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

DATE OF REPORT
12/16/2020

SHARE PRICE
$6.58

52-WK HI / LOW
$2.95 / $7.95

AVG DAILY VOL
591K

MARKET CAP
$901.6M

Prescience Point Research Opinions:

- Based on conservative assumptions, MDXG shares are worth $31.84, 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 **wound care business is poised to re-accelerate** in FY 21. MDXG has begun hiring addt'l 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 **far superior to HA and corticosteroids**, and that the product is **highly likely to receive FDA approval** and take significant share in the knee OA treatment market, leading to **multi-billions of dollars in potential peak revenue**
- 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 111% 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 **early FDA approval** after its Phase 2b knee OA trial
- The FDA's approval of Zilretta – an extended-release corticosteroid – despite mediocre clinical results indicates that the FDA 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 ailments beyond knee OA, including plantar fasciitis, shoulder arthritis, and ankle arthritis, and will likely receive approval for multiple indications
- Our conclusion that Amniofix will be a blockbuster treatment is supported by the fact that **3 of the top 5 selling drugs** 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 **$12Bn valuation** while its lead indication for knee OA was in Phase 2 trials

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Introduction

We are raising our price target for MiMedx Group ("MDXG" or the "Company") shares to $31.84 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 ailments.

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 $1.5m and $6.5m, 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 **re-acceleration of growth in the wound care business** 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 currently in Phase 2b trials for knee OA, as well as Phase 3 trials for plantar fasciitis and Achillles 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 musculoskeletal ailments:

- 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, NSAIDs, 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 **far more effective and safer treatment for knee OA than corticosteroids and HA**, and will likely receive FDA approval. Amniofix 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 Amniofix improved quality of life and pain scores by an average of 111% 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 **zero 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 **early FDA approval** 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 ailments, 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 multi-billions 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 $6.58 as of December 15th. 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 $4.3Bn, 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 biotechs with similar treatments for osteoarthritis have received. For example, Samumed was valued at an astounding $12Bn 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 383.9% higher than the current share price of $6.58**. 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 20.4% higher than MDXG's

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 pre-pandemic 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 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.

There are a number of imminent catalysts which we believe will propel MDXG shares higher. The most notable of these catalysts include 1) sellside analysts resuming their coverage of MDXG, 2) a readout of the Phase 3 plantar fasciitis trial results in early-to-mid-2021, and 3) a readout of the Phase 2b knee OA trial results in early-to-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.

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 turmoil 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 **multiple blockbuster drugs**, 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 Acelity'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 $13Bn gene therapy company, while Mr. Hawkins was the **former CEO of Medtronics**, the largest medical device company in the world.

- ***Recent capital raise gives MDXG ample liquidity to continue operating without restrictions:*** On July 2nd, 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.

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 ongoing 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 26th, 2019, it was announced that MDXG had paid just $1.5m 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 $1.5 million penalty.*

  Then, on April 6th, 2020, it was announced that MDXG had paid a modest $6.5m 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 announced on October 22nd, 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 lawsuit that alleges former executives' actions resulted in financial losses by its shareholders.*

- ***The recent relisting is highly positive for the equity:*** On November 3rd, 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

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 CGMP-compliant 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.

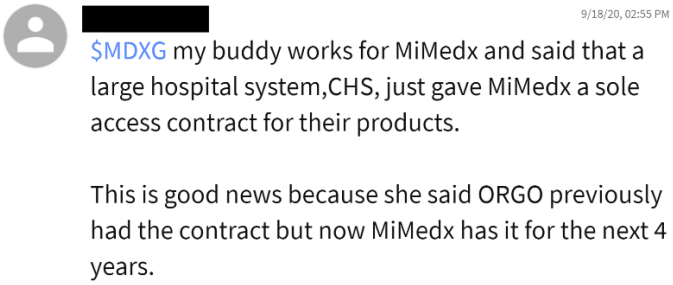
  On November 3rd, 2020, MDXG announced that the largest health insurance company in the US (i.e. UnitedHealthcare) would begin providing coverage for Epifix in the treatment of diabetic foot ulcers ("DFUs") effective December 1st. Importantly, they also disclosed that **Epifix was the only amniotic membrane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

  > *MiMedx Group…today announced that the largest U.S. Commercial payor will now provide coverage for EpiFix®, 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 Q3 2020 earnings call on November 5th, 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:



In addition to securing new insurance and contract wins, MDXG recently rolled out a new product extension. Specifically, on September 14th, 2020, the Company announced 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 core 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 **wound care sales to accelerate** over the coming quarters. Our conclusion is supported by the fact that, during its most recent earnings call, 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.

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 fasciitis, 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 fasciitis 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 fasciitis and Achilles tendonitis trials are nearing the end of Phase 3.

