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MiMedx Group, Inc. (MDXG - NASDAQ)

From Womb to Wound

Based on our multiple of earnings model and a 20% discount rate, MiMedx target price is approximately $16.00 per share. Our methodology applies a 25x multiple of earnings to 2026 EPS, a 17x multiple to 2026 EBITDA and discounts a blend of the two approaches to generate a one-year target price.

Current Price (2/12/2021)	$9.89
Valuation	**$16.00**

INITIATION

MiMedx is a wound care and therapeutic biologics company, developing and distributing allografts. The company derives its products from human placental tissues processed using the Purion® technology. MiMedx differentiates itself in the regenerative medicine market through the substantial library of supportive research for its products. The company's platform includes AmnioFix, EpiFix, EpiCord, EpiBurn, EpiCord Expandable, AmnioCord and AmnioFill. The products are derived from placental and umbilical cord tissue.

In addition to its marketed products, MiMedx has a development portfolio advancing assets in plantar fasciitis and knee osteoarthritis. Clinical trials were launched to address AmnioFix injectable, a product subject to enforcement discretion which may stop being sold mid-year 2021.

Legal matters are near conclusion with 12 of 15 issues resolved and major related costs largely behind the company.

We forecast a $20 million revenue impact from enforcement discretion, continued growth in commercialized products and success in the development pipeline that will drive topline growth. International opportunities include Japan, the UK and Germany which have approved MiMedx products and are in process for reimbursement.

SUMMARY DATA

52-Week High	**10.51**
52-Week Low	**2.95**
One-Year Return (%)	**40.4**
Beta	**1.67**
Average Daily Volume (sh)	**1,021,606**
Shares Outstanding (mil)	**137.3**
Market Capitalization ($mil)	**1,358**
Short Interest Ratio (days)	**8.5**
Institutional Ownership (%)	**12.1**
Insider Ownership (%)	**6.4**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**9.6%**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2020 Estimate	**N/A**
P/E using 2021 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	$66.6 A	$67.4 A	$88.9 A	$76.4 A	$299.3 A
2020	$61.7 A	$53.6 A	$64.3 A	$62.0 E	$241.7 E
2021					$240.5 E
2022					$274.1 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2019	-$0.12 A	-$0.16 A	$0.11 A	-$0.07 A	-$0.24 A
2020	-$0.04 A	-$0.08 A	-$0.18 A	-$0.05 E	-$0.35 E
2021					-$0.05 E
2022					$0.22 E

INITIATION

We are initiating coverage of MiMedx Group, Inc. (NASDAQ: MDXG) with a current valuation of $16.00 per share. This valuation is based on our estimates for continued growth of the company's Purion® processed orthobiologic tissue products for wounds and successful pivotal trials in plantar fasciitis and knee osteoarthritis. We anticipate a near term impact from the end of enforcement discretion in mid-2021. However, demand for existing wound repair solutions, growth from new products, international expansion and successful clinical trials in several indications are expected to dramatically offset this over the next few years. MiMedx differentiates itself from other regenerative medicine companies with a sizable library of preclinical and clinical research that supports the safety and efficacy of their placental and umbilical cord products.

Wounds are a common health concern in the United States and the rest of the world. Chronic wounds are present in about 6 - 8 million Americans[1] and have a prevalence of 1-2% globally. Despite standard of care treatment that includes debridement, dressing and treatment of superimposed infections, only about 40%[2] of wounds heal after 12 weeks, highlighting the need for improved approaches. We anticipate continued penetration into this market propelled by supportive clinical studies, inclusion on the largest managed care formulary and expansion into other geographies outside the US, especially Japan.

MiMedx has three clinical development programs underway in knee osteoarthritis, plantar fasciitis and Achilles tendonitis. These indications have annual prevalence rates of 4-6%, ~1% and ~60,000 respectively in the United States. While the AmnioFix injectable has been used in non-homologous applications, we believe that with supportive data and the FDA's assent, penetration into these markets can be substantially increased. Adjacent markets, such as in other joints and tendons may be expansion opportunities. To date there have been no reports of direct adverse reactions related to human uses of amniotic membrane products supporting a durable safety record and a strong rationale for eventual approval of ongoing studies.

We anticipate that the Phase III plantar fasciitis (PF) and Achilles tendonitis (AT) programs underway will be complete by 2021 and shortly after the company will file a Biologics License Application (BLA) with the FDA, dependent on the trial outcomes. The Phase II knee osteoarthritis program is targeting a late 2024 or early 2025 BLA filing with the agency. In parallel with regulatory submission in the US, we also see similar efforts in other selected geographies, especially Japan, the United Kingdom and Germany.

Pre-clinical work is underway in advanced wound care with three programs in effect including chronic wounds, surgical incisions and soft tissue defects. Increases in research and development spending have been allocated to support clinical trials following clearance of an investigational new drug (IND) or investigational device exemptions (IDE). These applications are expected to be filed in 2021.

MiMedx has suffered through a rough period over the last few years stemming from the unethical behavior of previous management. This included improper revenue recognition practices, false statements, action against whistleblowers and other wrongdoing. As a result, the company suffered considerable revenue loss, reputational damage and substantial legal action. In 2018, most members of the management team stepped down or were fired, all considered to be "for cause" separations. The company has since replaced the management team, settled 12 of 15 material litigation matters and is investing in clinical studies to expand the number of marketable indications for the product set.

MiMedx dominates the amniotic tissue market with an estimated 40% share in 2019.[3] While impacts from the end of enforcement discretion are expected to reduce revenues this year, after 2021 we see sales growth coming from the wound products segment, international markets and indications targeted by the development portfolio.

In 2013, MiMedx and other regenerative medicine companies were notified by the FDA that AmnioFix Injectable, EpiFix Micronized and AmnioFill did not conform to Section 361 human cells, tissues and cellular and tissue based products (HCT/Ps) regulation and would require clinical trials to obtain marketing approval. A delay in enforcement of this rule (enforcement discretion) was granted until mid-2021 after which the products may require FDA approval

[1] Nussbaum SR, Carter MJ, Fife CE, *et al.* An economic evaluation of the impact, cost, and Medicare policy implications of chronic non-healing wounds. Value Health 2018;21:27–32

[2] Fife, Caroline, *et al.* Publicly Reported Wound Healing Rates: The Fantasy and the Reality. Adv Wound Care (New Rochelle). 2018 Mar 1; 7(3): 77–94.

[3] Assumes amniotic products market size of $748 million based on data provided by Markets & Markets and 2019 full year revenues of $299 million.

to continue to be sold. MiMedx' clinical development portfolio is directly targeting these products and the most important related indications. While our model assumes all of these sales will be lost by mid-2021, it is possible that the FDA will recognize MiMedx' good faith efforts made with the active clinical trials and allow continued sales in order to address patients' needs.

MiMedx holds a strong position in the wound care market with a supportive set of preclinical and clinical work demonstrating safety and efficacy for the company's portfolio of products. With additional studies underway, new product launches and a favorable demographic trend, we anticipate double digit growth in the second half of 2022. We see a high degree of probability that the trials will be successful thereby supporting even greater penetration for AmnioFix and related products.

Key reasons to own MiMedx shares:

- **Existing high margin business in placental and umbilical cord tissue products**
  - **EpiFix**
  - **EpiCord**
  - **EpiCord Expandable**
  - **AmnioFix**
  - **AmnioFill**
  - **AmnioCord**
  - **EpiBurn**
- **Products recognized by payors**
  - **EpiFix on largest US health insurer formulary for diabetic foot ulcers**
  - **EpiFix and EpiCord allografts eligible for coverage by Medicare Administrative Contractors**
- **International growth opportunities**
  - **Japan – anticipated approval mid-2021**
  - **United Kingdom – approved, reimbursement in process**
  - **Germany – approved, reimbursement in process**
- **Development candidates**
  - **Plantar fasciitis – Phase III**
  - **Achilles tendonitis – Phase III**
  - **Knee Osteoarthritis – Phase II**
    - **Designated as a Regenerative Medicine Advanced Therapy (RMAT) by FDA**
  - **Multiple preclinical advance would care development projects**
- **Investigation and expenses related to prior management misconduct are largely complete**

In the following sections we review the source and use of amniotic tissue in the treatment of orthopedic disorders, MiMedx' primary market in wound care followed by a review of research and development projects in knee osteoarthritis, plantar fasciitis and Achilles tendonitis. The report provides background to Section 351 and 361 regulated products and the factors behind enforcement discretion, highlighting which products are affected. We then review the misconduct that took place in the years prior to 2018 and bring the investor up to date on resolution of the outstanding legal issues. Competitors and peers are discussed and compared along with a review of their market capitalizations and segment focus. Following a discussion of patents granted and pending, we provide an extended review of financial and operational results over the prior two years. Management is introduced and risks to the regenerative medicine industry and MiMedx specifically are discussed. Our final section discusses the assumptions behind our valuation, employing multiples of both earnings per share (EPS) and earnings before interest, taxes, depreciation and amortization (EBITDA). This analysis generates a one-year target price of $16.00.

SCIENTIFIC BRIEF

The use of biologics along with other standard of care treatments for various orthopedic disorders is increasing in importance and as a proportion of the health care market. As we improve our understanding of the effectiveness of these products, they fill a valuable role in addressing many common ailments that are not able to be easily managed with local or systemic treatments and often require surgical interventions. Intra-articular and periarticular injections of a variety of biological agents such as platelet rich plasma and mesenchymal stem cells are demanded by a range of patient demographics from young elite athletes to older patients with degenerative joint disease driven by data generated in clinical trials. With the use of these substances, researchers and physicians aim to change the cellular and chemical microenvironment of the affected tissues to promote healing and tissue regeneration.

History and Background on Amnion-Derived Products

Fetal tissues, consisting of the amniotic membrane, chorionic membrane, and umbilical cord, are well known for their healing characteristics via numerous growth factors, cytokines and matrix components they contain through which they promote reparative processes despite underlying confounding issues. They emphasize the regenerative stages, while resolving aberrant inflammation and downstream scarring.

Amniotic membrane was used as early as 1909 to address skin defects and has been used successfully for healing various tissues including skin (burns, ulcers, wounds), corneal lesions, retinal detachment and ligament injuries, nerve repairs in clinical settings, as well as cartilage and cardiac repair in preclinical animal models.

Below is a sample listing of various amniotic membrane products recently available for treatment of musculoskeletal conditions.

