaning that the patients who had received the Anniofix injection were having better results relative to the placebo group:

In this regard, we have three ongoing IND programs: plantar fasciitis, Achilles tendonitis and knee osteoarthritis. We are currently completing a Phase 3 plantar fasciitis study and are well advanced in the enrollment of subjects in a Phase 2B knee osteoarthritis study. Results of double-blinded, randomized, interim analyses of these studies revealed separation between treatment and control arous

Even more encouraging was Dr. Bob Stein's recent comments during MDX6's 03 2020 earnings call. In response to a question that we posed to him about the future revenue potential of Amniofix for the treatment of knee OA, Dr. Stein spoke in highly optimistic terms about the results of the Phase 2b trial.

Specifically, he mentioned that the results were "very promising" and in support he mentioned that the dropout rate of 3% was far lower than the 10% dropout rate that the Company expected. A low dropout rate is often a very positive sign in a clinical trial because it is an indicator that patients who are receiving treatment are experiencing a positive benefit:

I do believe that our AmnioFix injectable product is having very powerful impact pain and function in the osteoarthritis. Earlier studies by Dr. Alden have supported that. And our angoing study looks very promising at this stage. We were able to enroll the entire intended patient population into that study a little bit early. And the reason for that even in the face of COVID and slowed down enrollment for a while, is that our dropout rate is much lower than we had anticipated. Our study was designed for a anticipated 10% dropout rate and our actual dropout rates only been 3%. And that allowed us to accrue the number of patients we believe, we need to see a statistically and clinically significant difference, in a slightly smaller sample size.

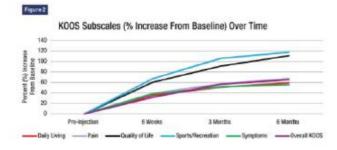
Overall, considering that the majority of the patients in the Phase 2b trial have already been treated and assessed, we believe the above updates strongly indicate that this trial will be a success.

The results of independent clinical studies were similarly positive: Over the past few years, several
physicians have conducted their own independent clinical studies on the effectiveness of Amniofix
and other micronized amniotic tissue products in treating knee OA. The results of these studies have
been overwhelmingly positive and support the positive preliminary Phase 2b results that the
Company has recently disclosed.

Perhaps the most compelling of these studies was the one conducted by Dr. Kris Alden, an orthopaedic surgeon at Hinsdale Orthopaedics in Chicago. In 2019, Dr. Alden <u>published</u> the results of a retrospective review of 100 knee OA patients who had been treated with Amniofix by his clinic. The results were extremely positive – At six months post-treatment, overal quality of life and sports/recreation measures for these patients improved by more than 100%, while pain scores improved by 87%. Additionally, no severe adverse events occurred with the most common side effect reported was pain in the injection site lasting 2 to 7 days:

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Overall mean KOOS for the cohort was 40 at baseline, improving to 52, 62, and 65 at 6 weeks, 3 months, and 6 months post-mdHACM injection. Percent increases were 32, 56, and 65%, respectively. Quality of life and sports/recreation domains improved by 11 and 118%, respectively, at 8 months. Paln scores improved by 67% at 6 months. All scores improved throughout the observation period. The most common adverse event was pain after injection lasting 2 to 7 days, observed in 68% of cases. This represents the largest singlephysician experience with mdHACM for treatment of knee OA reported to date. Injectable mdHACM appears to be a potentially useful treatment option for knee OA patients. Controlled studies are underway to confirm these observations.



In an article published in Today's Geriatric Medicine, Dr. Alden provided additional color on the results of his study which included a compelling testimonial from one of the participants:

Typical comments are similar to those of my patient, Laura, a 78-year-old. Laura has had both her shoulder and her knee injected with AmnioFix. She says, "I had the AmnioFix injection, and within four weeks I was moving quite a bit better and within six weeks it seemed the pain was gone. I had no more pain. I may be 78, but fm very active, and I just need that quality of life. I couldn't have been more pleased because fm back to my crafts and my quality of ife back to normal again."

Supporting Dr. Alden's findings is a <u>study</u> on Amniofix conducted by Dr. Ashish Anand, an orthopedist located in Virginia. In this study, a total of 40 knee OA patients who had previously failed all other standard treatment options – including corticosteroid and HA injections – were treated with Amniofix and their progress was measured for a total of six months. The results were, like the Dr. Alden study, very positive – 65% of these patients reported a more than 60% improvement in pain, 25% reported a more than 50% improvement, and just 10% did not have any improvement:

I am reporting my retrospective case series of 40 patients of variable age group who had failed all conservative treatment options including all other injections like steroids and viscosupplementation and were reluctant for surgery. Patients were injected with Amnio-fix injection and were followed at 4 weeks and 8 weeks and 8 months and contacted at 1 year. Failure rate was defined as improvement of < 50 percent in VAS scale. 85 percent Patients reported improvement in their VAS pain levels of more than 80 percent and 25 percent reported improvements of 50 percent and 10 percent did not have any improvement. The

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majority group above reported improvement in their walking distance...This retrospective review of cases suggests that Amnio-fix can be used in treatment of refractory arthritic knee pain.

 The use of Armiofix for the treatment of knee OA has also shown very promising results outside of a clinical study setting: Although Armiofix is not an FDA approved treatment, physicians have been able to use the product on an off-label basis for knee OA and other aliments for several years. Because of this, there are thousands of knee OA patients who have been treated with Armiofix outside of a clinical study setting. These patients, just like those in the clinical studies, have experienced very positive results.

A few months ago, we had the pleasure of speaking with Dr. Alden, the author of the 100 patient Amniofix study just cited above. During our conversation, we asked Dr. Alden whether he had treated any other knee OA patients, outside those he had treated in his clinical study, with Amniofix, and if so, whether the results for these patients were also encouraging. In response, he told us that he had in fact treated more than five hundred knee OA patients with Amniofix, and that the vast majority of these patients had experienced very positive results.

We also spoke with a physician from one of the leading hospitals in NYC about his experiences with using Amniofix. He told us that he had treated several hundreds of patients with Amniofix and that his patients had experienced a very high rate of success with the treatment. He also told us that he uses HA injections but that they were 'not a great drug' and only worked in a small percentage of his patients. Finally, he also spoke negatively about corticosteroids and stated that there was no question that they have a degenerative effect on knee cartilage. The relevant excerpts from our conversation are provided below:

The market [for Amniofix for the treatment of knee OA] is tremendous\_I define success in a couple of different ways. One was improvement of at least 30% over your baseline pain, and one is an improvement of 50% of your baseline pain. An improvement of 50% in the pain world, in the sort of knee pain world, an improvement of 50% is a lot. So, any drug or injection that gets you an improvement of 50% is a pretty potent product\_those [of my] patients that improved by more than 50% [from Amniofix] was like 75% [of my patients]\_Patients really like this drug [Amniofix] which is not the case with HA

With HA, my clinical experience is that it works well in a small percentage of patients, and maybe 20 to 30% of patients have a good response to HA\_the majority of patients though get a minimal if any benefit from HA\_the AAOS guidelines in 2013 issued a strong recommendation against HA\_it's not a great drug.

In 2017, there was a very well done paper in a very well regarded journal, JAMA, that came out looking at multiple steroid administration versus placebo administration over a two year period..and there was double the cartilage loss in the group that received steroids over two years. That's very significant I think and very concerning I think. And that's also backed up in a lot of pre-clinical studies and animal studies. So, there's very little doubt I think that steroid is overall degenerative..and steroids in many ways are negative for patients

In addition to speaking with physicians, we also reached out to and spoke with numerous knee OA patients who have been treated with Anniofix. Their experiences, like those of Dr. Alden's patients,

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were universally positive. Provided below are excerpts from some of these conversations (Note: one of the below patients was treated for a torn knee meniscus and not knee OA):

Patient #2: So, I had no cartilage in my left knee...so the bone was rubbing on bane...Before Amniofix, I went to the guy that actually, I had some surgery on my wrist too that he repaired the tendon. I went to him, and he tried to put in [an HA injection]...It's atmost like putting in like a gel...The only thing is after about a week and a half...my knee blew up because I guess whatever they used [the HA injection] it just didn't last.

So, that's why I was looking for something else, and [my friend] turned me onto the Amniofix. And I ve used that, I got that I guess it was I want to say going on two or three years now, two years maybe, and I have no problems. It doesn't swell up anymore like it did when I used to take stairs. I got no pain really, except for tired legs because I'm getting older, but that's it.

Patient #21 had a problem in my right knee, and when [the doctor] looked at the MRIs that I had paid for..he said 'Yeah, okay, so this is severe osteoarthritis. You're bone on bone'\_and he said 'listen let's do your knee [with Amniofix]..So he did a shot, and I have no pain in my knee at all\_like it [the pain] just purely went away...

Patient #3:1 had a fairly long history of knee problems from osteoarthritis. I had significant pain and it was hard for me to get up and sit down, like getting in and out of a car was really tough for me...So last year around oh I would say around July of last year, I got an Amniofix injection in both knees.

After the injection, I started to feel better and better and after a few days almost all of the pain in both knees was gone...Today I can move around a lot easier, I can get in and out of my car pretty easily and I'm able to exercise the way I want to...So, it's been pretty amazing, for sure. The results have been great.

Patient #4: I never had bad knees up until about two years ago, and then I tore a meniscus in my right knee\_J took a [Amniofix] shot in my right knee. He said it would be four to six weeks until I felt some relief, and I went from habbling around to basically nothing ever happened\_Jt went from habbling and intense pain in my knee to being absolutely normal\_It wasn't 90% it was 100%.

 There is evidence that Anniofix has regenerative qualities: Anniofix contains growth factors which, according to some studies, act as "stem cell magnets" which recruit a patient's own stem cells to the affected joint. These recruited cells can help to bring about healing of the damaged cartilage and may actually slowdown the progression of osteoarthritis.

Multiple physicians that we spoke with told us that they believe Amniofix can slowdown the progression of osteoarthritis and some have seen evidence of this in their patients. For example, a NYC-based physician who has treated several hundreds of knee OA patients with Amniofix recently told us that he believes Amniofix has regenerative properties and that the vast majority of his patients who have used the product are not getting knee replacements:

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I do think it does [have regenerative properties]. As I think about the sort of trajectory of all my patients over the many years that I ve been treating them. The ones that I treat with steroids and HA they just tend to follow this very predictable pattern where [you do] steroids for a while, you do HA for a while, that doesn't work, and [then] you say like "listen, we're just not making any progress, let's think about when we want to get the knee replaced," and then they're off and their knees are replaced.

There are so many of my patients treated with Amniofix who do not follow that trajectory. I just see them every year and we do Amniofix that I think at a minimum it is preventing progression of disease. I wouldn't consider it curing arthritis, but would suggest that it is <u>delaying progression</u> much more than any of the other therapies that we have. The ones who came in earlier [for an Amniofix injection], <u>the vast maiority are not getting their knees</u> <u>polyceaf</u>. They really aren't.

The results of a 2014 study provides further evidence that Amniofix may slowdown the progression of osteoarthritis. In this study, lab rats who were injected with micronized amniotic tissue ("dHACM") experienced less joint degradation than those who were injected with saline:

μ-dHACM is rapidly sequestered in the synovial membrane following intra-articular injection and attenuates cartilage degradation in a rat OA model. These data suggest that intraarticular delivery of μ-dHACM may have a therapeutic effect on OA development.

A 2018 study showed similar results in lab rabbits who were injected with micronized amniotic tissue.