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 ailments. 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

- ***Amniofix has shown tremendous promise as a treatment for knee OA and, in our view, will likely receive FDA approval:*** Our research indicates that Amniofix is a **far more effective and safer treatment for knee OA than corticosteroids and HA**, and will likely receive FDA approval. Amniofix 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 Amniofix improved quality of life and pain scores by an average of 111% and 67%, respectively, and 3) through off-label use by physicians and their knee OA patients, many of whom we spoke with. Additionally, Amniofix has a **flawless safety record** and has reportedly been used in >100,000 patients with zero severe adverse events. Lastly, our research also indicates that Amniofix 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 Amniofix's already high chance of FDA approval and could open the door to early approval:*** 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 a good chance of receiving **early approval** after its Phase 2b knee

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

- ***Amniofix has also shown promise as a platform treatment for various other musculoskeletal ailments:*** Based on considerable evidence, Amniofix will also likely receive approval for multiple indications beyond knee OA. This evidence includes the positive results that Amniofix has shown 1) in MDXG's Phase 2b plantar fasciitis trial, 2) in treating a variety of musculoskeletal ailments in independent studies, and 3) through off-label use for a variety of musculoskeletal ailments

- ***We believe that Amniofix will generate multi-billions of dollars in annual sales:*** Using conservative market share and pricing assumptions, we estimate that Amniofix's peak sales from the knee OA indication alone will be multi-billions of dollars. We also believe that Amniofix'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, affecting 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.

- ***Corticosteroid injections are of questionable efficacy and can actually cause significant damage to the knee joint:*** Corticosteroid 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 study

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 meta-analysis 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 article 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: -1.2 units in the triamcinolone group vs -1.9 in the saline group (between-group mean difference, -0.64; 95% CI, -1.6 to 0.29, P < .17). 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 guideline, 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) corticosteroids 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 corticosteroid injections inferior to hyaluronic 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.*

> *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 cartilage volume loss in the triamcinolone group than the saline group (-0.21 vs -0.10 mm cartilage thickness; between group difference -0.11 mm; 95% CI, -0.20 to -0.03; P < .01). 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 spottier 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 cited 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 does not recommend 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 YouTube, orthopedic doctors from respected medical institutions such as New York Langone Medical Center

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:*** *I'll 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 mary, the hyaluronic acid may not provide that.*
>
> ***Richard Lorio, MD at New York Langone Medical Center:*** *So, I'll 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 $600 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 $20Bn 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 466 patients in order to increase the chances of obtaining a clinically significant result.

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 FY 2018 Super 10-K 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 Amniofix 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 groups*

Even more encouraging was Dr. Bob Stein's recent comments during MDXG's Q3 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:

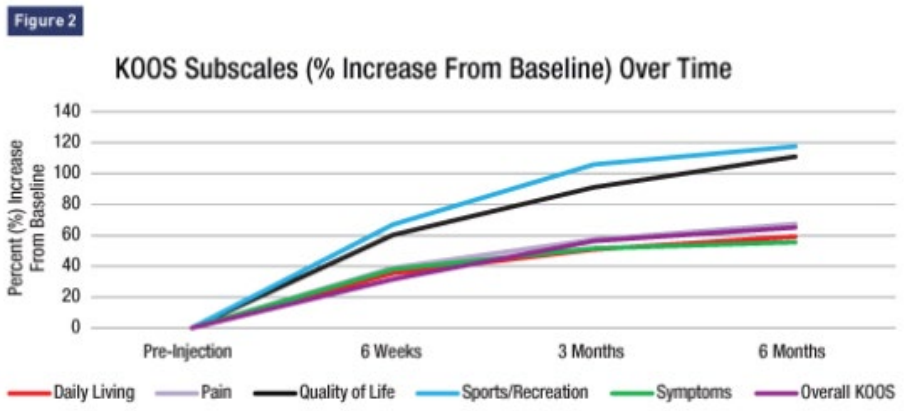
> *I do believe that our AmnioFix injectable product is having very powerful impact pain and function in the osteoarthritis. Earlier studies by Dr. Alden have supported that. And* ***our ongoing study looks very promising at this stage.*** *We were able to enroll the entire intended patient population 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 published 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, overall quality of life and sports/recreation measures for these patients improved by more than 100%, while pain scores improved by 67%. Additionally, no severe adverse events occurred with the most common side effect reported was pain in the injection site lasting 2 to 7 days:

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 111 and 118%, respectively, at 6 months. Pain 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 single-physician 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 I'm very active, and I just need that quality of life. I couldn't have been more pleased because I'm back to my crafts and my quality of life is back to normal again."