Exhibit I – Available Amniotic Membrane Products[4]

Product	Manufacturer	Details
Clarix FLO	Amniox Medical	Umbilical cord and amniotic tissue
AmnioFix	MiMedx	Dehydrated human amnion/chorion membrane (dHACM)
PX50	Human Regenerative Technologies	Amnion membrane particulates and products that are cryopreserved
PalinGen Flow/ SportFlow	Amnio Technology	Amniotic tissue allografts
Allogen	ViVex	Matrix allograft derived from amniotic fluid
FloGraft	Applied Biologics	Amniotic tissue allografts
NuCel	Organogensis	Cryopreserved, bioactive amniotic suspension allograft
Affinity	Organogensis	Fresh amniotic membrane

Structure, Source and Function of Human Placental Tissues

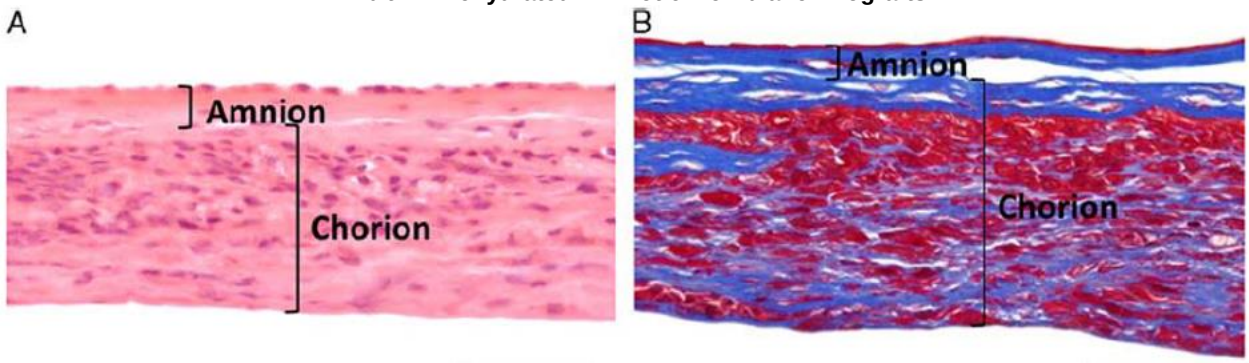
Placenta, which is composed of both fetal and maternal elements provides the basis for these amniotic-based products. The fetal elements are comprised of amniotic membrane, chorionic membrane, amniotic fluid and the umbilical cord. Cells from these tissues have pluripotent properties and have been the topic of research for regenerative medicine. The umbilical cord, which starts to be formed at the 4th week of pregnancy, is the main conduit of fetal oxygen transport and the removal of fetal byproducts through maternal circulation. The amnion and chorion are two membranes which together make up the placenta and encase the fetus along with the amniotic fluid in which it resides until birth.

[4] Huddleston, H.P., Cohn M.R., Haunschild, E.D., *et al*. Amniotic Product Treatments: Clinical and Basic Science Evidence. Curr Rev Musculoskelet Med (2020) 13:148-154

Starting from the second week of gestation, as the embryo implants into the inner surface of the uterus (the endometrium), the outer layer of embryonal cells start forming the chorionic villi, which are the main structures for gas exchange in utero. These villi are composed of specialized cells called cytotrophoblasts, syncyotrophoblasts and mesenchymal cells. The amnion is the thin 3-layered membrane directly surrounding the fetus and amniotic fluid. It contains no nerves, blood or lymphatic vessels and remains viable through diffusion of nutrients. It is composed of amniotic epithelial cells, amniotic mononuclear mesenchymal cells and fibroblasts. Fibroblasts are connective tissue cells which produce collagen, thus amniotic membrane is rich in Type I, type III, type V type VI and type VII collagen, fibronectin and laminin, increasing its mechanical strength. In its outer layer, there are also proteoglycans and glycoproteins which are essential components of any extracellular matrix from placental tissue to adult human cartilage.

In addition to physically protecting the fetus it also regulates the pH of amniotic fluid, secretes important cell signaling and bioactive molecules which serve as antimicrobials and anti-inflammatory substances.

Exhibit II – Dehydrated Amniotic Membrane Allografts[5]



Sourcing and Preparing Amniotic Membrane Products

Amniotic membrane is obtained from donors who undergo an uncomplicated elective cesarean section, as this is a relatively sterile procedure compared with a vaginal delivery. Donors undergo rigorous screening for viral and infectious diseases, including human immunodeficiency virus 1/2, hepatitis B/C, human T-cell lymphotrophic virus and syphilis. After collection, the amniotic membrane is stored in aseptic conditions and then subjected to either gamma irradiation or e-beam to achieve a sterility assurance level (SAL) of 10^{-6}. This translates to less than a one in one million chance of having a non-sterile unit. This is considered to be an advantage over tissue that is solely processed aseptically, which cannot provide the same SAL. Products that only use aseptic processing are primarily those that are marketed to contain "live-cells" and cannot utilize terminal sterilization as it would destroy both the unwanted microorganisms and the "live-cell" population.

MiMedx' Purion® process, in use since 2006, is a patented method for the aseptic processing of human amnion/chorion which involves gentle cleansing, lamination of the amnion and chorion, dehydration and terminal sterilization of the tissues under controlled conditions. This produces a dehydrated human amnion/chorion membrane (dHACM) as described in the United States Pharmacopeia and the National Formulary (USP-NF) monograph "Tissue Human Amnion Chorion Membrane Dehydrated."

dHACM allografts are provided in both membrane and micronized forms. In the latter, membrane tissue is cryomilled and sieved for particulate sizing prior to sterilization.[6] The micronized tissue is reconstituted in a saline solution and administered to patients in suspension. Not all amniotic allografts employ these same preparation techniques. Amniotic membrane grafts can be prepared as fresh or preserved allografts. When using fresh amniotic membrane grafts, immediate transplantation is often necessary; therefore, preservation techniques such as cryopreservation (cryopreserved human amniotic membrane-CHAM) or dehydration (dry human amniotic membrane-DHAM) are needed to extend storage time. In both techniques, the structural components and integrity of tissue remain intact. In cryopreservation tissue must be frozen at -80 C or below. MiMedx uses a different technique, consisting of dehydration and terminal sterilization to remove the moisture. This approach reduces enzymatic activity and viability of microorganisms and imparts ideal handling and storage properties. Thus, MiMedx allografts are room-temperature stable and have a five-year shelf life.

[5] Lei J, Priddy L.B, .Lim J.J. *et al.* Dehydrated Human Amnion/Chorion Membrane (dHACM). Allografts as a Therapy for Orthopedic Tissue Repair. Techniques in Orthopaedics, Volume 12, Number 3, 2017.
[6] Niknejad H, Peirovi H, Jorjani M, et al (2008) Properties of the amniotic membrane for potential use in tissue engineering. Eur. Cells Mater.

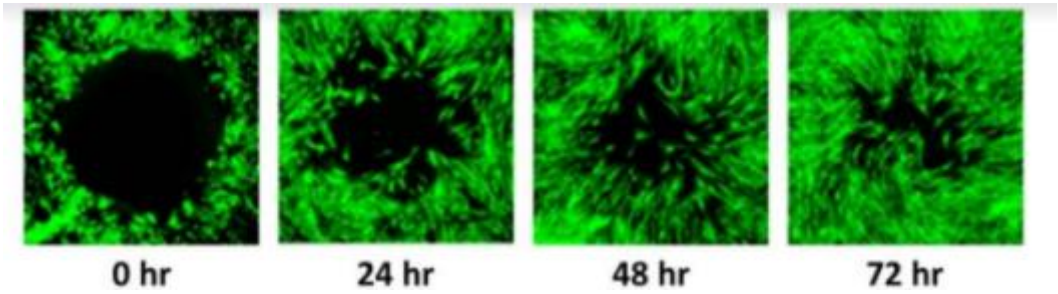
Contents and Mechanism of Action of dHACM

Studies have identified more than 226 growth factors, cytokines, chemokines, and protease inhibitors preserved within MiMedx allografts, including epidermal growth factors, fibroblast growth factor-4 and transforming growth factor-beta. *In vitro* studies confirmed the activity of these factors through dHACM treatment of fibroblasts, endothelial cells and stem cells. dHACM induced cellular changes in all cell types ranging from proliferation and migration to secretion of paracrine signaling factors, all of which contribute to promoting a healing response. The following excerpts from studies performed on dHACM, illustrate these fundamental properties of this tissue:

Cellular migration and proliferation

In vivo and *in vitro* results suggest that the combined impact of dHACM cytokine protein elution and regulation of stem cell activity at a wound site may be involved in enhancing tissue repair. The following exhibit represents time dependent *in vitro* cellular migration and recruitment by adipose stem cells and bone marrow mesenchymal stem cells following treatment with dHACM extract.[7]

Exhibit III – Stem Cell Recruitment After dHACM Extract in Cell Culture[8]



Biosynthesis

The three major groups of molecules that are stimulated by dHACM and provide an important function in tissue healing are:

- **Chemokines and proteins related to leukocyte migration:**
  - Upregulated chemokines include I-309, IL-8, IL-16, MCP-1, MIP-1a, and MIP-1b. These are known to direct chemotaxis of immune cells (monocytes and macrophages, neutrophils, T lymphocytes, dendritic cells, and eosinophils) into the damaged tissue site.[9]
  - ICAM-1, which is upregulated in all three stem cell types, is an adhesion molecule that facilitates leukocyte endothelial transmigration suggesting a potential role of ICAM-1 in the extravasation of circulating stem cells from the blood vessels toward the dHACM treated site.[10]
- **Immunomodulatory cytokines**:
  - These cytokines include GDF-15, IL-1RA and IL-6, which are also upregulated in all three types of stem cells. hey play a role in regulation of various pro- and anti-inflammatory cascades that are required for regulation of apoptosis, T cell activation, B cell and macrophage differentiation, hematopoiesis and additional downstream immunomodulatory cues.[11,12,13]
- **Mitogenic growth factors and proteins related to tissue growth:**
  - Growth factors and growth factor regulatory and tissue remodeling molecules that are secreted in response to dHACM include EGF, FGF-4, GH, IGFBP-1, IGFBP-2, SCF and TIMP-1. They stimulate cell proliferation, migration, differentiation, cell survival and protein synthesis. They are involved in tissue remodeling and have been shown to enhance healing of wounds.[14,15,16]

[7] Massee M. Chinn K, Lei J. et al. Dehydrated human amnion/chorion membrane regulates stem cell activity in vitro. 2015
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Wound Healing

Epidemiology and Background

As the largest organ of the body, skin is vital for body homeostasis, thermoregulation and protection of the host against infection as well as having important immunological, sensory and metabolic functions. Any breach in its integrity leaves the person prone to local and systemic infections, especially if there are underlying medical conditions such as diabetes mellitus, peripheral arterial or venous disorders which impair and delay wound healing by various mechanisms.