Chemical OA was developed in the knees of New Zealand rabbits. Once OA was established, the right knees only were treated with an intra-articular injection of human AM with the left knees considered as a negative control group.At 6 weeks post-injection, the left knees exhibited hypertraphy, cracks, cell clusters, decreased matrix staining and structure loss. However, the right knees exhibited cell clusters without evidence of disruption in cartilage integrity (P=0.015). These results suggested that the intra-articular injection of human AM delays histological changes of cartilage in OA.

Given its potential regenerative properties, we believe that Amniofix could save insurance companies a significant amount of money by eliminating the need for costly knee replacement surgeries in a significant portion of knee OA patients. Even if Amniofix is only able to delay the need for knee surgery by just a couple to a few years, then this would still result in substantial cost savings for insurance companies.

To illustrate, consider that the average knee replacement patient is in their early 60s. This is supported by a recent 4,500-person knee replacement <u>study</u> in which the average patient age was 61. If Amniofix is able to delay the need for surgery by just a couple to a few years, then this would allow insurance companies to "pass the buck" of knee replacement surgery to Medicare, which kicks-in at 65, for a sizable portion of patients. A physician who specializes in treating knee OA echoed these views during a recent conversation with us.

Medicare kicks-in when? At 85 i think\_When's the majority of that group [knee OA patients] getting their knees replaced? Like, in their 80s. And so, you don't need to delay knee

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replacement all that long to pass the buck to Medicare. So, if you come in at 63, but steroids and HA can't do it, and Amniofix can, and it gives you three or four years, that's a win right. I mean all of a sudden you [insurance companies] no longer have to pay for that. Yeah, it's one of these diseases that's like the seesaw tips, the fulcrum is right around mid-60s which is when people tend to be enrolling in Medicare

 Results from clinical studies and off-label use indicate that Amniofix has a significantly longer efficacy period than both HA and corticosteroid injections: In addition to being of highly questionable efficacy, both HA and corticosteroid injections only work for a relatively short time period for those patients that do respond to these treatments.

According to an <u>article</u> published by CreakyJoints, the efficacy period for HA injections is around 4 to 6 months:

"It is quite variable but many patients report six months of relief, and the injections may be repeated every six months or based on physician judgement," Dr. Miller says. Our Facebook community confirms this, with most patients telling us relief lasted from four to six months; they got the shots (or series of shots) every six months. But, as Sarah Quina shared, "they don't work repeatedly forever." Also, the shots may take several weeks to go into effect, unlike steroid injections, which work much faster.

According to an <u>article</u> published by Harvard Health, the efficacy period for corticosteroids is even shorter than HA injections at around just 4 to 6 weeks:

...the benefits usually last only four to six weeks. And the injections don't restore cartilage or slow the progression of osteoarthritis.

By comparison, according to the physicians and patients that we spoke with, the benefits of Amniofix typically last for around 9 to 12 months, which is significantly longer than the efficacy period of both HA and corticosteroids. This is supported by clinical studies such as the Dr. Alden knee OA study which, as we detailed earlier, showed that patients who were treated with Amniofix reported improvements in quality of life and pain scores of 11% and 67%, respectively, at six months post-injection, indicating that the effects of Amniofix last significantly longer than six months.

Amniativ is safe: In addition to being efficacious, Amniativ also has a <u>flawless safety track record</u>. To
date, no serious adverse events have been reported from the multiple past and ongoing clinical
studies of Amniativ, and according to MDXG, Amniativ has been used on an off-label basis in more
than 100,000 patients without any reports of serious adverse events. This was echoed by the <u>Bulfate
Medical Group</u> in a post on its website:

To date, more than 100,000 patients nationwide have been injected with AmnioFix®. There have been no reports of medical complications or serious side effects. Patients may experience some mild discomfort around the injection site for up to three days, but this is easily managed with ice and elevation to reduce any swelling that arises.

MDXG's successful recruitment of Dr. Bob Stein is a testament to the immense promise of Amniafix.
 We believe Dr. Stein's recent decision to join MDXG as its R&D head amounts to a ringing endorsement of Amniafix. Dr. Stein has had a long and distinguished career in the healthcare space spanning more

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than 40 years and has <u>led the development of multiple blockbuster drugs</u> including Eliquis and Promacta. We do not believe that someone as accomplished and experienced as Dr. Stein, who is in his 70s, would agree to join MDXG and lead its drug development efforts unless he believed that Amniofix had the potential to be a game-changing treatment for knee OA.

## RMAT Designation Further Increases Amniofix's Already High Chance of FDA Approval And Could Open The Door To Early Approval

In March 2018, the FDA granted Amniofix with an RMAT designation for the treatment of knee OA based on the positive preliminary results that it had shown in clinical studies.

The RMAT designation is a huge positive for Amniofix in two ways. First, treatments which are granted a fast track designation, such as an RMAT designation, are often held to a lower standard of evidence by the FDA. We believe this apparently 'lower bar' further increases Amniofix's already high chance of FDA approval. Second, the FDA can and often does give early approval to fast track designation treatments following a successful Phase 2 trial. Based on this, we believe there is a good chance that the FDA will grant early approval to Amniofix if the results of the Phase 2b knee OA trial are sufficiently positive.

 Due to its encouraging preliminary clinical results for the treatment of knee OA, the FDA granted an RMAT designation to Annulofic The RMAT designation is granted by the FDA to regenerative therapies, such as cell therapy, therapeutic tissue engineering product, and human cell and tissue product, which are intended to treat serious or life-threatening diseases for which there are currently little to no viable treatments. Further details on the RMAT designation is provided in a post on Bioinformant.com:

> To date, 47 RMAT (Regenerative Medicine Advanced Therapy) designations have been publicly announced. However, the FDA states it has received 149 requests and issued 55. Sponsors of cell and gene therapies [as well as human tissue products] are eligible to obtain an RMAT designation from the US. FDA if their product is intended to treat serious or lifethreatening diseases and there is preliminary clinical evidence that it can address unmet medical needs.

As we have detailed, current treatments for knee OA are wholly insufficient and are of questionable efficacy and/or safety. Due to this significant unmet medical need, and the encouraging preliminary results that Amniofix has shown in treating knee OA, the FDA granted an RMAT designation to Amniofix in <u>March 2018</u> for the treatment of knee OA:

MiMedx Group\_today announced that the U.S. Food and Drug Administration (FDA) has granted MiMedx's micronized amniatic tissue, AmnioFix® Injectable, the Regenerative Medicine Advanced Therapy (RMAT) designation for use in the treatment of Osteoarthritis (OA) of the knee...

...The FDA further stated that MiMedx has provided clinical information to demonstrate preliminary clinical evidence to indicate that the drug has the potential to address unmet medical needs for this condition.

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The RMAT designation further increases Anniofix's already high chance of FDA approval due to the
often lower standard of evidence required for approvat. The benefits of an RMAT designation are
similar to the breakthrough therapy designation assigned by the FDA to drugs. At a high-level, the
RMAT award is intended to provide a faster and more streamlined pathway for promising
regenerative therapies to obtain FDA approval. This is accomplished by giving company
representatives increased access and dialogue with the FDA throughout the clinical trial and
approval process:

By definition, an RMAT is an award from the U.S. FDA that allows for faster, more streamlined approvals of regenerative medicine products within the United States, such as cell and gene therapies, tissue engineering products, and combination products. RMAT designations make innovative products eligible for quicker development and review of a marketing application\_Benefits of an RMAT include increased opportunities to meet with FDA officials, as well as early meetings to discuss potential surrogate or intermediate endpoints.

However, as detailed in a September 2018 <u>article</u> from UNDARK, perhaps the biggest benefit of a fast track designation, such as an RMAT, is the often lower standard of evidence required by the FDA to grant approvat

It's a question that cuts to the heart of a program that allows the FDA to approve drugs using a lower standard of evidence. Under what's known as the Accelerated Approval Program, the FDA can reduce the bar for approval in cases where there is an unmet medical need for a serious condition. In such cases, a drug manufacturer need not show that the drug works. It only needs to demonstrate some reasonable expectation that the drug ought to work.

Due to this apparently lower standard of evidence that Amniofix will have to meet, we are even more confident that it will eventually be approved by the FDA for the treatment of knee OA.

 The approval of Zirretta, despite mediocre clinical results, indicates that knee OA treatments in general are held to a lower standard of evidence:
 In October 2017, the FDA approved Zirretta – Flexion Therapeutic's extended-release corticosteroid injection – for the treatment of knee OA. As detailed in an <u>article</u> posted on Evaluate.com, the FDA approved Zirretta even after the treatment had previously failed its Phase 2 trial and after its pivotal Phase 3 trial showed that the treatment was no better than traditional fast-acting corticosteroids in treating the symptoms of knee OA:

> Flexion investors had some reason to celebrate this morning. Their company's sole clinical asset, Zilretta, managed to score in a phase ill osteoarthritis knee pain study – having last September failed a similarly designed phase il trial.

> But there is a major caveat: Zilretta is just an extended-release formulation of triamcinolone, a generic steroid used for a variety of inflammatory conditions. And, while Zilretta beat placebo in the phase ill study, it failed to show superiority over generic, immediate-release triamcinolone.

The FDA's approval of Ziretta despite such weak results indicates that it has lowered the standard of evidence required for knee OA treatments, regardless of whether such treatments have an RMAT designation or not, most likely due to the fact that there is a lack of viable treatment options for this

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condition. This lends even more support for our conclusion that the FDA will meaningfully lower the bar for Anniofix to receive approval.

 The RMAT designation also gives MDXG an apportunity to receive early FDA approval of Amniotix following the completion of its Phase 2b triat As just discussed, the RMAT designation provides a faster and more streamlined pathway for prospective treatments to receive FDA approval. One of the ways in which the RMAT designation can accelerate the pathway is by giving companies the chance to apply for early FDA approval following Phase 2 clinical triats.

Over the past few years, several drugs which have been awarded a fast track designation have been granted early FDA approval. As detailed in a December 2013 <u>acticite</u> posted on Obroncology.com, two such examples were the multiple myeloma drugs Kyprolis and Pomalyst which were both granted a Breakthrough Therapy designation and were subsequently approved by the FDA following successful Phase 2 trials:

kyprolis® (carfitzomib, Amgen) was recently approved by the FDA for multiple myelioma (MM) through the Accelerated Approval program. Like imbruvica, kyprolis is a small molecule inhibitor approved based on Phase II data as a monotherapy for use in relapsed/refractory patients with a hematological malignancy.Pormalyst® (pomalidomide, Celgene), was also recently FDA approved in February 2013 for MM, and like kyprolis, it received accelerated approval in relapsed/refractory patients based on Phase II data.

Based on the above examples, and numerous other precedent examples, we believe that there is a good chance that the FDA could grant Amniofix an early approval for the treatment of knee OA if the results of the Phase 2b trial are sufficiently positive.

#### Amniofix Has Also Shown Promise As A Platform Treatment For Various Other Musculoskeletal Ailments

MDXG management has communicated to investors that it is confident that Amniofix can become a platform treatment for a variety of musculoskielatal aliments beyond just knee OA. In addition to its Phase 2b knee OA trial, MDXG is currently conducting Phase 3 clinical trials for the treatment of plantar fascitis and Achilles tendonitis, and the Company also plans on lounching trials for multiple, additional indications in the near future.

Given the positive preliminary results that Amniofix has shown both in clinical studies and when used on an offlabel basis by physicians to treat a wide range of joints and tendons throughout the body, we agree with management's assessment and believe that Amniofix will eventually be approved for multiple indications.