Supporting Dr. Alden's findings is a study 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 6 months and contacted at 1 year. Failure rate was defined as improvement of < 50 percent in VAS scale. 65 percent Patients reported improvement in their VAS pain levels of more than 60 percent and 25 percent reported improvements of 50 percent and 10 percent did not have any improvement. The

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 Amniofix for the treatment of knee OA has also shown very promising results outside of a clinical study setting:*** Although Amniofix is not an FDA approved treatment, physicians have been able to use the product on an off-label basis for knee OA and other ailments for several years. Because of this, there are thousands of knee OA patients who have been treated with Amniofix 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 Amniofix. Their experiences, like those of Dr. Alden's patients,

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 #1:*** *So, I had no cartilage in my left knee…so the bone was rubbing on bone…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 almost 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 #2:*** *I 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:*** *I 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…I 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 hobbling around to basically nothing ever happened…It went from hobbling and intense pain in my knee to being absolutely normal…It wasn't 90% it was 100%.*

- ***There is evidence that Amniofix has regenerative qualities:*** Amniofix 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:

> *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 **delaying progression** much more than any of the other therapies that we have…The ones who come in earlier [for an Amniofix injection], **the vast majority are not getting their knees replaced**. 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 intra-articular 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 hypertrophy, 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 study 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 65 I think…When's the majority of that group [knee OA patients] getting their knees replaced? Like, in their 60s. And so, you don't need to delay knee*

> *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 article 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 article 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 111% and 67%, respectively, at six months post-injection, indicating that the effects of Amniofix last significantly longer than six months.

- ***Amniofix is safe:*** In addition to being efficacious, Amniofix also has a **flawless safety track record**. To date, no serious adverse events have been reported from the multiple past and ongoing clinical studies of Amniofix, and according to MDXG, Amniofix 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 Buffalo Medical Group 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 Amniofix:*** We believe Dr. Stein's recent decision to join MDXG as its R&D head amounts to a ringing endorsement of Amniofix. Dr. Stein has had a long and distinguished career in the healthcare space spanning more

than 40 years and has **led the development of multiple blockbuster drugs** 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 Amniofix:*** 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 U.S. FDA if their product is intended to treat serious or life-threatening 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 March 2018 for the treatment of knee OA:

  > *MiMedx Group…today announced that the U.S. Food and Drug Administration (FDA) has granted MiMedx's micronized amniotic 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.*

- ***The RMAT designation further increases Amniofix's already high chance of FDA approval due to the often lower standard of evidence required for approval:*** 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 article 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 approval:

> *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 Zilretta, 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 Zilretta – Flexion Therapeutic's extended-release corticosteroid injection – for the treatment of knee OA. As detailed in an article posted on Evaluate.com, the FDA approved Zilretta 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 III osteoarthritis knee pain study – having last September failed a similarly designed phase II 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 III study, it failed to show superiority over generic, immediate-release triamcinolone.*

The FDA's approval of Zilretta 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

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

- ***The RMAT designation also gives MDXG an opportunity to receive early FDA approval of Amniofix following the completion of its Phase 2b trial:*** 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 trials.

  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 article 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® (carfilzomib, Amgen) was recently approved by the FDA for multiple myeloma (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…Pomalyst® (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 musculoskeletal ailments 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 fasciitis and Achilles tendonitis, and the Company also plans on launching 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 off-label 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 Amniofix will eventually be approved for the treatment of plantar fasciitis:*** In a press release on March 26th, 2018, MDXG announced the results of its Phase 2b clinical trial comparing Amniofix vs. a saline injection in the treatment of 145 patients with plantar fasciitis. The results of this trial were very positive and showed that patients who were treated with Amniofix experienced a clinically meaningful reduction in pain and improvement in function:

  > *The Phase 2B IND clinical trial evaluating the use of AmnioFix Injectable for the treatment of Plantar Fasciitis 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*

> *pain (p<0.0001) 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 2nd, 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 Fasciitis 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 (82.2%) patients in the treatment group, and 34 (47.2%) 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 fasciitis 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 FY 2018 Super 10-K 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 fasciitis 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 Amniofix was effective in treating a variety of musculoskeletal ailments:*** In 2017, Dr. Alfred Gellhorn – the Associate Professor of Clinical Rehabilitation Medicine at Weill Cornell Medicine in New York City – conducted a clinical study on the effectiveness of Amniofix as a treatment for a variety of degenerative joint and tendon injuries. In this study, a total

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 ailments – At 3-months, the percentage of patients achieving clinical success, which is defined as a reduction in pain of at least 30%, was 91%. 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. Patient-reported average pain scores decreased from a baseline value of 6.4 (95% confidence interval [CI] ¼ 5.7-7.0) to 2.7 (95% CI ¼ 2.1-3.3; P < .001) at 1 month, 1.7 (95% CI ¼ 1.1-2.2; P < .001) at 2 months, and 1.4 (95% CI ¼ 0.9-1.9; P < .001) at 3 months. The percentage of patients achieving clinical success, defined as 30% or greater improvement in pain levels, was 68% at 1 month, 82% at 2 months, and 91% 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 ¼ 20) or tendon disease (n ¼ 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 ailments 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 ailments.