6.5 million individuals in the United States are estimated to suffer from chronic diabetic or venous ulcers with cost of care more than $25 billion annually.[17] Approximately one in every 4 diabetic patients will develop a foot ulcer in their lifetime.[18,19]

In addition to diabetes and venous insufficiency, burns also constitute a major cause of skin defects and associated wounds. There are 1.2 - 2.5 million people with burn injuries in the United States annually.[20,21] In contrast to patients with chronic diabetic ulcers and circulatory disease-related wounds, a large segment of the burn victim population includes children. Approximately 6% of all unintentional injuries in children younger than 15 years of age are burns.[22]

Treatment

First line treatment in superficial ulcers includes debridement, off-loading, appropriate dressings, and/or multi-layer compression. Other therapies that are being used with increasing frequency include recombinant growth factors, living skin equivalents, negative pressure therapy, low-frequency ultrasonography and hyperbaric oxygen therapy.[23,24] The majority (60–80%) of foot ulcers will heal using this approach, however, a fraction of the refractory cases may eventually require amputation of the affected limb. Moreover, diabetic foot ulcers are associated with a first-year mortality rate of 5% and 5-year mortality rate of about 42%.[25]

Studies on wound healing in patients with diabetes and venous insufficiency revealed that standard of care treatment options establish healing in only 24.2% at 12 weeks and 30.9% at 20 weeks in neuropathic ulcers. Venous leg ulcers are also slow to heal, with less than two-thirds (62%) of all venous leg ulcers being healed by 24 weeks using standard care alone.[26,27,28]

For burns, temporary covering of the wounds with allografts, xenografts, synthetic materials and eventually skin grafts may be needed depending on the size and depth of the wound to achieve favorable healing.[29]

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[15] Werner S, Peters KG, Longaker MT, et al (1992) Large induction of keratinocyte growth factor expression in the dermis during wound healing. Proc Natl Acad Sci U S A. https://doi.org/10.1073/pnas.89.15.6896
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Normal Wound Healing

Normal wound healing requires a well-orchestrated and balanced sequence of events including hemostasis, inflammation, proliferation and remodeling. These interrelated physiologic processes create a reparative microenvironment characterized by high initial levels of growth factors and other soluble mediators of cell signaling and cellular interaction which leads to transition from one phase to the next, via establishing controlled levels of proteases and bacteria leading to proliferation of skin, connective tissue and vascular cells. In acute wounds, platelets aggregate within a fibrin matrix, providing an initial scaffold to direct cells into the site of injury. Pro-inflammatory factors recruit macrophages to the site to engulf bacteria and dying tissue. Upon clearance, the wound transitions to the proliferative phase, where granulation tissue begins to form. Another crucial step in normal wound healing is angiogenesis (the formation of new blood vessels). Platelets, inflammatory cells, and fibroblasts activate and secrete growth factors, which in turn initiate growth of vascular endothelial cells to form capillaries in the wound bed. Together with the provisional matrix, these newly formed blood vessels comprise the granulation tissue. Many advanced wound healing therapies such as negative pressure, growth factor therapies and living skin equivalents aim to stimulate angiogenesis in chronic wounds. Endothelial cells establish vasculature to supply nutrients to the newly deposited extracellular matrix, secreted by fibroblasts within the wound bed. The provisional matrix which is composed of fibrin and fibronectin provides a scaffold to direct cells into the wound. This provisional matrix is replaced with ECM, restoring the mechanical properties of the tissue in the last, remodeling, phase of wound healing.

Role of Stem Cells in Wound Healing

Mesenchymal and hematopoietic stem cells, which originate from bone marrow, are important in repair of wounded tissues through their ability to differentiate into several cell and tissue lineages such as cartilage, fat, muscle, and connective tissue cells. They also take part in remodeling of the extracellular matrix (ECM), modulation of the immune response and secretion of growth factors and cytokines that stimulate cell migration and neovascularization.[30,31,32] Data suggests that a balance of stem cell secreted immunoregulatory proteins in a chronic wound may be crucial to transition the wound out of the inflammatory phase and into healing phase to achieve regeneration of epithelial tissue.

Stem cells are actively involved in regulation of wound healing via secretion of immunomodulatory cytokines, enhancing proliferation, migration and secretion of biologically active molecules by paracrine signaling.[33,34] As a result, autologous and allogeneic stem cell therapies have been considered as a form of treatment to stimulate healing of various damaged tissues, including chronic wounds.

Hematopoietic stem cells are, to a certain extent, found in the blood circulation and can differentiate into white blood cells (including lymphocytes, neutrophils, monocytes, and macrophages) which stimulate and control local inflammation, disposing of pathogens and apoptotic cells in blood and tissue, thereby eliminating damaged tissue.[35,36] Particularly, macrophages aid in wound healing by performing dual roles. In early inflammation, they phagocytose bacteria and damaged tissue; however, in late inflammation, they promote fibroblast proliferation and angiogenesis through the release of basic fibroblast growth factor (bFGF) and platelet-derived growth factor (PDGF) in the wound and the recruitment of endothelial cells.

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Chronic Wounds

When the normal healing process is interrupted due to pre-existing conditions such as diabetes or venous insufficiency, the wound may become chronic, often stalling in the inflammatory phase. Chronic or delayed wound healing is characterized by an unfavorable wound microenvironment, including persistent inflammation, cell aging, growth factor depletion, superimposed infectious agents and increased levels of destructive proteases. Local hypoxia, bacterial colonization, repeated ischemia–reperfusion injury result in a chronic inflammation and impair healing by preventing appropriate angiogenesis, granulation tissue formation and epithelialization.[37,38] Regardless of the underlying etiology (diabetes, venous insufficiency, peripheral arterial disease, pressure ulcers) in all chronic wounds one or more of these cascades are impaired.

Human Amniotic Membrane In Wound Healing

Amniotic membrane products have been used for over 100 years in chronic wounds but the new data regarding the use of amniotic membrane products sheds more light on how they actually work. Although presence of multipotent mesenchymal stem cells in both layers of placental tissue has been a relatively new discovery, wound healing has been the oldest clinical use of human amniotic membrane, by learning more about the mechanism of action, the applications of this technology become substantially more far reaching.

In prospective, randomized, controlled clinical trials, dHACM tissue has demonstrated the ability to resolve chronic inflammation and accelerate healing in a variety of refractory wounds.[39] Although the exact mechanism of its action has not been entirely understood, animal models have shown that subcutaneously implanted dHACM attracts a host's circulating mesenchymal and hematopoietic stem cells in the injury site.

Some important properties of amniotic membrane products that play a key role in wound healing include its non-immunogenic nature (immune-privileged), antibacterial properties, ability to modulate inflammation while reducing pain and scarring. The membrane also provides a matrix for supporting cellular migration and proliferation.[40,41,42,43,44,45] Most data supporting the benefit of amniotic membrane for wound repair have been obtained from studies of dehydrated human amnion/chorion membrane (dHACM) allograft (EpiFix, AmnioFix, Marietta, GA)[46,47,48,49,50,51,52] in studies conducted by MiMedx Group.

Dehydrated human amnion/chorion membrane is a human allograft composed of laminated amnion and chorion membranes used in the treatment of chronic wounds, such as diabetic and venous foot ulcers.[53,54,55,56] Numerous

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[49] Fetterolf DE, Snyder RJ (2012) Scientific and clinical support for the use of dehydrated amniotic membrane in wound management. Wounds
[50] Zelen CM, Serena TE, Denoziere G, Fetterolf DE (2013) A prospective randomised comparative parallel study of amniotic membrane wound graft in the management of diabetic foot ulcers. Int Wound J. https://doi.org/10.1111/iwj.12097
[51] Zelen CM (2013) An evaluation of dehydrated human amniotic membrane allografts in patients with DFUs. J Wound Care. https://doi.org/10.12968/jowc.2013.22.7.347
[52] Zelen CM, Serena TE, Fetterolf DE (2014) Dehydrated human amnion/chorion membrane allografts in patients with chronic diabetic foot ulcers: A long-term follow-up study. Wound Med. https://doi.org/10.1016/j.wndm.2013.10.008
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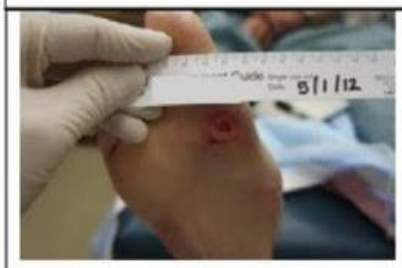
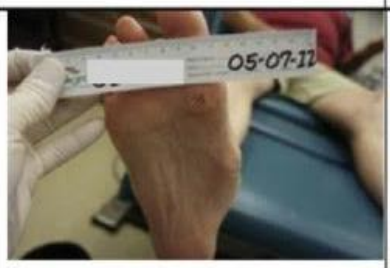
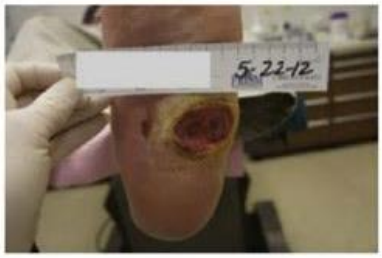
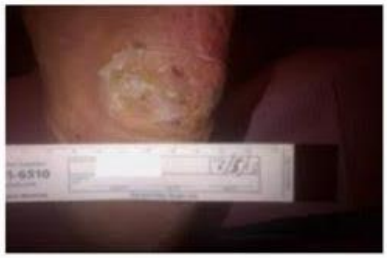
[55] Zelen CM, Serena TE, Fetterolf DE (2014) Dehydrated human amnion/chorion membrane allografts in patients with chronic diabetic foot ulcers: A long-term follow-up study. Wound Med. https://doi.org/10.1016/j.wndm.2013.10.008

growth factors, cytokines, chemokines, and tissue inhibitors of metalloproteinases (TIMPs) have been identified in dHACM tissues, many of which are known to stimulate paracrine responses in cells involved in healing and tissue repair, such as human dermal fibroblasts, microvascular endothelial cells and stem cells. Additionally, cell culture studies showed that dHACM has improved proliferation and migration of all three types of stem cells (bone marrow mesenchymal, adipocytic and hematopoietic lineage) over 24-72 hours and animal models have shown recruitment of hematopoietic and mesenchymal stem cells to the site of injury.[57,58]

Exhibit IV – Diabetic Foot Ulcers Treated with EpiFix[59]

1st dHACM Application	Healed	Long Term Follow-up
Week 0	Healed in 1 week	13 months later
		
Week 0	Healed in 8 weeks	11 months later
		

The preceding exhibit displays progress of diabetic foot ulcers in two different patients treated with dHACM. The top row images represent a relatively small ulcer that shrinks in size over the course of a week and appears to have completely re-epithelized by the end of 13 months. The second patient in the bottom row images has a much wider and deeper ulcer with elevated edges that look highly inflamed. By 8 weeks, the lesion shows evidence of healing and by the end of 11 months, the ulcer crater appears to have regained epithelial coverage.