 Positive Phase 2b and interim Phase 3 trial results strongly indicate that Anniofix will eventually be approved for the treatment of plantar fascilitis: In a press release on March 28<sup>th</sup>, 2018, MDXG announced the results of its Phase 2b clinical trial comparing Anniofix vs. a saline injection in the treatment of 145 patients with plantar fascilitis. The results of this trial were very positive and showed that patients who were treated with Anniofix experienced a clinically meaningful reduction in pain and improvement in function:

> The Phase 28 IND clinical trial evaluating the use of AmnioFix Injectable for the treatment of Plantar Fascilitis demonstrated a clinically and statistically significant difference compared to patients in the Control Group in their reduction in the visual analog scale (VAS) score for

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pain (p<0.000) and Foot Function Index-Revised (FFI-R) scores (p=0.0004) at 3 months compared to baseline. Additionally, the safety of the product was demonstrated by the absence of serious, unanticipated, product-related adverse events and the relative absence of an elicited immune response post-injection demonstrated by the Treatment Group.

In a subsequent press release on August 2<sup>nd</sup>, 2018, the Company provided additional details on the encouraging results of this trial – At the 3-month follow-up visit, patients who had received an Amniofix injection reported a 76% reduction in pain vs. a much lower 45% reduction for the control group. Furthermore, the study showed that 82% of patients who were treated with Amniofix reported at least a 50% reduction in pain vs. just 47% for the control group:

MiMedx Group\_today announced that the positive pain and foot function results from its Phase 2B clinical trial of micronized dHACM (dehydrated Human Amnion/Chorion Membrane) in the treatment of Plantar Fascilitis have been published in the peer-reviewed journal, Foot & Ankle International\_

The primary efficacy endpoint was the mean change in VAS score for pain between baseline and the 3-month follow-up visit. The secondary efficacy endpoint was the mean change in Foot Function Index – Revised (FFI-R) score between baseline and 3 months. The baseline VAS and FFI-R scores were similar between groups. At the 3-month follow-up, the mean VAS score was reduced by 76% for patients in the Treatment Group compared with a 45% reduction for the Control Group (p=0.0001), and the mean FFI-R score was reduced by 60% for patients in the Treatment Group, while the Control Group had mean reduction of 40% versus baseline (p=0.0004).

Overall, at the three-month study follow-up visit, 60 (822%) patients in the treatment group, and 34 (472%) patients in the control group reported at least a 50% reduction in VAS score from baseline (p<0.0001).

Because the interim results of its Phase 2b plantar fascilits trial were so positive, the Company decided to initiate its Phase 3 trial prior to the completion of its Phase 2b trial, and enrolled its first patient in this pivotal trial in January 2018. Approximately 2.5 years later, in its <u>FY 2018 Super IO-K</u> filed in July 2020, the Company disclosed to investors that the preliminary results of the Phase 3 trial were positive, and specifically disclosed that a separation between the treatment and control groups was observed.

We are currently completing a Phase 3 plantar fascilitis study\_Results of double-blinded, randomized, interim analyses of these studies revealed separation between treatment and control groups

With its Phase 3 plantar fasciitis trial nearing completion, the Company anticipates submitting a BLA filing for this indication to the FDA in the first half of FY 2022 (as disclosed in its November 2020 investor presentation). Based on the positive Phase 2b and interim Phase 3 results that MDXG has reported, we expect that the FDA will ultimately approve this application.

 An independent clinical study in 2017 showed that Anniofix was effective in treating a variety of musculosteletal aliments: in 2017, Dr. Alfred Gellhorn – the Associate Professor of Clinical Rehabilitation Medicine at Weill Cornell Medicine in New York City – conducted a <u>clinical study</u> on the effectiveness of Anniofix as a treatment for a variety of degenerative joint and tendon injuries. In this study, a total

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of 40 patients were treated with Amniofix. Of these patients, 20 had joint injuries, while the other 20 had tendon injuries. Joints and tendons all over the body were treated, including those in the knee, ankle, foot, shoulder, and elbow.

The results of this study were very positive and showed that Amniofix was effective in treating a variety of musculoskeletal aliments – At 3-months, the percentage of patients achieving clinical success, which is defined as a reduction in pain of at least 30%, was 9%. The results also showed that Amniofix was similarly effective in treating patients with joint injuries and those with tendon injuries:

Patient pain and function were measured at 1, 2, and 3 months after the procedure. Patientreported average pain scores decreased from a baseline value of 6.4 (95% confidence interval [CI] % 67-70) to 27 (95% CI ½ 2J-33; P < 0.01) at 1 month; 17 (95% CI ½ 1J-22; P < 0.01) at 2 months, and 1.4 (95% CI ½ 0.9-19; P < 0.01) at 3 months. The percentage of patients achieving clinical success, defined as 30% or greater improvement in pain levels, was 66% at 1 month; 82% at 2 months, and 98% at 3 months.

Because of the different pathogenesis and natural history of joint and tendon disorders, we performed subgroup analysis of the cohort, dividing the patients by pathologic category into joint disease (n ½ 20) or tendon disease (n ½ 20). When evaluating changes in pain scores in these 2 groups, there were no significant differences between patients with tendon pathology and joint pathology.

Amniofix has also shown very promising results in treating a variety of musculoskeletal aliments
outside of a clinical study setting. Physicians and their patients have also experienced very positive
results when using Amniofix outside of a clinical study setting on an off-label basis to treat a variety
of musculoskeletal aliments.

For example, a NYC-based physician who has used Amniofix extensively for a variety of joint issues, including for shoulder OA, told us the following:

In the shoulder, so shoulder arthritis is a problem as well. It's not nearly the magnitude of problem as knee arthritis, but when people have it, it's bad. And I us'ed this [Amniofix] in shoulder arthritis, and I expect even better benefits than knee arthritis. People do great with shoulder OA who get Amniofix, like really great. Like I have a guy who did everything and then we did Amniofix and that was like five years ago, and he's still fine, and we haven't done a thing for him since. It was amazing, and that's not that unusual for the shoulder.

A Tennessee-based physician who has used Amniofix to treat around 200 patients with ankle OA and other foot & ankle aliments had similarly positive results. He also told us that Amniofix is superior to corticosteroid injections, and that, after he began to use Amniofix, he eventually completely stopped using HA injections:

Amniafix five been using probably for three years\_as far as efficacy goes\_fd probably say like ballpark 75 to 83 percent is like the gut number that feels normal that people come back at three or four weeks with just a at least a significant decrease in the symptoms that they/ve had\_

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I would say that my joint to soft tissue spread is probably even 50/50. Fifty percent live put it [Amniofix] into joints and then the other fifty percent of my patients more of the sports med realm. I'm putting it in tendons and things like that...[I treat] ankle and the first MTP and live put it into the subtalar joint as well...and then the first big toe joint is another joint that is commonly, at least in the foot & ankle realm, injected. It's a high area of OA...[I've treated] probably just under 200 [patients]. The math should say like 160 to 200...

I also use corticosteroid injections for these end-stage OAs and it works but Amniofix just physically works better from a pain scale\_I don't even do really hyaluranic acid or Synvisc anymore. I haven't done one of those in a year and a half easy. Because I'm doing now all Amniofix instead.

In addition to speaking with physicians, we also reached out to and spoke with numerous patients who have been treated with Amniofix for various musculoskeletal aliments. Their experiences were also very positive. Provided below are excerpts from some of these conversations:

Patient #IL fore my rotator cuff\_and I got a shot of that [Amniofix] there [in the shoulder] and Im 100% better\_they wanted to do the surgery and that's an absolute bear to have surgery, and I ended up having a shot [of Amniofix instead] about six months ago\_it's fike it never happened\_it was not a major tear, but it was a pretty good tear\_it was funny the other day I was saying to my wife 'it's done, there's no pain at all."

Patient #2 So I flew to New York and I had the expensive kind of MRLso when I got there, I had a problem in my toe\_so he did a shat [of Amniofix]\_absolutely never had a pain in my toe again, and it was the kind of thing where, it was my big toe the big joint on my big toe, where I couldn't walk previously. I have never had any issue with that again.

#### We Believe That Amniofix Will Generate Multi-Billions Of Dollars In Annual Sales

Given the huge addressable market of patients with osteoarthritis and other musculoskeletal ailments, and in particular knee OA, combined with the promising results that Amniofix has shown both inside and outside of a clinical study setting, we believe that Amniofix will achieve blockbuster sales.

As detailed below, based on conservative assumptions for market share and pricing, we estimate that Amniofix's peak sales from the knee OA indication alone will amount to multi-billions of dollars. We also believe that Amniofix's peak sales from other potential indications beyond knee OA could amount to an additional several hundreds-of-millions to one billion dollars. Our bullish sales projections are supported by the multibillions of dollars in annual sales that the top treatments for rheumatoid arthritis and psoriasis – which have similar disease burden characteristics as osteoarthritis – generate each year, and is further supported by the lofty sales of HA injections despite their highly questionable efficacy.

 Based on conservative market share and pricing assumptions, Amniotix's annual revenue from the knee OA indication alone could amount to multi-billions of dollars: Using assumptions around market share and pricing, we have calculated what Amniofix's peak annual revenue from the knee OA indication could be in a base, downside and upside scenario.

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In regards to market share, in the US alone, it is estimated that a total of around 5.4m knee OA patients receive intra-articular injections annually (per slide 16 of Flexion Therapeutics' September 2020 Investor presentation). Given the positive results that Amniofix has shown in clinical studies and through off-label use, and the lack of effective treatment options for knee OA, we believe that Amniofix will be able to capture a significant share of this massive market. However, for the purpose of being conservative, we have assumed fairly modest market share for Amniofix of 20% (10m patients annually), 10% (0.5m patients annually), and 30% (1.6m patients annually) in our base, downside and upside case, respectively.

In regards to prioing, given the substantial cost savings that Amniofix could provide for insurance companies by delaying or eliminating the need for costly surgery for a significant portion of patients – a knee replacement costs between \$50K - \$55K – we believe that Amniofix could command a price of \$5K or higher per injection. In support, consider that, prior to Unity Biotechnology's knee OA injectable treatment failing its Phase 2 study, it was <u>projected</u> that this treatment would command a price of around \$15K per injection due to its potential regenerative properties. That being said, we have once again erred on the side of being conservative and have assumed that Amniofix will be priced at \$2,500, \$1500, and \$3,500 per injection in our base, downside, and upside case, respectively.

As shown in the table below, based on the above key assumptions, we estimate that Amniofix's peak sales from the knee OA indication alone will significantly exceed \$18n in both the base case and upside case - \$4.18n and \$8.58n, respectively. Even in our downside case, we estimate that Amniofix's peak sales from the knee OA indication would still amount to \$1.28n.

	Base	Downside	Upside
# Of Patients Receiving Knee OA Injections Annually (1)	5.4	5.4	5.4
(*) % Market Share	20.0%	10.0%	30.0
Total # Of Patients Receiving Amniofix Injection Annually	1.1	0.5	1.6
(*) # Of Injections Per Patient Per Year	1.5	1.5	1.5
Total # Of Amniofix Injections Annually	1.6	0.8	2.4
(*) Price Per Amniofix Injection	\$2,500	\$1,500	\$3,500
PP-Estimated Peak Sales For Knee OA Indication For Amniofix	\$4,050	\$1,215	\$8,505

Source: Prescience Point estimates.

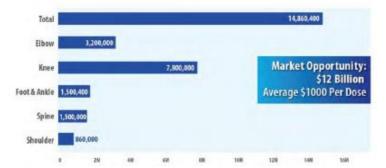
(1) Per slide 16 of Flexion Therapeutics' September 2020 investor presentation

 Amniofix's annual revenue from other indications outside of knee OA could amount to up to one billion dollars of adalitional revenue: While the knee OA indication is the largest opportunity, the market potential for Amniofix outside of knee OA is also significant.