  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 ailments 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:

  > *Amniofix I've been using probably for three years…as far as efficacy goes…I'd 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…*

I would say that my joint to soft tissue spread is probably even 50/50. Fifty percent I've 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 I've 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 hyaluronic 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 ailments. Their experiences were also very positive. Provided below are excerpts from some of these conversations:

Patient #1: *I tore my rotator cuff…and I got a shot of that [Amniofix] there [in the shoulder] and I'm 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 like 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 MRI…so when I got there, I had a problem in my toe…so he did a shot [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 multi-billions 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, Amniofix'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.

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% (1.1m patients annually), 10% (0.5m patients annually), and 30% (1.6m patients annually) in our base, downside and upside case, respectively.

In regards to pricing, 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 projected 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, $1,500, 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 $1Bn in both the base case and upside case – $4.1Bn and $8.5Bn, respectively. Even in our downside case, we estimate that Amniofix's peak sales from the knee OA indication would still amount to $1.2Bn.

Peak Sales Estimate For Knee OA Indication For Amniofix

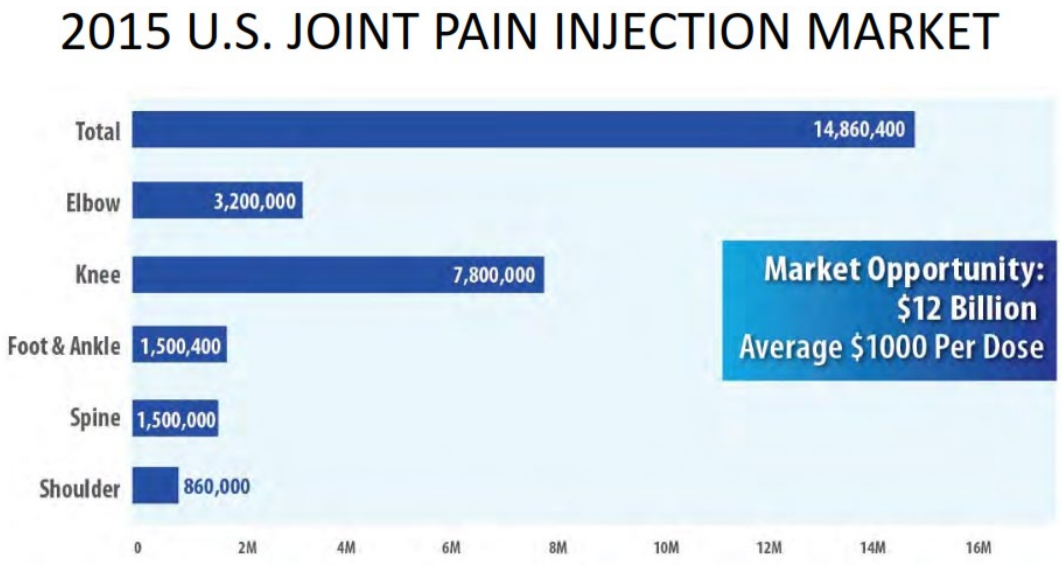
($ and amounts in millions, except per patient and per injection amounts)

	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 additional 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 $7.1Bn in 2015. This includes $3.2Bn for the elbow, $1.5Bn for the foot & ankle, $1.5Bn 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.



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 osteoarthritis: 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

Drug	Main Indication	Total Sales
Humira	Rheumatoid Arthritis	$21.4Bn
Eliquis	Anticoagulant	$9.9Bn
Enbrel	Rheumatoid Arthritis	$8.1Bn
Stelara	Psoriasis	$6.6Bn
Keytruda	Oncology	$6.5Bn

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 Amniofix 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.

According to Grand View Research, the size of the global HA injectables market was $3.8Bn 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 investor presentation, ~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 Synvisc/Synvisc-One, the most popular HA injectable treatment on the market. Synvisc/Synvisc-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 $271.3m, which is calculated by annualizing MDXG's reported 2H 2019 revenue, adjusted for a one-time $29.6m 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:

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 success rate 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:

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.

(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.

Adding it all up, as shown in the table below, our sum-of-the-parts analysis yields a valuation of $31.84 for MDXG shares. This is 383.9% higher than the current share price of $6.58 as of December 15th. 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 20.4% higher than MDXG's 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 pre-pandemic 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 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 trials is lorecivivint, 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 $12Bn.

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 10th, 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 $12Bn valuation Samumed 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.

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 fasciitis trial, we believe our multi-billion dollar valuation for Amniofix is not only reasonable and justified, but conservative.

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