MiMedx Group offers a broad range of amniotic membrane products in different forms which can be used to treat various wounds. The following chart summarizes the 6 main products, their mechanism of action and common clinical uses.

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[58] Massee M, Chinn K, Lei J, et al (2016) Dehydrated human amnion/chorion membrane regulates stem cell activity in vitro. J Biomed Mater Res - Part B Appl Biomater. https://doi.org/10.1002/jbm.b.33478
[59] Zelen CM, Snyder RJ, Serena TE, Li WW. The use of human amnion/chorion membrane in the clinical setting for lower extremity repair: a review. Clin Podiatr Med Surg. 2015 Jan;32(1):135-46. doi: 10.1016/j.cpm.2014.09.002. PMID: 25440424.

Exhibit V – Summary of MiMedx Products[60]

Product Name	Available Forms	Content	Mechanism of Action	Clinical uses
EpiFix	Sheet and particulate configurations in a variety of sizes	Dehydrated human amnion/chorion membrane allograft	Provides a semi-permeable protective barrier that supports the healing cascade. Protects the wound bed to aid in the development of granulation tissue. Provides a human biocompatible extracellular matrix that retains 300+ regulatory proteins	Diabetic foot ulcers, venous leg ulcers, pressure ulcers. Following tissue debridement, in patients with comorbidities leading to delayed wound healing
EpiCord	Thick graft and expandable configurations in a variety of sizes	Human umbilical cord	Provides a protective environment to support the healing process. Comprised of an extracellular matrix of hyaluronic acid and collagen. Retains 250+ regulatory proteins.	It allows for suturing to keep the graft in place providing a protective environment to support the healing process. Usable in smaller, deeper wounds or surgical sites. When graft fixation is needed EpiCord Expandable (expands in size) can be used on uneven surfaces
AmnioFix	Sheet and particulate configurations in a variety of sizes	Dehydrated human amnion/chorion membrane allograft	Provides a semi-permeable protective barrier that supports the healing cascade. Protects the wound bed to aid in the development of granulation tissue. Provides a human biocompatible extracellular matrix. Retains 300+ regulatory proteins.	Comorbid patients with complex defects or delayed healing, debridement, amputations, dehiscence, flaps, decubitus ulcers, trauma, pilonidal cysts, port sites, burns
AmnioFill	Particulate configuration in a variety of sizes	Placenta-based tissue matrix	Replaces or supports damaged or inadequate integumental tissue in acute and chronic wound closures in comorbid patients. Provides a human biocompatible extracellular matrix. Retains 300+ regulatory proteins.	Challenging chronic and acute closures in patients with comorbidities, complex defects or delayed healing. Large and uneven areas, deep tunneling wounds, debridement, amputations, dehiscence, flaps, decubitus ulcers, trauma, pilonidal cysts, port sites, and burns.
AmnioCord	Thick graft in a variety of sizes	Derived from human umbilical cord	Allows for suturing to keep the graft in place and works with deep surgical sites. Provides a protective environment to support the healing process. Comprised of an extracellular matrix of hyaluronic acid and collagen. Retains 250+ regulatory proteins.	Comorbid patients with complex defects or delayed healing, smaller or deeper surgical sites, tendon, bone, or hardware coverage, diabetic foot ulcers , venous leg ulcers, or decubitus ulcers. Debridement, amputations, dehiscence, flaps and trauma. When graft fixation is desired
EpiBurn	Sheet configuration in a variety of sizes	Dehydrated human amnion/chorion membrane allograft	A semi-permeable protective barrier that supports the healing cascade. Protects the wound bed to aid in the development of granulation tissue. Provides a human biocompatible extracellular matrix. Retains 300+ regulatory proteins.	Supports acute and chronic closures (e.g. partial-thickness and full-thickness burns). Potential target areas include points of articulation, head/face, hands, genitals, bone & tendon, and feet.

[60] Source: Zacks' analyst work, MiMedx website, management interviews and financial filings.

Indications & Development Candidates

MiMedx offers a development portfolio of indications which take advantage of its amniotic membrane, chorionic membrane and umbilical cord products, specifically AmnioFix injectable and EpiFix micronized. The company has sponsored a vast array of preclinical and clinical research to demonstrate the utility and safety of its products. To further support revenue growth, the company is developing a portfolio of assets focused on the musculoskeletal, sports medicine and advanced wound care markets. MiMedx' pipeline consists of three clinical and three preclinical candidates that serve to expand the number of approved regenerative medicine applications for the company's portfolio of products. In Phase III studies, MiMedx is conducting studies in plantar fasciitis and Achilles tendonitis which are expected to produce biologics license applications (BLA) in 1H:22[61] and 2H:21 respectively, assuming favorable data readouts. In Phase II development, MiMedx is advancing an indication in knee Osteoarthritis (KOA), which is targeting a late 2024 or early 2025 BLA submission following pivotal studies.

In earlier development, the company has three indications in advanced wound care in the preclinical stage. These projects will target chronic wounds, surgical incisions and soft tissue defects. MiMedx will submit an investigational device exemption (IDE) or investigational new drug (IND) application on behalf of each indication in the first half of 2021.

Below we summarize the pathophysiology of each of the clinical assets MiMedx is developing and review the prevalence of each of the conditions.

Knee Osteoarthritis

Osteoarthritis or degenerative joint disease is the most common form of arthritis and is associated with the wear-and-tear that results in cartilage loss in joints over time. In knee osteoarthritis (KOA) articular cartilage lining the knee joint, including femoral, tibial and patellar joint surfaces are eroded and lost over time. Normal joint cartilage is made up of hyaline cartilage, a special type of connective tissue which is rich in water, collagen, proteoglycans and hyaluronic acid (the latter three are also found in abundance in amniotic tissue) and has a smooth surface. Together with joint fluid, the main function of articular cartilage is lubrication and buffering at opposing bony interfaces. Starting from softening and surface fibrillation and progressing into full thickness cartilage loss with associated subchondral bone (bone beneath the articular cartilage) changes such as remodeling, flattening, subchondral cysts, sclerosis, osteophyte (bony spur) formation, KOA is evaluated in different stages based on its severity. The stages and progression of the disease are assessed on plain radiographs of the knee and the most commonly used the x-ray based Kellgren-Lawrence scoring system. In its final stage, with full thickness cartilage loss, the joint space narrows and the opposing tibia and femur approach each other, most commonly at the medial knee compartment which bears the majority of the body's weight. As the damage feeds upon itself, eventually bone contacts bone and the knee is painfully inflamed. Today it is known that OA has an inflammatory component and inflammation-inducing substances (inflammatory cytokines and prostaglandins) within the synovial fluid that accelerate the degenerative process.

Symptoms of KOA include pain in the knee that scales with activity, swelling, stiffness, decreased mobility and audible creaking or cracking with joint movements.

The chances of developing osteoarthritis rise after age 45, with women being more prone than men. Additional risk factors include age, obesity, heredity factors, gender, repetitive stress injuries, participation in athletics and also comorbidity with other forms of arthritis such as rheumatoid arthritis (RA). According to the Centers for Disease Control,[62] over 32.5 million adults in the US have osteoarthritis, the knee among the most commonly affected areas. Cui *et al.* estimated that 654 million people worldwide had KOA.[63]

To date there is still no definitive cure for KOA. The two mainstay treatment options target pain and regaining function but are mostly palliative. The most common options include weight loss, exercise, pain relievers, intra-articular hyaluronic acid injections and steroid injections. Surgical intervention includes arthroscopic repairs, osteotomy and joint replacement arthroplasty. Arthroscopy can be used to remove damaged cartilage and loose bodies, clean the bone surface and perform minor tissue repair. In cases of asymmetrical wear, osteotomy may reshape the bone to realign the knee to prevent additional uneven wear. Finally, replacement of the knee where the degenerated joint surfaces and bones are excised and replaced with metallic implants (also known as "knee arthroplasty"), though a

[61] The submission of a BLA will be dependent on the strength of the data in the ongoing Phase III trial.
[62] https://www.cdc.gov/arthritis/basics/osteoarthritis.htm
[63] Cui A, Li H, Wang D, Zhong J, Chen Y, Lu H. Global, regional prevalence, incidence and risk factors of knee osteoarthritis in population-based studies. EClinicalMedicine. 2020;29:100587. doi:10.1016./j.eclinm.2020.100587

last resort, is quite common. The artificial replacement can last up to 20 years but eventually requires revision surgery.[64]

The amniotic membrane contains several anti-inflammatory and anti-fibrotic compounds such as interleukin-1 receptor antagonist (IL-1 RA), IL-10 that can potentially inhibit inflammation, slowing down cartilage degeneration. Additionally, by promoting expression of TIMP gene, amniotic membrane can downregulate proteoglycan and collagen degradation. Thus, it has a high potential in the treatment of OA. Experimental studies in rodents injected with various AM products, (amniotic membrane and umbilical cord matrix, injectable formulation of dehydrated human amniotic/chorionic membrane (dHACM) or lyophilized amniotic membrane) after experimentally induced cartilage damaged showed better preservation of their remaining cartilage tissue at 3 to 6 weeks. Other studies in a rat model also give promising results with regard to pain relief, decreased joint swelling and better weight bearing.[65]

KOA is the largest future opportunity for MiMedx given the size of the market and the lack of other effective treatments. Based on data provided in Wallace *et al.*[66] About 19% of adults over 45 years of age present KOA. The 2010 census indicated that approximately 122 million Americans are over this age, suggesting over 23 million million cases of the condition in the United States. If we make further assumptions that AmnioFix injectable can achieve 10% penetration, and pricing is at $1,000 per injection, this is a market size of over $2 billion before adjustment for product success. Frequently, patients require treatment for both knees, and according to a study by Metcalfe *et al.*, from 26% to 80% of patients have or develop bilateral KOA,[67] suggesting in many cases two injections are appropriate. Our estimate only assumes one knee is treated and that only one injection per knee is administered. Data from the trial may indicate multiple injections may be appropriate. These numbers presume low expectations and if results from the pivotal trial are strongly supportive of safety and efficacy, penetration and pricing could be substantially greater.