Based on data provided by SmartTRAK Business Intelligence, the total size of the joint pain injection market, excluding knee OA, amounted to a whopping \$7.IBn in 2015. This includes \$3.2Bn for the elbow, \$15Bn for the foot & anke, \$15Bn for the spine, and \$0.9Bn for the shoulder. Given the billions of dollars that are spent on these joints, we expect that Amniofix's revenue, excluding knee OA, will be sizable and will likely amount to several hundreds-of-millions of dollars and potentially up to one billion dollars if it is approved for multiple indications.

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#### 2015 U.S. JOINT PAIN INJECTION MARKET



Our conclusion that Amniofix will be a blockbuster treatment is supported by the fact that three of the top five selling drugs in the US are for rheumatoid arthritis and psoriasis, which are conditions that have similar disease burden characteristics as asteoarthritis. Both rheumatoid arthritis and psoriasis are conditions that are chronic, debilitating and widespread with millions of diagnosed patients globally. Due to their immense burden on patients and the healthcare system, the top treatments for these conditions generate multi-billions of dollars in annual sales. As shown in the table below, three of the top five selling drugs in the US in 2019 were for the treatment of rheumatoid arthritis and psoriasis:

Top Five Selling Drugs in The US in 2019		
Main Indication	Total Sales	
Rheumatoid Arthritis	\$21.4Bn	
Anticoagulant	\$9.9Bn	
Rheumatoid Arthritis	\$8.1Bn	
Psoriasis	\$6.6Bn	
Oncology	\$6.5Bn	
	Main Indication Rheumatoid Arthritis Anticoagulant Rheumatoid Arthritis Psoriasis	

Source: IQVIA Institute August 2020 report.

Osteoarthritis is a condition which has similar disease burden characteristics as rheumatoid arthritis and psoriasis in that it is also chronic, often debilitating and widespread. Given this, along with the promising results Amniofix has shown in treating osteoarthritis, we believe that Amniofix should, like the top treatments for rheumatoid arthritis and psoriasis, also achieve blockbuster sales.

 Further supporting our conclusion that Armiofik will be a blockbuster treatment is the lofty sales of HA injections despite their highly questionable efficacy: As we have detailed, although the addressable market for knee OA is massive, the current FDA-approved treatments for this condition are few and carry considerable drawbacks in terms of efficacy and/or safety. Because of this, HA injections continue to be widely used by physicians despite their highly questionable efficacy, and despite the fact that the AAOS and the Arthritis Foundation have recommended against their use.

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According to <u>Grand View Research</u>, the size of the global HA injectables market was \$388n in 2019 and is expected to grow at a CAGR of 9.2% from 2019 to 2027. The US accounts for a sizable portion of this market – As disclosed in Flexion Therapeutics' September 2020 <u>investor presentation</u>, -0.9m knee OA patients in the US receive HA injections annually.

Perhaps the biggest beneficiary of the popularity of HA injections has been Sanofi, the owner of Synvisa/Synvisa-One, the most popular HA injectable treatment on the market. Synvisa/Synvisa-One's sales peaked at -\$500m in FY 2014, and even after being on the market for more than 20 years, it continues to generate annual sales of several hundreds-of-millions of dollars today.

The fact that Synvisc/Synvisc-One sales peaked at a lofty \$500m despite the highly questionable efficacy of HA injections, combined with the preliminary evidence which shows that Amniofix is a far superior treatment to Synvisc/Synvisc-One and HA injections in general, lends further support for our conclusion that Amniofix will generate blockbuster sales.

#### MDXG Shares Are Worth Multiples More Than The Current Share Price

Although MDXG's share price has risen by 204.6% since our January 2019 report, due in large part to our increased optimism over the potential of Amniofix, we believe that MDXG shares are still trading at just a fraction of their fair value.

To illustrate, we have provided below a sum-of-the-parts analysis based on separate valuations for MDXG's wound care business, which accounts for the vast majority of the Company's current revenue, and its pipeline of clinical trials for Amniofix.

To value the wound care business, we have used the following assumptions:

- 4.0x sales multiple, which represent a meaningful discount to the almost 5x LTM sales that Smith & Nephew paid in early 2019 to acquire Osiris, one of MDXG's primary wound care competitors. We believe our valuation multiple is conservative given that MDXG has higher market share and higher margins than Osiris, which suggests that it should be valued at a premium to or at least in-line with Osiris.
- Pre-pandemic run-rate revenue of \$2713m, which is calculated by annualizing MDXG's reported 2H 2019 revenue, adjusted for a one-time \$29.8m benefit from a change in revenue recognition, of \$135.7m (\$135.7m \* 2 = \$271.3m). Note that, although a small portion of MDXG's revenue is generated from non-wound care products, for the purpose of simplicity, we have included non-wound care sales in our wound care valuation.

Using the above assumptions, we value the wound care business at \$7.92 per share.

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#### Valuation For Wound Care Business

(\$ and amounts in millions, except per share amounts)	
Pre-Pandemic Run-Rate Sales (1)	\$271.3
(*) Sales Multiple	4.0x
Enterprise Valuation For Wound Care Business	\$1,085
(+) Cash on Balance Sheet as of 9/30/20	\$109.6
(-) Debt on Balance Sheet as of 9/30/20	(\$47.6)
Equity Valuation For Wound Care Business	\$1,147
(+) Total Shares Outstanding (2)	137.0
Valuation Per Share For Wound Care Business	\$7.92

Source: Prescience Point estimates and MDXG filings with the SEC (1) Equal to 2H 2019 reported revenue, adjusted for a \$29.6m one-time benefit from

a change in revenue recognition, of \$135.7m \* 2. (2) Equal to 111.0m shares outstanding as of October 26, 2020 + 26.0m shares from the full conversion of preferred stock held by EW Healthcare and Hayfin Capital Management.

To value the knee OA indication for Amniofix, we have used the following assumptions:

- 4.0x peak sales multiples, which represents the midpoint of the 3-5x peak sales multiple that disruptive biotech products typically command.
- · FDA approval in FY 2025. We believe this is a conservative assumption given our belief that Amniofix will leverage its RMAT designation to receive early approval.
- Peak sales in FY 2030, 5 years after approval
- Peak sales of \$4.1Bn, which is equal to the base case peak sales estimate for the knee OA indication that we calculated in the previous section
- FDA approval probability of 50%, which is in-line with the average <u>success rate</u> of drugs that make it to Phase 3 trials. We believe this is a very conservative assumption given our belief that Amniofix's chances of approval for the knee OA indication are meaningfully higher than 50%.

Using the above assumptions, and after discounting the resulting valuation to present value at a 10% rate, we value the knee OA indication for Amniofix at \$22.79 per share:

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#### Valuation For Knee OA Indication For Amniofix

(\$ and amounts in millions, except per share amounts)	
Peak Sales For Knee OA Indication For Amniofix	\$4,050
(*) Peak Sales Multiple	4.0x
(*) Probability Of FDA Approval	50.0%
Undiscounted Equity Valuation For Knee OA Indication	\$8,100
(+) Total Shares Outstanding (1)	137.0
Undiscounted Valuation Per Share For Knee OA Indication	\$59.12
Discounted Valuation Per Share For Knee OA Indication (2)	\$22.79

Source: Prescience Point estimates.

- (1) Equal to 111.0m shares outstanding as of October 26, 2020 + 26.0m shares from the full conversion of preferred stock held by EW Healthcare and Hayfin Capital Management.
- (2) Based on our projection that peak sales will occur in FY 2030, we have discounted the undiscounted valuation for a period of ten years at a 10% discount rate.

Finally, to value the other potential indications for Amniofix, we have used the following assumptions:

- 4.0x peak sales multiple
- · Peak sales in FY 2030, the same year as the peak sales for the knee OA indication
- Peak sales of \$200m. We believe this is a conservative assumption given our belief that other
- indications could bring in up to one billion dollars in annual revenue
- FDA approval probability of 50%

Using the above assumptions, and after discounting the resulting valuation to present value at a 10% rate, we value the other potential indications for Amniofix at \$1.13 per share:

Valuation For Other Potential Indication For Amniofix	
(\$ and amounts in millions, except per share amounts)	
Peak Sales For Other Potential Indication For Amniofix	\$200
(*) Peak Sales Multiple	4.0x
(*) Probability Of FDA Approval	50.0%
Undiscounted Equity Valuation For Other Potential Indications	\$400
(+) Total Shares Outstanding (1)	137.0
Undiscounted Valuation Per Share For Other Potential Indications	\$2.92
Discounted Valuation Per Share For Other Potential Indications (2)	\$1.13

Source: Prescience Point estimates.

 Equal to 111.0m shares outstanding as of October 26, 2020 + 26.0m shares from the full conversion of preferred stock held by EW Healthcare and Hayfin Capital Management.
 Based on our projection that peak sales will occur in FY 2030, we have discounted the

undiscounted valuation for a period of ten years at a 10% discount rate.

Adding it all up, as shown in the table below, our sum-of-the-parts analysis yields a valuation of \$3184 for MDXG shares. This is 3839% higher than the current share price of \$658 as of December 15<sup>th</sup>. In addition to showing

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that MDXG shares are grossly undervalued, our sum-of-the-parts analysis also shows that <u>the market is</u> <u>assigning little-to-no value to Amniofix</u>. We estimate that the wound care business by Itself is worth \$7.92 per share, which is 20.4% higher than MDXG's current share price. This means that <u>investors who purchase MDXG</u> shares today are buying the wound care business at a substantial discount and on top of this are receiving Amniofix an asset that we believe is worth multi-billions of dollars, essentially for free.

We believe there is considerable upside to our \$31.84 price target given that this target is based on what we believe are very conservative assumptions. Specifically, our wound care valuation is based on MDXG's prepandemic run-rate revenue and does not give the Company any credit for future growth from its recent insurance and contract wine, as well as its newly released product extension, while our Amniofix valuation assumes 1) no early FDA approval, 2) an only 50% chance of FDA approval, 3) just 20% market share for the knee OA indication, 4) a very conservative pricing of \$2,500 per injection for the knee OA indication, and 5) just \$200m of peak revenue from all other potential indications beyond knee OA.

MDXG Sum-of-the-Parts Valuation	
Wound Care Business	\$7.92
Knee OA Indication For Amniofix	\$22.79
Other Potential Indications For Amniofix	\$1.13
MDXG Sum-of-the-Parts Per Share Valuation	\$31.84
Premium / (Discount) to Current Share Price - \$	\$25.26
Premium / (Discount) to Current Share Price - %	383.9%

Source: Prescience Point estimates.

#### The Lofty Valuations of Pre-Revenue Biotechs With Comparable Treatments To Amniofix Supports Our Conclusion That MDXG Is Grossly Undervalued

Our conclusion that the market is grossly undervaluing MDXG, and more specifically is grossly undervaluing its attractive pipeline of clinical trials for Amniofix, is supported by the lofty valuations that pre-revenue biotechs with comparable treatments to Amniofix have received early on in the clinical trial process.

For example, Samumed is a privately-held, pre-revenue biotech company whose primary product in clinical tridis is lorecitivint, an injectable treatment for knee OA and other forms of osteoarthritis with potential regenerative properties. Despite being a pre-revenue company whose lead indication for the treatment of knee OA was only in Phase 2 trials, in August 2018, Samumed raised \$438m from outside investors at a staggering valuation of <u>\$28n</u>.

As another example, Unity Biotechnology is a publicly-traded (Ticker: UBX), pre-revenue biotech company whose primary product in clinical trials is UBX0101, an injectable treatment for knee OA and other forms of osteoarthritis with potential regenerative properties. Days prior to the release of its Phase 2 trial results, Unity's shares reached a peak of \$15.44 on August 10<sup>®</sup>, 2020, which translates to an enterprise value of \$705m. Although \$705m is significantly lower than the multi-billion dollar valuation we have assigned to Amniofix and the \$128n valuation Samurmed received, Unity's peak valuation is impressive and quite rich when taking into account that UBX0101's prior Phase 1 knee OA trial results were decidedly mixed.

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Given the lofty valuations of Samumed and Unity, combined with the fact that Amniofix 1) is similar to both lorecivivint and UBX0101 in that it is a treatment for osteoarthritis with potential regenerative properties, and 2) has shown superior results than these treatments – both lorecivivint and UBX0101 eventually failed their primary endpoints in their Phase 2 knee OA trials, while Amniofix reported positive preliminary results for its Phase 2b knee OA trial and positive results for its Phase 2b plantar fascilits trial, we believe our multi-billion dollar valuation for Amniofix is not only reasonable and justified, but conservative.

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This is not an offer to sell or a solicitation of an offer to buy any security, nor shall any security be offered or sold to any person, in any jurisdiction in which such offer would be unlawful under the securities laws of such jurisdiction.

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# Ninded Innovating treatments through advanced placental science

January 11-14, 2021

2021 J.P. Morgan 39th Annual Healthcare Conference

## 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; 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.
- 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"); to the extent our products do not qualify for regulation as human cells, tissues and cellular and tissue-based products solely under Section 361 of the Public Health Service Act ("Section 361"), this could result in removal of the applicable products from the market, would make the introduction of new tissue products more expensive and would significantly delay the expansion of our tissue product offerings and subject us to additional post-market regulatory requirements.
- our 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; future revenue growth will require continued or additional market, regulatory, and payor acceptance of our products.
- ongoing and future effects arising from the COVID-19 pandemic and the Company's plans to adhere to
  governmental recommendations with respect thereto; the COVID-19 pandemic and governmental and societal
  responses thereto have adversely affected our business, results of operations and financial condition, and the
  continuation of the pandemic or the outbreak of other health epidemics could harm our business, results of
  operations, and financial condition.
- our expectations regarding market opportunities, expected growth in certain markets, and demographic and market trends; there can be no assurance that the demand for our products will grow.
- our expectations regarding future staffing levels and future levels of cash, nets sales, gross margin, investments, and
  expenses; future operating results and financial conditions are subject to numerous risks and uncertainties; and
- our expectations regarding our ability to resolve certain legal matters. We are currently, and may in the future be, subject to substantial litigation and ongoing investigations that could cause us to incur significant legal expenses and result in harm to our business and we can provide no assurance that we will resolve such matters on terms that are reasonable or that existing resources will be adequate to resolve such matters.

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# IMPORTANT CAUTIONARY STATEMENT (CONT.)

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 the result 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.



# LEADING PRODUCT PORTFOLIO POSITIONED FOR GROWTH

\$256M TTM Net Sales <sup>1</sup>	84% Gross Margin	1 <sup>2</sup>	<b>\$1.1B</b> Market Cap <sup>3</sup>		WELCOME BACK
<b>2,000,000+</b> Allografts Distributed <sup>4</sup>	<b>725+</b> Employees⁵		<b>265+</b> Field Sales Personnel <sup>5</sup>		MIMedx MDXG-11/4/2020 MDXG NasdaqListed
with diabetes <sup>6</sup> Medicare	- <b>\$18.7B</b> cost of DFU/yr <sup>8</sup> <b>(</b> /yr nputation care <sup>9</sup>	cove	nbursement erage, U.S.: OOM+	• 5-year sh • Room te	The Purison And And And And And And And And And An
<b>17.5M+</b> U.S. KOA patients <sup>10</sup>	2M+ U.S. patients tre for PF annually <sup>11</sup>		1,000+ p studied under clinical progra	IND	10,000+ ft <sup>2</sup> of ISO Class 7 clean room space

## FROM TRANSFORMATION TO INVESTMENT

Investing in core business for growth

5

Positioning for pipeline acceleration

Focusing capital on strategic initiatives

# MIMEDX IS A PIONEER IN PLACENTAL BIOLOGICS



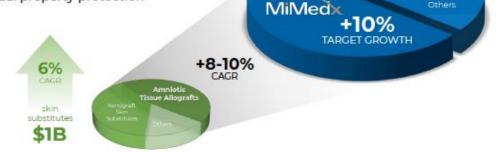
Distinct drivers of significant shareholder value with current and future growth potential

6

## DIFFERENTIATED PLATFORM POSITIONED TO EXCEED MARKET GROWTH

#### All amniotic products are not the same

- · Shelf-stable with 5-year shelf life
- Human-derived, immunologically privileged & terminally sterilized
- Full vertical integration with scalable donation & recovery network
- Peer-reviewed, published data recognized by AHRQ
- Broad reimbursement coverage
- Strong intellectual property protection

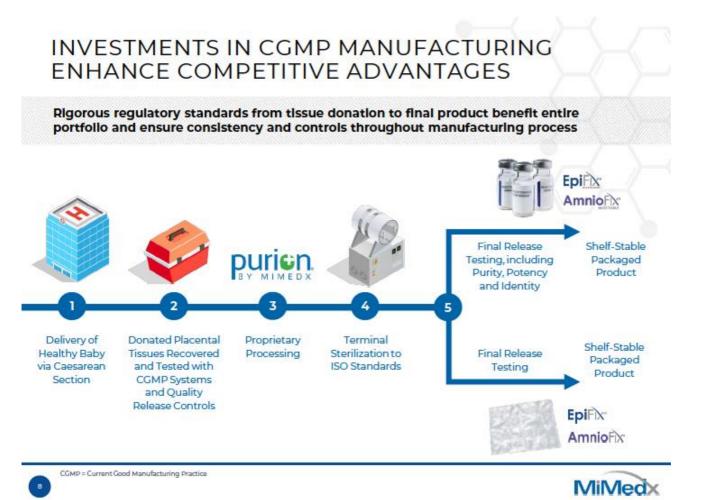


Source: BioMed GPS SmartTrak; CAGR 2019-2024E; AHRQ = Agency for Healthcare Research and Quality

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Competitor C

**U.S. Amniotic Tissue Market** 



## ROBUST COMMERCIAL INFRASTRUCTURE DIFFERENTIATES FIELD SALES FORCE

Q3 2020 Revenue (TTM)



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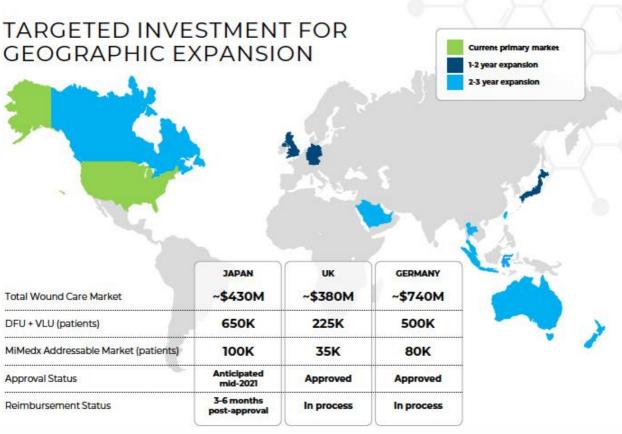
- 265+ field sales personnel supported by an expanding Medical Science Liaison team to educate customers
- Robust clinical evidence to differentiate within the category and stabilize reimbursement shifts
- Current multi-year contracts in place with the largest GPOs and IDNs
- Product attributes are easily integrated into multiple sites of care to ensure broad patient access
- Field-based reimbursement & national account teams aligned to field sales personnel to accelerate commercial execution
  - Patient Insurance Verification Team for intake and processing of insurance to determine coverage

GPO = Group Purchasing Organization; IDN = Integrated Delivery Network



## NEAR-TERM INVESTMENTS PRIORITIZE 10%+ FIELD SALES TEAM EXPANSION





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.

## 2021 INVESTMENTS REPRESENT SIGNIFICANT INCREASE IN R&D TO SUPPORT CORE MARKET AND PIPELINE GROWTH OBJECTIVES



BLA = Biologics License Application

# INVESTMENTS IN R&D POSITION US TO ACCELERATE PROGRAM TIMELINES

Synergistic activities contribute to overall BLA program efficiencies



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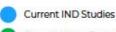
According to recordly updated FDA guidance, FDA generally intends to exercise enforcement discretion through May 31,2021, with respect to the investigational New Drug (IND) and the premarket approval requirements for cartain Humain Cells, Tissues, and Cellular and Tissue-Based Products (HCT)Pa), provided that use of the HCT/P does not raise reported safety concernse or potential significant safety concerns. Timoline represents current plans and estimates only. Actual insults 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.



# INCREASING OPTIMISM IN **PIPELINE AS A** PLATFORM TECHNOLOGY

- Promising retrospective data1,2
- Phase 2B Plantar Fasciitis trial demonstrated statistically significant benefit in pain and function
- Phase 2B Knee Osteoarthritis trial:
  - Drop-out rates lower than expected
  - Additional dosing potential
  - Evolving competitive landscape

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

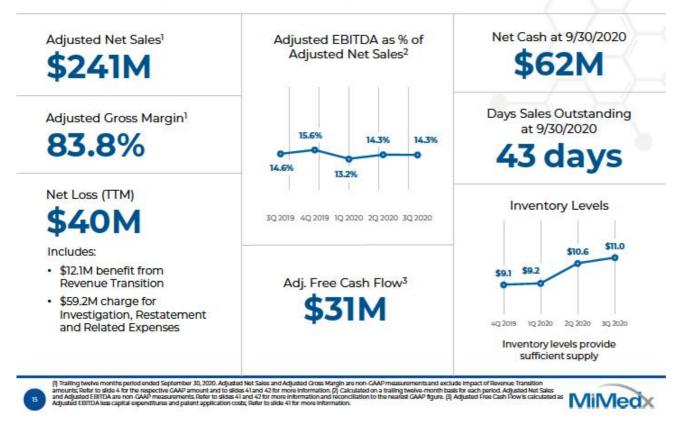


Planned Near-Term IND Studies

Potential Long-Term IND Studies

(1) Alden KO, Harris S, Hubbs B, Kot K, Istwan NB, Mason D. Micronized Dehydrated Human Amnion Chorion Membrane Injection in the Treatment of Knee Ostearthritis-A Large Retrospective Case Senies (published online ahead of print, 2019 Novo 28). J Knee Surg. 2019;0:1055/s-0039-3400951. doi:10.1055/s-0039-3400951; (2) Gellhorn AC, Hun A. The Use of Dehydrated Human Amnion/Chorion Membrane Allograft Injection for the Treatment of Tendinopathy or Arthritis: A Case Senies Involving 40 Patients. PM R. 2017 Dec;9[12]:1236-1243. doi: 10.1016/j.pmrj.2017.04.011. Epub 2017 May 6. PMID: 28483683.

### FINANCIAL STRENGTH FORTIFIES SUSTAINABLE AND PROFITABLE GROWTH



## 2021 TOP-LINE GROWTH WITH SIGNIFICANT INVESTMENTS IN GROWTH DRIVERS

#### Outlook for 2021 consistent with growing in excess of market

**Enforcement Discretion:** Full Impact<sup>1</sup> No Impact \$235-250M<sup>2</sup> \$255-270M<sup>2</sup> 2021 Net Sales Investing proceeds from Plan to increase sales mid-2020 capital raise in professionals to growth drivers: Decline expected in 290+ by 12/31/21 Investigation, R&D expense expected to be Restatement and Related expenses, prior 35-40M Adjusted gross margins to any settlement of the expected to be consistent pending securities class with 2020 levels of SG&A expense will reflect action matter.3 impact of investment in 83-85% Commercial initiatives

MiMedx

(1) If Enforcement Discretion expires at the end of May 2021 and the Company can no longer sell micronized products, management estimates a negative imp to Net Sales of approximately \$20 - 25 million in 2021. (2) The above outlook assumes full access to hospitals and health care provider facilities; continuation or escalation of access restrictions or lockdown orders as a result of the pandemic will adversely affect our results. (3) See slides 25 and 24 for more information.