The most comprehensive data provided for osteoarthritis of the knee to date is data generated from a retrospective study[68] by Dr. Kris Alden which included 82 patients with a median KOOS[69] score improvement of 12, 22 and 25 at 6 weeks, three months and six months following the dHACM injection. The steady improvement over the period of the trial is supportive of efficacy. The interim readout also demonstrated improvement in daily living, pain and quality of life. Details from the trial are included below.

Exhibit VI – Mean KOOS Over Time[70]

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

AmnioFix for KOA has been granted the Regenerative Medicine Advanced Therapy (RMAT) designation which provides a number of benefits to sponsors. The RMAT provides all of the benefits of fast track and breakthrough designations including early and close interaction with the FDA and a lower hurdle for approval. The RMAT designation does not require evidence to indicate that the drug may offer a substantial improvement over available therapies. The classification as RMAT only requires that preliminary clinical evidence shows the product to address an unmet medical need. If allowed, MiMedx may be able to accelerate the submission of the BLA from its forecasted timeline, substantially advancing the eventual commercialization of AmnioFix injectable relative to our modeled timeline.

[64] https://www.webmd.com/osteoarthritis/ostearthritis-of-the-knee-degenerative-arthritis-of-the-knee
[65] Willettt N.J., Thote T, Lin ASP et al. Intra-articular injection of micronized dehydrated human amnion/chorion membrane attenuates osteoarthritis development. Arthritis Res Ther. 2014;16:R47.
[66] Wallace, I.J., *et al.* Knee osteoarthritis has doubled in prevalence since the mid-20th century. Proc Natl Acad Sci U S A. 2017 Aug 29; 114(35): 9332–9336. Published online 2017 Aug 14. doi: 10.1073/pnas.1703856114
[67] Metcalfe, A.J. *et al.* Is knee osteoarthritis a symmetrical disease? Analysis of a 12 year prospective cohort study. BMC Musculoskeletal Disorders. August 22, 2012.
[68] Alden, K. *et al.* Micronized Dehydrated Human Amnion Chorion Membrane Injection in the Treatment of Knee Osteoarthritis—A Large Retrospective Case Series. J Knee Surg DOI: 10.1055/s-0039-3400951
[69] The KOOS (Knee Injury and Osteoarthritis Outcome Score) is measured on a scale of 0 – 100 with the low end of the rage representing the severe problems and 100 representing no knee problems. A resource here provides additional detail on the scale.
[70] Source: MiMedx January 2021 corporate presentation which in turn was sourced form Alden, K. *et al.* Micronized Dehydrated Human Amnion Chorion Membrane Injection in the Treatment of Knee Osteoarthritis—A Large Retrospective Case Series. J Knee Surg DOI: 10.1055/s-0039-3400951

Plantar Fasciitis

Plantar fasciitis (PF), also known as jogger's heel, is inflammation of the plantar fascia, the ligament on the bottom of the foot that connects the heel bone to the toes. PF is very common with an estimated 10% of the population presenting heel pain over a lifetime.[71] Heel spurs were once thought to be the cause of the pain but are now thought to be the result of the condition. Symptoms of PF include pain in the front or center of the heel bone, which can be heightened in the morning, or exacerbated after exercise.

Risk factors for PF include sex (females more prone than males), age, obesity, either flat feet or high arches, tight Achilles tendons and unusual gait. Lifestyle risks that contribute are standing for long hours during the day, wearing high-heeled shoes or wearing thin soled shoes.

Standard of care first line treatment choices include rest, ice, non-steroidal anti-inflammatory drugs, heel padding, orthotics and stretching exercises. In refractory cases, corticosteroid injections are used which do not demonstrate consistent outcomes between patients and bear certain risks and side effects such as plantar fascia rupture. Clinical studies in PF have shown that amniotic membrane products may provide comparable outcomes to steroid injections.[72]

Achilles Tendonitis

Achilles tendonitis (AT) is an overuse injury of the Achilles tendon that connects the gastrocnemius to the heel. The injury is common in runners or middle-aged individuals who engage in recreational sports.

Symptoms of AT can begin with mild pain or ache in the back of the leg or above the heel, especially after physical activity. More severe pain can result from intense activity involving plantar flexion. Risk factors of AT include sex, age, flatness in foot arch, medical conditions and medications. Running in worn out shoes can increase risk of AT.

Treatment of AT includes exercises that stretch and strengthen the Achilles tendon. Orthotic devices such as sole inserts and wedges can relieve strain on the tendon. However, if the tendon is ruptured or torn, surgical intervention is necessary.

Human research on amniotic membrane products in Achilles tendon disorders are limited but animal models showed substantial potential of use for these substances in tendon repair.[73,74]

[71] https://lermagazine.com/article/the-epidemiology-of-plantar-fasciitis
[72] Hanserlman AE, Tidwell JE, Santrock RD. Cryopreserved Human Amniotic Membrane Injection for Plantar Fasciitis: A Randomized, Controlled, Double-Blind Pilot Study. Foot Ankle Int. 2015;36:151-8.
[73] Nicodemo MC, Neves LR, Aguiar JC, Brito FS, Ferreira I, Sant'Anna LB, Raniero LJ, Martins RÁ, Barja PR, Arisawa EA. Amniotic membrane as an option for treatment of acute Achilles tendon injury in rats. Acta Cir Bras. 2017;32:125-139.
[74] Coban I, Satoğlu IS, Gültekin A, Tuna B, Tatari H, Fidan M. Effects of human amniotic fluid and membrane in the treatment of Achilles tendon ruptures in locally corticosteroid-induced Achilles tendinosis: an experimental study on rats. Foot Ankle Surg. 2009;15:22-7.

Additional Considerations

Regulatory Structure for HCT/Ps

MiMedx' products have been historically regulated by the FDA as human cell, tissue, and cellular and tissue-based products (HCT/Ps) regulated under Section 361 of the Public Health Service Act. Section 361 products contrast with Section 351 products in that the latter are considered drugs or biological products and are required to obtain marketing approval before sale in the United States.

Sections 351 and 361 of the Public Health Service Act provide authority and requirements for marketing traditional biologics, human cells, tissues and cellular and tissue-based products. Each of these sections promulgates its own specific definition and requirements for products marketed under its purview.

Section 351

Human cell, tissue, and cellular and tissue-based products (HCT/Ps) may be regulated as biological products and fall under section 351 of the PHS Act. The products require premarket approval and must undergo clinical trials. A biologics license application (BLA) is required following clinical studies and a determination by the FDA that the product is safe, pure and of appropriate potency is necessary before approval is granted. Section 351 summarizes a list of products that are regulated in this category which includes viruses, therapeutic serums, vaccines, blood and blood components, among others.

Section 361

The sale of HCT/Ps may also be regulated under section 361 of the Public Health Service (PHS) Act and Code of Federal Regulations (CFR) Part 1271. Products subject to the section do not require premarket approval prior to sale provided they meet established eligibility requirements. Certain criteria are applicable to the marketing constraints for HCT/P. The tissue must be minimally manipulated, intended for homologous[75] use, generally not combined with other items and is either not systemic in its effect or falls under certain constraints if it does have a systemic effect. If the HCT/P does not fall under these criteria, it must be regulated as a drug, device or biologic.

Some examples of 361 HCT/Ps include bone, tendon, ligaments, fascia, cartilage, skin, amniotic membrane, allografts, hematopoietic stem cells among other tissues. The human cells or tissues must be intended for implantation, transplantation, infusion or transfer into a human recipient.

Minimally manipulated tissue:

1) For structural tissue, does not undergo processing that alters the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement;

2) For cells or nonstructural tissues, does not undergo processing that alters the relevant biological characteristics of cells or tissues.

Amniotic membrane and umbilical cord are considered structural tissues supporting its categorization as minimally manipulated. The tissue must be original, or present in the tissue of the donor and the processing must not alter "the original relevant characteristics of the structural tissue related to its utility for reconstruction, repair or replacement."[76] The definition of minimally manipulated also allows the extraction or separation of cells from structural tissue that does not change its underlying utility.

While a license is not required for sale of HCT/P under section 361, there are certain requirements that include registration with the FDA, submission to the FDA of each HCT/P manufactured product and compliance with applicable requirements.

[75] As defined in 21 CFR 1271.3(c), homologous use means the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor.
[76] Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use. Guidance for Industry and Food and Drug Administration Staff. November 2017.

Enforcement Discretion

The FDA promulgated new guidance in November of 2017 that informed manufacturers, healthcare providers and other related parties that over the following three years the agency would review HCT/Ps that did not conform to Section 361 requirements and mandate that products that meet the definition of a drug biologic or device would be required to obtain premarket review and approval before sale. In July 2020, due to the impact of the pandemic, the guidance was updated and the FDA extended the period of discretionary enforcement until May 31, 2021.

Several of MiMedx products were allowed to continue to be sold under enforcement discretion but will be regulated following its expiration. These products must undergo premarket clearance and receive approval prior to sale. The company has identified its micronized products AmnioFix Injectable and EpiFix Micronized as subject to this requirement as they do not meet the minimally manipulated requirement of Section 361. Other products, such as AmnioFill will also be regulated under Section 351. The products subject to enforcement discretion comprise approximately 15% of revenues, or ~$34 million on an annualized basis.[77] MiMedx expects that the FDA will continue to regulate the amniotic membrane sheet products used in wound treatment AmnioFix, EpiFix, EpiBurn and EpiXL and umbilical cord products (EpiCord and AmnioCord) as Section 361 HCT/Ps.