# INVESTMENTS POSITION ACCOMPLISHMENT OF 2021 GROWTH DRIVERS

Commercial	<ul> <li>Top-line growth &gt;10% (excludes potential impact of enforcement discretion)</li> <li>Sales force growth &gt;10%</li> <li>Japan approval</li> <li>Pursue organic and inorganic growth opportunities</li> </ul>
Operations	CGMP compliance
	Interim data readouts (PF/KOA/AT)
	Peer-reviewed clinical, scientific and economic publications
R&D	Accelerate late-stage pipeline
	File additional INDs



## FROM TRANSFORMATION TO INVESTMENT

Investing in core business for growth

18

Positioning for pipeline acceleration

Focusing capital on strategic initiatives

# QUESTION & ANSWER SESSION





# **EXPERIENCED LEADERSHIP TEAM**

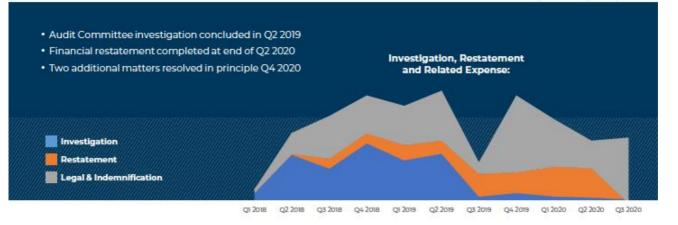


) = Joined since 2018



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# CONTINUED PROGRESS TO RESOLVE REMAINING LEGAL CONTINGENCIES



#### Current spend relates to legal matters involving the company (fees and resolution) and indemnification costs for former officers and directors

- · Company has utilized some of the applicable Directors & Officers insurance, and has some remaining coverage available
- 12 of 15 material litigation matters disclosed in 2019 Form 10-K now resolved; See Slide 24 for more information.
- Securities class action matter remains outstanding; mediation scheduled for December



# MATERIAL LITIGATION CLOSURE UPDATE

12 of 15 "Material Litigation" matters disclosed in 2019 Form 10-K now resolved

#### Matters Resolved in Last 16 Months

Matters	Pending
---------	---------

Matter	Type of Matter	Timing of Resolution
Annual Meeting Litigation	Two Cases to Compel Shareholder Meetings	Q2/Q3 2019
Kruchoski	Retaliation	Q3 2019
Fox	Retaliation	Q4 2019
Scott	Retaliation/Gender Discrimination	Q4 2019
S.E.C. Civil Enforcement	Civil Enforcement	Q4 2019
OSHA	Retaliation	Q2 2020
Shareholder Derivative Litigation	Derivative Claims for Breach of Fiduciary Duty	Q2 2020
V.A/DOJ Pricing Practices	Qui Tam Action	Q2 2020
NuTech	Patent	Q3 2020
Osiris	Breach of Contract Trade Secret Theft	Q3 2020
MDNC	Healthcare Industry Compliance Investigation	Q4 2020 <sup>1</sup>
PAN	Qui Tam Action	Q4 2020 <sup>1</sup>

Matter	Type of Matter
Securities Litigation	Civil Class Action
Sparrow	Defamation
Viceroy	Defamation

(I) Reached agreement in principle on two matters in Q4 2020



# REGULATORY ENVIRONMENT OVERVIEW

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

#### Enforcement Discretion:

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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.

\* Homologous use means that the donated tissue serves the same basic function in a recipient as the tissue does in the donor

## CLINICAL EVIDENCE DEMONSTRATES DIFFERENTIATION & SUPPORTS REIMBURSEMENT

#### **BEST-IN-CLASS CLINICAL EVIDENCE**

- Statistically significant results\*
- Randomized controlled trials across multiple applications
- Head-to-head study results demonstrate superior clinical outcomes & substantially lower cost-toclosure compared to Apligraf®
- Studies demonstrate Low Risk of Bias\*

STUDY **	RESULT
EpiFix DEU RCT study <sup>1</sup>	Complete Wound Closure 92% at 6 weeks (pr. 001)
EpiFix DFU RCT – Weekly vs. Biweekly Application <sup>2</sup>	Overall Complete Wound Closure: 925% heating in 12 weeks Mean time to Heating: - Weekly applications: 24 weeks - Blweekly applications: 41 weeks
EpiFix DEU RCT – EpiFix vs. ApligntR vs. SOC Study <sup>44</sup>	Complete Woand Clower, 85% at 6 weeks 95% at 6 weeks Case Effectiveness - Subjects receiving EpiFix used 58% freer grafts - Subjects receiving EpiFix used 58% freer grafts - Median cest of graft material for EpiFix was 1935 lines than Apigrafts
EpiFix DFU Multicenter RCT <sup>6</sup>	Complete Wound Closure: 81% at 12 weeks (PP: Per-Protocol) 70% at 12 weeks (ITT: Intent-to-Treat)
EpiFix VLU Surrogate Endpoint Study <sup>6</sup>	62% of patients achieved > 40% wound closure at 4 weeks
EpiFixVLU Multicenter RCT <sup>1</sup>	Complete Wound Closure: 60% at 12 weeks 21% at 16 weeks
EpiCord Multicenter RCT <sup>0</sup>	Complete Wound Closure: 6% at 32 weeks (PP:Per-Protocol) 20% at 12 weeks (ITI: Intent-to-Treat)

### VALIDATION OF DATA IN RECENT AHRQ<sup>®</sup> REPORT

"intended to help health care **decision makers** patients and clinicians, health system leaders, and policymakers, among others — make **wellinformed decisions** and thereby improve the quality of health care services"

\*Skin Substitutes for Treating Chronic Wounds Technical Brief, Technology Assessment Program; Agency for Healthcare Research and Quality, Feb 2, 2020 \*\*Please see Appendix for Clinical Study Summary (slide 27) and references



# CLINICAL STUDY SUMMARY

STUDY	RESULT	
EpiFix DFU RCT Study <sup>1</sup>	Complete Wound Closure: 92% at 6 weeks (p=.001)	>
EpiFix DFU RCT – Weekly vs. Biweekly Application <sup>2</sup>	Overall Complete Wound Closure: 92.5% healing in 12 weeks Mean time to Healing: – Weekly applications: 2.4 weeks – Biweekly applications: 4.1 weeks	
EpiFix DFU RCT – EpiFix vs. Apligraf® vs. SOC Study <sup>34</sup>	Complete Wound Closure: 85% at 4 weeks 95% at 6 weeks Cost Effectiveness: • Subjects receiving EpiFix used 58% fewer grafts • Median cost of graft material for EpiFix was 83% less than Apligraf®	
EpiFix DFU Multicenter RCT <sup>5</sup>	Complete Wound Closure: 81% at 12 weeks (PP: Per-Protocol) 70% at 12 weeks (ITT: Intent-to-Treat)	
EpiFix VLU Surrogate Endpoint Study <sup>6</sup>	62% of patients achieved ≥ 40% wound closure at 4 weeks	
EpiFix VLU Multicenter RCT <sup>7</sup>	Complete Wound Closure: 60% at 12 weeks 71% at 16 weeks	
EpiCord Multicenter RCT <sup>8</sup>	Complete Wound Closure: 81% at 12 weeks (PP: Per-Protocol) 70% at 12 weeks (ITT: Intent-to-Treat)	

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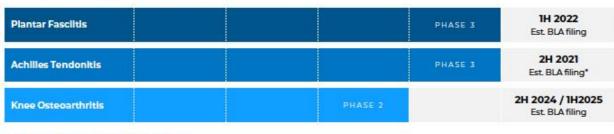


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# LATE-STAGE PIPELINE AIMED AT SIZABLE MARKETS

Potential to address unmet patient needs as a platform technology across multiple markets

### MUSCULOSKELETAL/SPORTS MEDICINE



### ADVANCED WOUND CARE

Chronic Wounds	PRE-CLINICAL	1H 2021 Est. IND/IDE filing
Surgical Incisions	PRE-CLINICAL	1H 2021 Est. IND/IDE filing
Soft Tissue Defects	PRE-CLINICAL	IH 2021 Est. IND/IDE filing

\* Dependent on data readout



IDE - Investigational Device Exemption; 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 HCTPs, provided that use of the HCTP 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.



## PF STUDY INFORMS SAFETY, EFFICACY AND OTHER FUTURE INDICATIONS

## Plantar Fasciitis (PF)

# 2M+

U.S. Patients treated for PF annually<sup>1</sup>

## 200K+ Candidates for

advanced therapies<sup>2</sup>

## **Current Treatments**

- Conservative (RICE/NSAIDS)
- Custom orthotics
- Corticosteroid injections

### Emerging therapies

# ~20K-50K

Potential candidates for injectable amnion/ chorion<sup>3</sup>

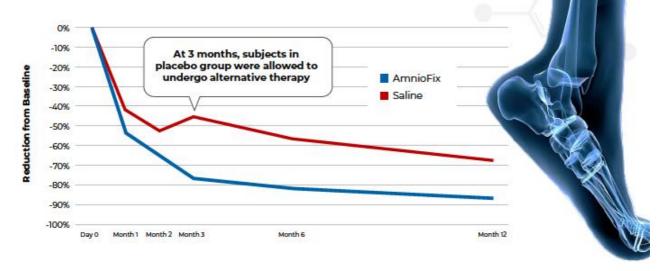
Recovery for chronic PF tends to be lengthy and **recurrence is common** 

(1) Tong KB, Furia J. Economic burden of plantar fasciitis treatment in the United States. Am J Orthop (Belle Mead NJ). 2010;39(5):227-231; (2) Ang TW. The effectiveness of conticosteroid injection in the treatment of plantar fasciitis. Singapore Med J. 2015;56(8):425-432. doi:10.11622/smedj.2015118; (3) Plantar Fasciitis. Primary Research/Conjoint Analysis (n=171) performed by Market Vision December 2019 https://www.mv-research.com/ (data on file).



## 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



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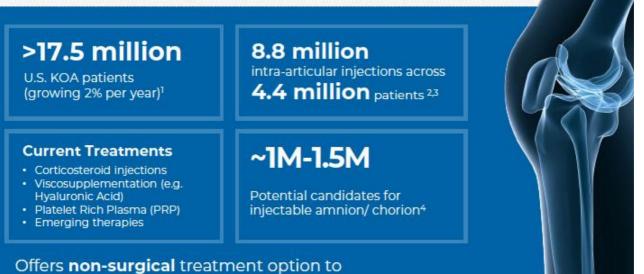
 Timeline represents current plans and estimates only. Actual results and timing may differ materially. There can be no assurance that clinical trials are conducted or completed on schedule, that trial results are favorable, or that we obtain regulatory approval for our products and indications.



## GAPS IN CURRENT TREATMENT OPTIONS PROVIDE OPPORTUNITY TO ADVANCE NON-SURGICAL TREATMENT ALGORITHM

## Knee Osteoarthritis (KOA)

reduce pain & improve function



**MiMedx** 

(i) Global Data Kinee Reconstruction Data Model United States 2020 (2) 2014 (QVIA Claims data with 2% growth rate; (2) Barnuru R9, Brodie CR, Sullivan MC, McAlindon TE. Saltity of Repeated injuctions of Sodium Hyaluronate (SUPARTZ) for Kinee Osteoarthritis: A Systematic Review and Meta-Analysis: Carollogo. 2016;7(4):322-332. doi:10.1177/194748033564227f; Managament Estimates based on at least two injuctions par patient; (4) Kinee CA Primary Research(Conjoint Analysis (n=162) performed by Market Vision December 2019 <u>https://www.search.com/</u>

## INJECTABLE DEHYDRATED HUMAN AMNION/CHORION MEMBRANE (dhacm) in the treatment of knee osteoarthritis

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

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 Octooarthritis Outcome Score (KOOS) scores routinely recorded at baseline and 6 weeks, and 3

 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 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

ered to represent meaningful positive clinical

KOOS scores at 6 weeks, and 3 and 6 months. An improvement in KOOS score of at least 10 points is

and 6 months, post-treatment. Treatment with Injectable dHACM

xd).

consider change.

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

#### Purpose

Methods Study Design

#### Results

nom

- Data from 82 patients with 100 treated knees were included for analysis. Of these 82 patients, the majority were female (51/82, 62%). To present our clinical experience using micronized dHACM injection as a treatment for symptomatic knee QA.
  - Mean age at treatment was 61.6 ± 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.

#### Table 1 Alone KDCL or

NOS salvante fremerica		E M	3.000	A.mes .
Dalylining	-46.61.18.8	618.2180	7131184	TC0+163
Pain.	41.5 1:3.8	$80.3 \pm 12.5$	88.6±15.0	12.8 + 18.1
Quality of No.	11.0 5 9.8	412:155	\$1,71,22.3	1180.225
(prob) Recipition	14.7 + 21.2	413+255	30.0+26.7	13.8 + 26.8
Symplotes .	44.7 ± 9.3	817 - 122	\$7.8±19.3	05.5 + (8.5
Overall KODS -	R61.93	\$13.117.0	61.94184	45.4320.0

#### 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 potential knee OA
- Further controlled studies are required to confirm these observations.

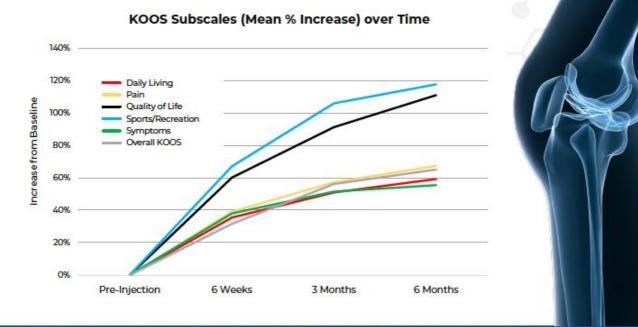
- Percent increases in KOOS scores were 32%, 56% and 65% respectively. (Table 2)
- The largest improvements at 6 months were in the quality of life and sports/recreation domains, 111% and 118% respectively.
- Pain scores improved by 67% at 6 months. All scores improved throughout the observation period.
- Short term pain or soreness around the knee post-injection was a common observation.
- No serious or ongoing, unresolved advorse events were observed in this cohort.

KOOS subscale	Preinjection	6 VA	3 ma	6 150
Daily living	876	353	5136	585
Pain	015	391	\$2%	675
Quality of life	0%	601	91%	1313
Sports/Recreation	UL	675	10616	1180
Symptoms	05	385	\$1%	356
Overall KOOS	05	325	36%	655



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



MiMedx

Source: Alden KJ, Harris S, Hubbs B, Kot K, Istwan NB, Mason D. Micronized Dehydrated Human Amnion Chorion Membrane Injection in the Treatment of Knee Osteoarthritis-A Large Retrospective Case Series [published online ahead of print, 2019 Nov 28. J Knee Surg. 2019;10.1055/s 0039-3400951. doi:10.1055/s-0039-3400951.



# KNEE OSTEOARTHRITIS (OA) CURRENT STATUS

Critical success factors

Advantaged by CGMP

provides frequent

dialogue with the FDA

**MiMedx** 

Fasciitis BLARMAT designation

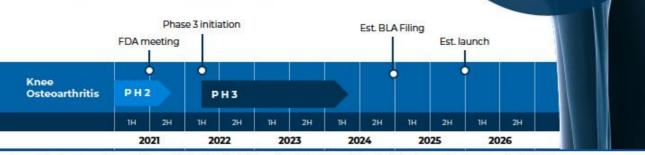
readiness for Plantar

### 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



 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. RMAT = Regenerative Medicine Advanced Therapy.

## INTELLECTUAL PROPERTY OVERVIEW



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### PATENT PORTFOLIO OVERVIEW

- Domestic patents issued: 97
- Domestic patents pending: 39
- · Foreign patents issued: 99
- · Foreign patents pending: 54

### ISSUED PATENTS BY TECHNOLOGY CATEGORY

- Placental Tissue:
  - 58 domestic
  - 35 foreign
- CollaFix:
  - 36 domestic
  - 64 foreign
- HydroFix:
  - 3 domestic



## ADJUSTED NET SALES TRENDS REFLECT STABILIZATION POST COVID-19 DOWNTURN

Revenue presentation includes impact of 2019 transition in revenue recognition



(1) Adjusted Net Sales excludes impact of Revenue Transition amounts. See slide 41 for reconciliation to Net Sales.

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# SUMMARY BALANCE SHEETS

					Unaudited				
(\$ millions)	1Q19	2Q19	3Q19	4Q19	1Q20	2Q20	3Q20		
Assets									
Cash and Cash Equivalents	28.4	96.9	94.1	69.1	53.5	48.2	109.6		
Accounts Receivable, net	0.0	0.0	21.4	32.3	31.9	30.1	33.0		
Inventory, net	16.4	15.0	12.0	9.1	9.2	10.6	11.0		
Other Current Assets	12.4	10.6	6.5	12.7	21.2	18.7	17.9		
Total Current Assets	57.2	122.5	134.0	123.2	115.9	107.6	171.5		
Property and Equipment	16.4	14.7	13.2	12.3	11.8	10.8	10.3		
Other Assets	33.9	33.1	32.1	31.6	31.2	32.5	31.5		
Total Assets	107.4	170.3	179.3	167.2	158.9	150.9	213.3		
Liabilities and Stockholders' Equity	_								
Current Liabilities	64.3	78.1	73.4	67.3	63.7	63.7	57.3		
Long Term Debt, net	0.0	63.1	62.2	61.9	61.6	ଗ.୨	47.6		
Other Liabilities	4.7	4.5	4.2	3.5	3.2	2.9	4.4		
Total Liabilities	69.1	145.6	139.7	132.8	128.6	128.1	109.3		
Convertible Preferred Stock	0.0	0.0	0.0	0.0	0.0	0.0	91.1		
Stockholders' Equity	38.4	24.7	39.6	34.4	30.3	22.9	12.9		
Total Liabilities and Stockholders' Equity	107.4	170.3	179.3	167.2	158.9	150.9	213.3		

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# SUMMARY INCOME STATEMENTS

					Unaudited					
(\$ millions)	1Q19	2Q19	3Q19	4Q19	1Q20	2Q20	3Q20			
Net Sales	66.6	67.4	88.9	76.4	61.7	53.6	64.3			
Cost of Sales	7.4	9.7	13.2	12.7	10.0	82	10.3			
Gross Profit	59.1	57.7	75.7	ഒ.7	51.7	45.4	54.0			
Research & Development	29	2.8	2.7	2.7	2.7	2.3	3.4			
Selling, General, and Administrative	50.9	50.6	51.3	45.4	46.9	37.3	48.0			
Investigation, Restatement, and Related	18.1	21.0	7.2	20.1	15.6	11.4	12.0			
Amortization of Intangible Assets	0.2	0.3	0.3	0.3	0.3	0.3	03			
Impairment of Intangible Assets	0.4	0.0	0.0	0.0	0.0	0.0	0.0			
Operating (Loss) Income	(13.4)	(17.1)	14.2	(4.9)	(13.7)	(5.9)	(9.7)			
Loss on extinguishment of debt	0.0	0.0	0.0	0.0	0.0	0.0	(8.2)			
Interest Expense, net	0.2	(0.3)	(2.3)	(2.4)	(2.4)	(2.6)	(1.5)			
Other Income, net	0.0	0.2	0.1	0.0	0.0	0.0	0.0			
Pretax (Loss) Income	(13.2)	(17.2)	12.1	(7.3)	(16.1)	(8.4)	(19.4)			
Income Tax Provision Benefit (Expense)	0.0	0.0	0.3	(0.2)	11.3	0.0	0.0			
Net (Loss) Income	(13.3)	(17.2)	12.4	(7.5)	(4.8)	(8.5)	(19.4)			

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# SUMMARY CASH FLOW STATEMENTS

						Unaudited	
(\$ millions)	1Q19	2Q19	3Q19	4Q19	1Q20	2Q20	3Q20
Net (Loss) Income	(13.3)	(17.2)	12.4	(7.5)	(4.8)	(8.5)	(19.4)
Effect of Change in Revenue Recognition	0.0	0.0	(17.4)	0.0	0.0	0.0	0.0
Share-Based Compensation	3.0	3.5	2.7	2.9	3.3	4.4	3.7
Depreciation	1.7	1.6	1.6	1.6	1.5	1.4	1.5
Other Non-Cash Effects	1.8	0.9	1.1	1.2	1.2	1.3	9.5
Changes in Assets	0.0	3.6	1.3	(14.2)	(8.2)	2.9	(1.8)
Changes in Liabilities	(8.4)	9.7	(4.9)	(7.0)	(5.3)	(4.7)	1.9
Net Cash Flows Used in Operating Activities	(15.3)	2.1	(3.2)	(23.1)	(12.3)	(3.1)	(4.6)
Purchases of Property and Equipment	(0.6)	(0.3)	(0.2)	(0.7)	(0.1)	(0.4)	(0.7)
Principal Payments from Note Receivable	0.4	0.0	2.3	0.0	0.0	0.0	0.0
Patent Application Costs	(0.2)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	0.0
Net Cash Flows Used in Investing Activities	(0.4)	(0.3)	2.1	(0.8)	(1.1)	(0.5)	(0.7)
Preferred Stock Net Proceeds	0.0	0.0	0.0	0.0	0.0	0.0	93.4
Proceeds from Term Loan	0.0	72.8	0.0	0.0	0.0	10.0	49.5
Repayment of Term Loan	0.0	0.0	(0.9)	(0.9)	(0.9)	(0.9)	(72.0)
Prepayment Premium on Term Loan	0.0	0.0	0.0	0.0	0.0	0.0	(1.4)
Deferred Financing Cost	0.0	(6.0)	(0.6)	0.0	0.0	0.0	(2.8)
Stock Repurchased for Tax Withholdings on Vesting of Restricted Stock	(0.1)	(0.1)	(0.2)	(0.2)	(1.5)	(0.8)	(0.1)
Proceeds from Exercise of Stock Options	0.0	0.1	0.0	0.0	0.3	0.0	0.1
Net Cash Flows Used in Financing Activities	(1.0)	66.7	(1.7)	(1.1)	(2.2)	(8.1)	66.7
Beginning Cash Balance	45.1	28.4	96.9	94.1	69.1	53.5	48.2
Change in Cash	(16.7)	68.5	(2.8)	(25.1)	(15.5)	(5.3)	61.4
Ending Cash Balance	28.4	96.9	94.1	69.1	53.5	48.2	109.6