Our model assumes that all products subject to enforcement discretion will not be sold after May 31, 2021; however, the FDA may allow further discretion due to MiMedx' good faith efforts. This allowance may be granted due to work being performed in ongoing late stage clinical trials for the identified products and efforts to obtain compliance with the FDA's current Good Tissue Practices (cGTP) and current Good Manufacturing Practices (cGMP). In September 2018, the FDA inspected one of the company's facilities for cGTP, following which, the agency made no observations and ruled No Action Indicated (NAI). NAI certifies that no objectionable conditions or practices were identified during the inspection or the objectionable conditions found do not justify further regulatory action.[78] Another inspection took place in December 2019 at both of MiMedx' locations which was to assess cGMP. The FDA produced a Voluntary Action Indicated (VAI) report for one facility and has not yet provided a report for the second facility. VAI indicates that some discrepancies were found; however, the facility meets minimally acceptable compliance standards with regard to cGMP.

MiMedx' good faith efforts and the continued medical need for these products may result in further discretion by the agency and the impact may be delayed or minimal. It is not known when the FDA will make its determination related to enforcement discretion and we will update our estimates as additional information becomes available.

Legal Difficulties, Contingencies and Background Related to Former CEO Parker Petit

Former CEO Parker Petit, MiMedx' chief executive from 2009 to 2018, and other former management team members were involved in several actions that disregarded accounting rules, manipulated recognition of revenue and made false statements to auditors and shareholders over the period of 2012 to 2018. These activities led to security and exchange commission (SEC) and Department of Justice (DoJ) investigations that identified wrongdoing by Mr. Petit and other former members of the management team.

Short sellers publicized discrepancies related to revenue recognition in 2017 and 2018 which ultimately resulted in the company delaying the filing of financial statements and payors electing to halt reimbursement of MiMedx' products, including the Medicare Administrative Contractor (MAC), Noridian Healthcare Solutions. Without current filings, the company was delisted from the NASDAQ in November 2018.

Former management was also accused of submitting false commercial pricing disclosure to the Veteran's Administration (VA) and charging the agency higher prices for human tissue graft products. The allegations were first brought in a lawsuit filed by former MiMedx sales representatives under the qui tam, or whistleblower, provisions of the False Claims Act, which permit private parties to sue on behalf of the government for false claims and to receive a share of any recovery. The allegations were resolved in a $6.5 million settlement that closed the matter in April 2020.

A June 2019 press release provided additional detail regarding the illegal conduct identified by the investigation of an accounting and law firm. Former CEO Parker Petit and others members of his management team managed and manipulated the timing and recognition of revenue. The press release identifies several other activities related to improper activity with distributors, side deals, false testimony and improper actions against employees.

[77] MiMedx 2021 guidance identified approximately $20 million impact from the loss of sale of the identified enforcement discretion products over the June 1 to December 31 period. Adjusted for full year, this is approximately $34 million ($20mm/7 months x 12 months = $34 mm)
[78] Source for inspection frequently asked questions. FDA Website.

In the company's most recent corporate presentation, a summary of resolved and pending legal issues is provided. In addition to the matters disclosed below, former CEO Petit was convicted of securities fraud and is scheduled to be sentenced on February 23, 2021. William Taylor, the former Chief Operating Officer, was convicted of conspiracy to commit securities fraud and is scheduled for sentencing February 24. We anticipate that MiMedx' obligation to provide legal support to these two executives will end following the sentencing. There is one other former executive that is subject to an outstanding investigation; however, it is unclear how far this will advance.

Exhibit VII – Matters Resolved Over Last Two Years[79]

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

Only three outstanding legal items are pending for the company, which we include below. Of the three, MiMedx management only considers the securities litigation to be material. The securities litigation is a class action suit that includes several pension funds against MiMedx, the former management team and former auditor. There are also two defamation claims by asset managers Sparrow Fund Management and Viceroy Research related to former management publicly discrediting individuals at the firms. Sparrow's complaint seeks monetary damages and injunctive relief.

Exhibit VIII – Pending Legal Matters[80]

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

[79] Source: MiMedx January 2021 Corporate Presentation
[80] Source: MiMedx January 2021 Corporate Presentation

Competitors, Peers & Competing Therapies

MiMedx' peers, competitors and competing technologies are defined in terms of products and indications. MiMedx participates in the amniotic tissue and regenerative medicine market. It also targets indications in wound care, orthopedics, tendon healing, osteoarthritis, soft tissue defects and surgical repair.

Amniotic Tissue
Peers in the amniotic tissue space include Amniox, which provides wound allografts, umbilical cord matrix for surgical applications and umbilical cord particulate injectable which is used in sports medicine. Biotissue uses cryopreserved amniotic membrane and umbilical cord graft to promote regenerative healing in eye diseases. Osiris, which was acquired by Smith & Nephew in 2019, manufactures cryopreserved placental membrane for its Grafix and Stravix products for wound and surgical repair. Pluristem Therapeutics is developing placenta-derived, mesenchymal-like stromal cells in multiple indications including hip fracture and acute radiation syndrome.

Wound Care
Biolab Sciences provides an autologous skin graft product called MyOwn Skin rapidly grown in the lab, Membrane Wrap a dual-layered dehydrated human amnion membrane (dHAM), Fluid Flow an amniotic liquid allograft and Amnio Restore and amniotic liquid allograft. Sweden-based Ilya Pharma is using a gene therapy based approach with lactobacillus in a Phase II study for wound healing in patients with diabetes. Integra LifeSciences is a wound and surgical reconstruction product company. It markets amniotic products including allograft membrane, allograft suspension, dermal regeneration matrix and dermal repair scaffold among other products. Mediwound develops and markets products for wounds and burns including EscharEx and NexoBrid. Among other products, Misonix produces the allograft TheraSkin for use with diabetic foot ulcers, venous leg ulcers and other difficult to heal wounds. Organogenesis is a wound care, surgical and sports medicine company with multiple products, including Dermagraft and Apligraf which have been used as comparators in studies against MiMedx' EpiFix. The company also offers cryopreserved amniotic suspension allograft for the healing of musculoskeletal injuries, including degenerative conditions such as osteoarthritis (OA) and tendonitis. Organogenesis was recently granted the RMAT designation for its amniotic suspension allograft ReNu for knee osteoarthritis.

PolarityTE uses autologous cells to manufacture functional tissue for use of its SkinTE product in diabetic foot ulcers and other wound repair applications. Another Swedish company, Promore Pharma, uses regenerative medicines including hyaluronic acid and antimicrobial proteins in its primary products Ensereptide and Ropocamptide for tendon repair surgery and healing of chronic wounds. Sanuwave is a shockwave technology company developing patented, noninvasive devices for the repair and regeneration of skin, musculoskeletal tissue and vascular structures. Its lead product is the dermaPACE System. It is FDA cleared and CE marked for the treatment of diabetic foot ulcers. Vericel manufactures advanced cell therapies for the sports medicine and severe burn care markets by using the patient's own cells.

Osteoarthritis (OA)
Flexion Therapeutics uses a microsphere technology to treat osteoarthritis related knee pain. Their sole product, Zilretta, combines triamcinolone acetonide with a poly lactic-co-glycolic acid matrix to provide knee pain relief. Samumed is a California-based regenerative medicine company with lead compound Lorecivivint in development for knee osteoarthritis and degenerative disc disease.

Tendons
Orthocell is an Australian regenerative medicine company offering tendon, cartilage, collagen and other regenerative tissue based products.

Other
Wright Medical, a division of Stryker, has a broad set of products including amniotic barrier membrane tissue, placental tissue matrix, bone and joint products, wound care using Bioskin amniotic wound matrix as well as other orthopedic products. Zimmer Biomet offers products used to treat injuries to bones, joints and supporting soft tissues. Knee, hip and shoulder replacements are addressed with the company's implants and joint systems.

Exhibit IX – Competitors and Peers[81]

Ticker	Company	Price	MktCap (MM)	EV (MM)	Therapeutic Area
ATHX	Athersys	$2.69	$532	$470	Regen med for neurological damage, inflammatory & immune disorders
AXGN	Axogen	$19.07	$775	$719	Nerve grafts, porcine submucosa ECM, umbilical soft tissue membrane
BIXT	Bioxytran	$0.18	$18	$18	Peptide based product (PXL01 & LL-37) for wound care
CRY	CryoLife	$24.93	$969	$1,196	Implantable human tissue & medical devices
FLXN	Flexion Tx	$11.68	$576	$599	Zilretta for knee osteoarthritis
IART	Integra LifeSci	$69.15	$5,827	$6,937	Implants/instruments for neurosurgery, reconstruction, orthopedics
MDWD	MediWound Ltd	$5.56	$151	$126	Proteolytic enzyme based therapy for burns/eschar
MESO	Mesoblast Ltd	$10.60	$1,246	$1,194	Mesenchymal lineage stem cell based allogeneic cellular medicines
MSON	Misonix	$17.52	$305	$313	Ultrasonic devices & skin substitute for wound care and surgery
OCC.AX	Orthocell Ltd	$0.55	$106	$86	Orthopedic regeneration products. Celgro, Ortho-ACI
OFIX	Orthofix Medical	$43.19	$835	$777	Musculoskeletal healing products and therapies
ORGO	Organogenesis	$12.74	$1,373	$1,437	Advance wound care, surgical & sports medicine/Apligraf,Dermagraft
PRED	Predictive Tech	$0.12	$36	$42	HCT/Ps for regenerative medicine applications
PROMO	Promore Pharma	$2.66	$98	$67	Therapeutic peptides for the bio-active wound care market
PSTI	Pluristem Tx	$7.86	$248	$205	Placental based cell therapy
PTE	PolarityTE	$1.69	$102	$80	Regen med: Skin, wound care dressing, bone & cartilage regen
SNN	Smith & Nephew	$44.04	$19,311	$20,890	Tissue & stem cells for orthopedic, sport med & wound care apps
SNWV	Sanuwave Health	$0.19	$90	$95	Acoustic treatment for revascularization & microcirculatory enhance
SYK	Wright Medical	$248.15	$93,354	$103,560	Orthopedic implants, surgical solutions for extremities & biologics
VCEL	Vericel	$50.68	$2,302	$2,217	Cellular therapies for sports medicine & severe burn care market
XTNT	Xtant Medical	$1.92	$149	$226	Regen med & med devices for orthopedic & neurological uses
ZBH	Zimmer Biomet	$161.38	$33,451	$40,275	Musculoskeletal products, joint replacement, deformity reconstruction
pvt	Amniox				Birth tissue for wound, surgical & injectable products. Sports med
pvt	BioLab Sciences				Autologous skin grafts grown in the lab, amniotic allograft membrane
pvt	Biotissue				Amniotic membrane and umbilical cord products for eye diseases
pvt	Ilya Pharma				Wound healing using lactobacillus (ILP100)
pvt	Samumed				Lorecivivint: injectable knee & other OA in Ph3
MDXG	MiMedx	$9.89	$1,098	$1,036	Placental tissue allografts for wound care & orthopedic use

[81] Price and market capitalization data is as of February 12, 2021.