# NON-GAAP METRICS RECONCILIATION

								[		Una	audited	-	=/
(\$ millions)	1	Q19	2Q19	-	5Q19	4	4Q19	1	Q20	2	Q20	3	5Q20
Net Sales – Reported	\$	66.6	\$ 67.4	\$	88.9	\$	76.4	\$	61.7	\$	53.6	\$	64.3
Less: Revenue Transition Impact <sup>1</sup>		2	8		21.5		8.2		4.5		1.7		1.0
Adjusted Net Sales	\$	66.6	\$ 67.4	\$	67.3	\$	68.2	\$	57.2	\$	51.9	\$	63.3
Gross Profit	\$	<b>5</b> 9.1	\$ 57.7	\$	75.7	\$	63.7	\$	51.7	\$	45.4	\$	54.0
Less: Revenue Transition Impact <sup>1</sup>		-	-		18.6		7.1		3.9		1.5		0.9
Adjusted Gross Profit	\$	59.1	\$ 57.7	\$	57.1	\$	56.6	\$	47.8	\$	44.0	\$	53.1
Adjusted Gross Margin		88.7%	85.6%		84.8%		83.0%		83.6%	3	84.8%		83.9%
Adjusted EBITDA	\$	10.9	\$ 9.5	\$	7.6	\$	14.1	\$	3.1	\$	10.2	\$	6.9
Less: Capital Expenditures		(0.6)	(0.3)		(0.2)		(0.7)		(1.0)		(0.4)		(0.7)
Less: Patent Application Costs		(0.2)	(0.1)		(0.1)		(0.1)		(0.1)		(0.1)		0.0
Adjusted Free Cash Flow	\$	10.1	\$ 9.1	\$	7.3	\$	13.3	\$	2.0	\$	9.7	\$	6.2

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(1) Impact of revenue transition includes the Transition Adjustment during 3Q2019 and cash collected in 4Q2019, 1Q2020, 2Q2020, and 3Q2020 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 year ended December 31, 2019, and the respective Form 10-Qs for the noted quarterly periods.



# ADJUSTED EBITDA RECONCILIATION

(\$ millions)	4Q19	1Q20	2Q20	3Q20
Net Loss	(7.5)	(4.8)	(8.5)	(19.4)
Depreciation & Amortization	1.8	1.8	1.7	1.8
Interest Expense	2.4	2.4	2.6	1.5
Loss on Extinguishment of Debt	0.0	0.0	0.0	8.2
Income Tax	0.2	(11.3)	0.0	0.0
EBITDA	(3.0)	(12.0)	(4.2)	(7.9)
Investigation, Restatement & Related	20.1	15.6	<mark>11.</mark> 4	12.0
Revenue Transition	(5.9)	(3.9)	(1.5)	(0.9)
Share-Based Compensation	2.9	3.3	<mark>4.</mark> 4	3.7
Adjusted EBITDA <sup>1</sup>	14.1	3.1	10.2	6.9

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, and indemnification costs under agreements with former officers and directors

Revenue transition excludes gross profit impact of shipments prior to 10/1/19 (see slide 39)

(1) Adjusted EBITDA consists of GAAP net loss excluding: (i) depreciation, (ii) amortization of intangibles, (iii) interest expense, (iv) loss on extinguishment, (v) income tax provision, (vi) costs incurred in connection with Audit Committee Investigation and Restatement, (vii) the effect of the change in revenue recognition on net loss, and (viii) share-based compensation.





### **CERTAIN INFORMATION CONCERNING THE PARTICIPANTS**

Prescience Point (as defined below), together with the other Participants (as defined below), intends to file a definitive proxy statement and accompanying GOLD proxy card with the Securities and Exchange Commission (the "<u>SEC</u>") to be used to solicit proxies for votes (a "<u>Proxy Solicitation</u>") in connection with the solicitation of proxies from the shareholders of MiMedx Group, Inc. (the "<u>Company</u>") at the Company's 2021 annual meeting of shareholders.

THE PARTICIPANTS STRONGLY ADVISE ALL SHAREHOLDERS OF THE COMPANY TO READ THE PROXY STATEMENT AND OTHER PROXY MATERIALS AS THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. SUCH PROXY MATERIALS WILL BE AVAILABLE AT NO CHARGE ON THE SEC'S WEB SITE AT HTTP://WWW.SEC.GOV. IN ADDITION, THE PARTICIPANTS IN THIS PROXY SOLICITATION WILL PROVIDE COPIES OF THE PROXY STATEMENT WITHOUT CHARGE, WHEN AVAILABLE, UPON REQUEST. REQUESTS FOR COPIES SHOULD BE DIRECTED TO THE PARTICIPANTS' PROXY SOLICITOR, OKAPI PARTNERS LLC BY PHONE AT (844) 343-2621 (TOLL-FREE) OR (212) 297-0720 OR BY EMAIL TO INFO@OKAPIPARTNERS.COM.

The Participants in any future Proxy Solicitation are anticipated to be: Prescience Investment Group, LLC d/b/a Prescience Point Capital Management LLC ("<u>Prescience Management</u>"), Prescience Partners, LP ("<u>Prescience Partners</u>"), Prescience Point Special Opportunity LP ("<u>Prescience Opportunity</u>"), Prescience Capital, LLC ("<u>Prescience Capital</u>"), Eiad Asbahi ("<u>Mr. Asbahi</u>" and together with Prescience Management, Prescience Partners, Prescience Opportunity and Prescience Capital, "<u>Prescience Point</u>"), Alfred G. Merriweather ("<u>Mr. Merriweather</u>"), Charlotte E. Sibley ("<u>Ms. Sibley</u>") and William F. Spengler ("<u>Mr. Spengler</u>") (all of the foregoing, collectively the "<u>Participants</u>").

As of the date hereof, the Participants may be deemed to beneficially own (within the meaning of Rule 13d-3 under the Securities Exchange Act of 1934), in the aggregate, 9,062,021 shares of common stock, par value \$0.001 per share of the Company (the "<u>Common Stock</u>"). Of the 9,062,021 shares of Common Stock beneficially owned in the aggregate by the Participants: (a) 9,058,250 shares of Common Stock may be deemed to be beneficially owned by Prescience Point; (b) 1,270 shares of Common Stock may be deemed to be beneficially owned by Mr. Merriweather; (c) 1,241 shares of Common Stock may be deemed to be beneficially owned by Mr. Spengler. Of the 9,058,250 shares of Common Stock beneficially owned, in the aggregate, by Prescience Point: (a) 6,058,430 shares of Common Stock may be deemed to be directly and beneficially owned by Prescience Partners; (b) 2,098,644 shares of Common Stock may be deemed to be directly and beneficially owned by Prescience Opportunity; (c) 8,157,074 shares of Common Stock may be deemed to be beneficially owned by Prescience Capital by virtue of it being the general partner of each of Prescience Partners and Prescience Opportunity; (d) 9,058,250 shares of Common Stock may be deemed to be beneficially owned by Prescience Partners and Prescience Opportunity; and the investment manager to certain separately managed accounts; and (e) 9,058,250 shares of Common Stock may be deemed to be beneficially owned by Mr. Asbahi by virtue of him being the managing member of Prescience Management.

The Prescience Point entities expressly disclaim beneficial ownership of the shares of Common Stock held by Mr. Merriweather, Ms. Sibley and Mr. Spengler. Mr. Merriweather expressly disclaims beneficial ownership of the shares of Common Stock held by the Prescience Point entities, Ms. Sibley and Mr. Spengler. Ms. Sibley expressly disclaims beneficial ownership of the shares of Common Stock held by the Prescience Point entities, Ms. Merriweather and Mr. Spengler. Mr. Spengler expressly disclaims beneficial ownership of the shares of Common Stock held by the Prescience Point entities, Ms. Merriweather and Mr. Spengler. Ms. Sibley. Each Participant disclaims beneficial ownership of the Common Stock reported above except to the extent of his, her or its actual pecuniary interest therein.

### Item 4. PURPOSE OF TRANSACTION.

Item 4 is hereby amended and supplemented by the addition of the following:

On April 15, 2021, Prescience Partners delivered a notice to the Issuer (the "<u>Notice</u>") of its intent to (i) propose each of the four (4) Nominees for election at the Issuer's 2021 annual meeting of shareholders of the Issuer (including any adjournment or postponement thereof or any special meeting held in lieu thereof, the "<u>Annual Meeting</u>"); (ii) present a non-binding advisory proposal asking the board of directors of the Issuer (the "<u>Board</u>") to declassify the Board so that the directors are all elected on an annual basis; (iii) present a nonbinding advisory proposal asking the Board to amend the appropriate governing documents of the Issuer to give shareholders owning not less than 25% of all votes entitled to be cast on any issue proposed to be considered at a meeting of shareholders the power to call a special meeting of shareholders by a request in writing to the Secretary of the Issuer; and (iv) in the event that the Issuer determines that only three (3) directors are up for election, present a non-binding advisory proposal to increase the size of the Board by one seat and appoint Mr. Spengler to the newly-created vacancy (the "<u>Director Proposal</u>").

The Notice further disclosed that the presentation of the Director Proposal would be contingent upon there being less than four (4) Board seats up for election at the Annual Meeting. If the Issuer discloses that four (4) Board seats are up for election, Prescience Partners intends to withdraw the Director Proposal.

Additionally, on April 16, 2021 Prescience Capital issued a press release (the "<u>Press Release</u>") announcing, among other things, its nomination of the Nominees and containing a letter to shareholders of the Issuer. The description of this Press Release is qualified in its entirety by reference to the full text of the Press Release, which is attached hereto as <u>Exhibit D</u> and is incorporated by reference herein.

- We have announced our nomination of four highly-qualified, diverse and independent director candidates to the MiMedx Board as we believe the company remains deeply undervalued, based largely on the enormous potential of its Amniofix product. MDXG needs a Board that is committed to realizing substantial value for ALL shareholders, not just a select few. We believe our candidates can help direct MiMedx to craft a more compelling narrative about Amniofix for the investment community and court potential strategic partners. Full release can be found here: https://t.co/jxACLXtU4I?amp=1 #MaximizeMDXG
- Today, Prescience Point announced the nomination of four directors to the MiMedx Board. These nominations are aimed at ensuring the Board is composed of members who are fully committed to continuing the process of unlocking value and who will advocate for the best interests of ALL shareholders. Full release can be found here: https://lnkd.in/e9duE9K #MaximizeMDXG
- Today we announced the nomination of 4 highly qualified candidates to the @MiMedx Board bringing extensive biopharma experience and a commitment to unlocking value for ALL shareholders, not just a select few \$MDXG #MaximizeMDXG https://t.co/ixACLXtU4I?amp=1
- Today's public letter to our fellow \$MDXG shareholders outlines the substantial, unrealized shareholder value of the Company and its Amniofix product and the Board's failure to capture this value #MaximizeMDXG
- We believe \$MDXG has failed to effectively communicate the immense potential of Amniofix to the investment community, resulting in a chronic undervaluing of its equity #MaximizeMDXG
- Further, the \$MDXG Board has allowed current and former affiliates of PE firm EW Healthcare to take control of 33% of the board seats, giving EW an outsized influence over the Co's direction
- We are troubled by this consolidation of power into the hands of EW, whose interests may not align with those of ALL \$MDXG shareholders
- If Board is not reconstituted, we believe EW will continue to pack the Board. Thus, \$MDXG will not reach its full potential & its shares will continue to fail to reflect the true value of the biz #MaximizeMDXG
- @PresciencePoint today nominated 4 highly qualified candidates to \$MDXG Board, sharing its letter to fellow \$MDXG shareholders citing the current Board's failure to maximize SH value #MaximizeMDXG https://t.co/jxACLXtU4I?amp=1