Intellectual Property

MiMedx' business relies on its ability to harvest, process and distribute tissue. The harvesting process leverages MiMedx' network of clinical staff that facilitate the collection, inspection and shipment of the tissue for processing. Processing of the tissue utilizes a combination of patented techniques as well as proprietary internal knowledge and trade secrets. MiMedx' Purion® process allows the collected tissue to be completely sterilized and have excellent shelf life, while retaining its therapeutic activity. The core intellectual property (IP) used for the Purion® process and other methods of use are codified in the company's patents and internal know-how.

Compiled below is a list of key patents. The patents cover a range of art including collection and processing of placental tissue grafts and modifications to the grafts including joining and reinforcing grafts. The patents also cover production of micronized products. Applications of the products such as subdermal injection for treating wrinkles and scars, integration with sutures, inclusion of chelators or antimicrobial/antifungal agents, Wharton's jelly derivatives or biostaples. MiMedx currently has 97 patents granted in the US.

Exhibit X – Recent Patent (Granted) Summary[82]

Pat. No.	Title
10,874,697	Placental tissue grafts and improved methods of preparing and using the same
10,869,952	Tissue grafts modified with a cross-linking agent and method of making and using the same
10,857,266	Reinforced placental tissue grafts and methods of making and using the same
10,849,933	Placental tissue component compositions for treatment of skin defects and methods using same
10,842,824	Method for inducing angiogenesis
10,736,990	Collagen and micronized placental tissue compositions and methods of making and using the same
10,689,621	Kits and materials for implantable collagen devices
10,653,514	Collagen fiber ribbons with integrated fixation sutures and methods of making the same
10,617,785	Collagen reinforced tissue grafts
10,517,931	Non-surgical, localized delivery of compositions for placental growth factors
10,449,220	Micronized placental compositions comprising a chelator
10,441,680	Placental tissue grafts produced by chemical dehydration/freeze-drying and methods for making and using the same
10,441,664	Cross-linked collagen with at least one bound antimicrobial agent for in vivo release of the agent
10,376,546	Micronized placental tissue compositions and methods of making and using the same
10,350,049	Laminated tissue grafts composed of Wharton's jelly and methods of making and using the same
10,335,433	NDGA polymers and metal complexes thereof
10,307,443	Micronized Wharton's jelly
10,258,327	Biostaples suitable for wrist, hand and other ligament replacements or repairs
10,238,773	Methods of making collagen fiber medical constructs and related medical constructs, including nerve guides and patches
10,206,977	Isolated placental stem cell recruiting factors

[82] Results compiled by Zacks' analysts from USPTO.gov

MiMedx also has 93 patent applications under review domestically and internationally.[83] The patent applications indicate continued IP development along the lines of collagen fiber and collagen reinforcement, continued development of micronized placental tissue including derivatives with chelators, methods of production of placental tissue grafts via chemical dehydration and lyophilization, NDGA polymers and others. The applications show novel developmental direction as well, including wound debridement, applications in hernias and utilization of amniotic fluid.

Exhibit XI - Recent Patent (Application) Summary[84]

App. No.	Title
20210015972	Collagen And Micronized Placental Tissue Compositions
20200376154	Proteins Having Wound Healing Efficacy And Method For Isolation From Human Hair
20200360019	Apical Surgical Wound Debridement
20200330522	Method Of Treating Or Preventing Hernia Formation
20200237498	Collagen Fiber Ribbons With Integrated Fixation Sutures
20200215221	Collagen Reinforced Tissue Grafts
20200129562	Compositions And Methods Of Treatment With Amniotic Fluid
20200113973	Non-Surgical, Localized Delivery Of Compositions For Placental Grow th Factors
20200069326	Systems, Devices, And Non-Invasive Surgical Methods For Treating Plantar Fasciitis
20200061122	Micronized Placental Tissue Compositions With Optional Sealant
20200046872	Collagen Constructs And Methods Of Making The Same
20190388239	Surgical Tools And Kits For Cartilage Repair Using Placental, Amniotic…
20190381107	Micronized Placental Compositions Comprising A Chelator
20190374584	Micronized Placental Tissue Compositions
20190350983	Placental Tissue Component Compositions For Treatment Of Skin Defects
20190350690	Making Collagen Fiber Medical Constructs And Related Medical Constructs, Including Patches
20190307921	Laminated Tissue Grafts Composed Of Wharton's Jelly
20190307812	Micronized Wharton'S Jelly
20190192736	Tissue Grafts Modified With A Cross-Linking Agent And Method Of Making And Using The Same
20190091371	Fenestration Kits For Making Fenestrated Placental Tissue Allografts

[83] This consists of a total of 86 pending and 7 which have received notices of allowance and will issue shortly.
[84] Results compiled by Zacks' analysts from USPTO.gov

Review of Recent Financial and Operational Results

Corporate Milestones

- Filing 2018 Annual Report – March 2020
- Peter M. Carlson announced as CFO – March 2020
- VA pricing investigation settlement – April 2020
- William L. Phelan appointed Chief Accounting Officer – May 2020
- Concurrent $150 million PE and debt financing – July 2020
- Filing of 2019 Annual Report – July 2020
- Filing of 1Q:20 10-Q – July 2020
- Rohit Kashyap Ph.D. appointed EVP and Chief Commercial Officer – July 2020
- Filing of 2Q:20 10-Q – August 2020
- Robert Stein, M.D., Ph.D. added as EVP Research and Development – August 2020
- Launch of EpiCord – September 2020
- Relisting on NASDAQ - October 2020
- UnitedHealth Group Coverage for EpiFix in Diabetic Foot Ulcers – November 2020
- Filing of 3Q:20 10-Q – November 2020
- KOA Phase II enrollment completion – 2020
- BLA filing for plantar fasciitis – 2022
- KOA Phase III trial initiation – 2022

In FY:19, financial reporting was postponed as resources were channeled towards investigation and restatement. Costs related to the investigation have persisted through at least 3Q:20, but management has guided that the firm has reduced the level of uncertainty through the resolution of 12/15 litigation matters, and is now ready to invest in sales and R&D, supported by its $150 million raise in July of 2020.

MiMedx began 2020 by filing its delayed 10-K and publishing its 2018 Annual Report, an event announced in a press release on March 17, 2020. Highlights from FY:18 included net sales of $359 million. The report also included restated sales from 2014-2017 on a cash basis for all years.

Exhibit XII – Restated Revenues 2014-2019[85]

Revenues (Restated)	2014	2015	2016	2017	2018	2019
(in thousands)	$105,257	$153,131	$221,712	$321,139	$359,111	$299,255
Growth		45.5%	44.8%	44.8%	11.8%	-16.7%

The restated revenues show a trend of increasing sales until a peak of $359 million in 2018. Gross margin was reported to be 89.9% in 2018 compared to 89.0% in 2017, increasing in part due to product mix sold as well as improvement in manufacturing efficiency. R&D expense decreased 11.9% from 2017 levels due primarily to decrease in clinical trial activity, completion of previously initiated studies and reduction in pre-clinical study investment. 2018 SG&A expense increased 17.4% over the prior year due to compensation for additional personnel and sales commissions as well as an increase in accounting fees with change in audit firm.

April 6, 2020 saw the settlement of the VA investigation that examined the accuracy of commercial pricing disclosures to the US Department of Veterans Affairs (VA) for one of MiMedx's products listed on its Federal Supply Schedule. Without admission to the allegations, MiMedx agreed to pay $6.5 million to the DOJ to resolve the matter.

[85] MiMedx SEC Filings

On July 2, 2020, MiMedx announced $150 million in private equity and debt financing. Equity financing was pursuant to Securities Purchase Agreement with an EW Healthcare Partners controlled entity and funds managed by Hayfin Capital Management. Debt financing was pursuant to a Loan Agreement with Hayfin as well Martin P. Sutter and William A. Hawkins III from EW Healthcare Partners were designated to serve on MiMedx' board as preferred directors, as part of the financing agreement. The Securities Purchase Agreement saw the issuance of a newly created Series B Convertible Preferred stock totaling $100 million in value, with $90 million purchased by EW Healthcare Partners and $10 million by Hayfin. The convertible preferred shares and any accrued/unpaid dividends may be converted into Mimedx common stock at any time, exercisable at $3.85 per share. The Series B preferred shares pay a dividend of 4% in the first 12 months after closing and 6% thereafter. The debt instrument has a duration of five years with a principal amount of $50 million, accruing interest at the higher of 8.25% or LIBOR+6.75%. The 6.75% margin is eligible to decrease to 6.5% or 6.0% after December 31, 2020 based on MiMedx' leverage. It is also accompanied by one-year delayed draw term loan facility totaling $25 million that has not been drawn.

On July 6, 2020, MiMedx announced its FY:19 Annual Report and 10-K filing. FY:19 saw net sales of $299 million, down approximately 17% from FY:18, including a decline in sales partially offset by an approximately $30 million benefit related to changes in revenue recognition. Sales decline was primarily attributed to unfavorable insurance coverage developments, fewer units sold, reduction in personnel, 50% of which were sales, negative publicity from the Audit Committee investigation and discontinuation of the OrthoFlo and AminoFix Sports Medicine product lines. Gross margin fell to 86% from 90% as overhead costs were spread over lower production levels and increased costs of production due to higher cGMP standards in 2H:19. SG&A decreased 23% compared to 2018 due to reduced headcount and sales commissions. Expenses related to the investigation and restatement were $66 million in 2019 and are not expected to continue. Finally, MiMedx complied with the corrective comments made in the FDA's Form 483 for both of its processing facilities and has notified the FDA the remediation actions were complete.

In the same month, 1Q:20 results and the related 10-Q filing were announced. 2Q:20 announcement and filing came in August 2020, and 3Q:20 filing and announcement came in November 2020.

FY:20 Year to Date

Quarterly net sales for 2020 have decreased year over year versus 2019. The decrease has been attributed largely to the COVID-19 pandemic, which decreased patient elective procedures and hindered in-person sales activity. Comparison of quarterly net sales is also obscured by changes in revenue recognition where MiMedx transitioned from cash-receipt recognition to as-shipped. In the transition, revenues that would have previously been recognized on a cash basis, were recognized earlier upon shipment of product. As a result, 3Q:19 net sales included a $21.4 million benefit. Subsequent quarterly revenues primarily consisted of as-shipped recognized revenues. Some revenue was still recognized on cash-receipt from sales prior to transition. 1Q:20, 2Q:20 and 3Q:20 included cash-accrued revenues of $4.5 million, $1.7 million, and $1.0 million, respectively.

Regarding the transition, MiMedx now recognizes revenue, on an "as-shipped" basis, using a five-step model:

- Identify contract with customer;
- Identify contractual performance obligations;
- Determine transaction price;
- Allocate transaction price across performance obligations;
- Recognize revenue as performance obligations are satisfied;

For the first nine months of the year, gross margins declined, on average, year over year. This was primarily attributed to adherence to higher manufacturing process standards. Lower manufacturing yield and investment in a biologics license application contributed as well.

Quarterly SG&A expense was down year-over-year versus 2019 due primarily to the pandemic and quarantine measures that reduced overall sales and associated travel expenses and commissions. Sales personnel also saw a reduction in wages.

Costs related to investigation and restatement decreased compared to the prior year as the Audit Committee concluded its investigation in May 2019. This was partially offset by $5 million in insurance coverage payments related to litigation and costs incurred under indemnification agreements with former management in 2Q:20 and 3Q:20, respectively.

During 2020, the pandemic impacted R&D costs bringing them down as patients were less likely to enroll in trials due to quarantine. Management has guided toward an expected increase in R&D costs as MiMedx returns to research and product development.

In the most recent quarter, 3Q:20, and versus 3Q:19:

- Net sales were $64.3 million, down 28% from $88.9 million. The difference was abnormally high as the $88.9 million in the prior year included a $21.4 million benefit resulting from the transition in revenue recognition from cash accrual to "as-shipped". Excluding the "as-shipped" revenues, the two periods were comparable. Revenues also included $1 million recognized in cash accrual from sales that had been made prior to the transition;
- Gross margin declined to 84.0% from 85.1%, largely due to the costs of manufacturing at higher cGMP standards and lower production yield;
- SG&A expenses were $48.0 million, down 6.3% from $51.2 million on reduced travel expenses, severance expenses and fewer legal, consulting and accounting expenses outside of those related to the investigation;
- Investigation and restatement related expenses were $12.0 million, up 67% from $7.2 million as a result of costs related to the indemnification agreements with former management and resolution of legal matters;
- R&D expenses were $3.4 million, up 26% from $2.7 million. This was driven by clinical research consulting fees and are expected to increase as MiMedx reinvests into its research and product development pipeline.

On September 30, 2020, MiMedx held $109.6 million in cash after a raise of $150 million in July 2020. Burn rate for the quarter was approximately ($4.6) million, suggesting approximately six years of financial runway, although management expects an increased $35-$40 million investment into R&D as well a larger sales force with a target of over 290 sales professionals employed by end of 2021, compared with the 265 employed as of December 2020.

A new product was announced on September 14, 2020 called the EpiCord Expandable placental allograft. The allograft expands to twice its original size and provides protective structure to support wound healing. The product has demonstrated clinical efficacy in diabetic foot ulcers and is pending issuance of a patent.

MiMedx announced on November 3, 2020 the adoption of coverage for EpiFix by the largest US Commercial payor, UnitedHealth Group, effective December 1, 2020. Appearing on the formulary of the managed care provider is a milestone for MiMedx' flagship membrane tissue product for treatment of diabetic foot ulcers. EpiFix was selected in part due to supportive third-party analysis showing EpiFix to have the most randomized controlled trials, a low risk of overall study bias and statistically significant findings.

MANAGEMENT PROFILES

Timothy R. Wright, Chief Executive Officer

Mr. Wright was appointed Chief Executive Officer effective May 13, 2019. He has more than 30 years of experience in the pharmaceutical, biotech and medical devices industries. Previously, Mr. Wright served as a Partner at Signal Hill Advisors, LLC, a consulting practice, since February 2011. Mr. Wright served as President and Chief Executive Officer of M2Gen Corp., a privately held cancer and health informatics company, between July 2017 and September 2018. Prior to M2Gen Corp., Mr. Wright served as Executive Vice President, Mergers and Acquisitions, Strategy and Innovation for Teva Pharmaceutical Industries Ltd., a pharmaceutical company specializing in generic medicines, from April 2015 until August 2017. Prior to that, Mr. Wright was the founding partner of The Ohio State University Comprehensive Cancer Drug Development Institute. Mr. Wright also served as Chairman, Interim Chief Executive Officer and a director of Curaxis Pharmaceutical Corporation, a pharmaceutical company specializing in the development of drugs for the treatment of Alzheimer's disease and various cancers, from July 2011 to July 2012. Mr. Wright has been a director of Agenus, Inc. (NASDAQ: AGEN), an immune oncology company, since 2006 and its lead director since 2009. Mr. Wright also serves as Chairperson of The Ohio State University Comprehensive Cancer Center Drug Development Institute, serves as Director of The Ohio State Innovation Foundation and sits on The Ohio State University College of Pharmacy Dean's Corporate Council. Mr. Wright earned a Bachelor's of Science in Marketing from The Ohio State University.

Peter M. Carlson, Chief Financial Officer

Mr. Carlson was appointed Chief Financial Officer in March 2020, after joining MiMedx in December 2019 as Executive Vice President of Finance. Previously, Mr. Carlson served as Chief Operating Officer at Brighthouse Financial, Inc., where he helped establish the $200 billion (assets) U.S. life and annuity insurance company as a separate entity following its August 2017 spin-off from MetLife, Inc. He was the Chief Accounting Officer at MetLife, Inc. for eight years where his global responsibilities included accounting, financial planning, tax and investment finance. Prior to joining MetLife in 2009, Carlson was the Corporate Controller at Wachovia Corporation. He currently serves as a director of White Mountains Insurance Company (NYSE: WTM). Mr. Carlson holds a Bachelor of Science from Wake Forest University and is a trustee of the university. He is licensed as a certified public accountant in North Carolina and New York.

Mark P. Graves, Chief Compliance Officer

Mr. Graves joined MiMedx in July 2018 and brings more than 20 years of pharmaceutical and biotech industry experience, ranging from compliance and sales management to government affairs. He most recently was the U.S. leader for the global Patient Experience & Value function in the neurology division of UCB, Inc. From 2011 to 2015, he was UCB's Deputy Compliance Officer involved in all aspects of compliance including the implementation and management of the company's corporate integrity agreement. Prior to that, Graves was Senior Director in the Office of Ethics and Compliance for the Pharmaceutical Products Division of Abbott Laboratories, as well as Deputy Ethics & Compliance Officer for Takeda Pharmaceuticals North America, Inc. and TAP Pharmaceutical Products, Inc. Prior to his pharmaceutical and biotech career, he practiced labor and employment law. Mr. Graves holds a B.A. in Criminology and Law, and a J.D. from the University of Florida as well as an MBA from the University of Chicago Booth School of Business.

William F. Hulse IV, General Counsel and Secretary

Mr. Hulse joined MiMedx in December 2019, bringing more than twenty years' experience in large law firms and life sciences organizations, with significant legal, risk management, compliance and operational expertise. Prior to joining the Company, Mr. Hulse was a member of Dykema, a national law firm, since 2017. Prior thereto, he was with Acelity, LP, Inc. (formerly Kinetic Concepts, Inc.) from 2008-2017 in a variety of roles of increasing responsibility. In his last role with Acelity, he served as Chief Compliance Officer and Senior Vice President for Enterprise Risk Management, Quality, and Regulatory. Prior to that, he served as Division General Counsel and Associate General Counsel for litigation matters. Mr. Hulse holds a Bachelor of Arts from Angelo State University and a Juris Doctorate from the Baylor University School of Law.

Rohit Kashyap, Ph.D., Chief Commercial Officer

Dr. Kashyap joined the Company as Executive Vice President and Chief Commercial Officer in August 2020. Dr. Kashyap has more than 20 years in the medical device sector. Most recently, he served as the President of Global Commercial at Acelity, L.P. Inc. (formerly known as Kinetic Concepts, Inc.) since April 2019. Prior thereto, Dr. Kashyap was the President of Americas, since January 2017 and President of North America, since October 2014. In these roles he led Acelity's growth objectives by expanding core market leadership, identifying and developing new high-growth markets, and enhancing the overall product portfolio through the integration of additional businesses. Prior to that, Dr. Kashyap served as Senior Vice President of Strategy and Business Development at Acelity, Inc. from 2012 to 2014, and as Senior Vice President of Corporate Development from 2007 to 2010, with responsibility for the development of global strategic planning initiatives that incorporated organic growth, licensing, and strategic acquisitions. Since joining the company in 1998, Dr. Kashyap contributed in various roles within the R&D, Licensing and Acquisition, and Global Marketing groups, including as Commercial Leader for international and emerging markets. Dr. Kashyap earned his bachelor's degree in Instrumentation and Control from the L.D. College of Engineering in Ahmedabad, India, and his master's degree and doctorate in Biomedical Engineering from Case Western Reserve University. He also completed his MBA from the Kellogg School of Management at Northwestern University.

Robert B. Stein, Executive Vice President, Research and Development

Dr. Robert B. Stein, M.D., Ph.D. joined MiMedx in August 2020 as Executive Vice President, Research and Development. After completing his Bachelors of Science with honors, earning a double major in both biology and chemistry at Indiana University, Dr. Stein received his M.D. and Ph.D. in Physiology and Pharmacology and completed his internship, residency and Board Certification in Anatomic and Clinical Pathology, all at Duke University. Following residency, Dr. Stein worked at Merck, with contributions to Cozaar, Sustiva, and Gardasil. He was then recruited as the first head of Research and Development for Ligand Pharmaceuticals, with responsibility for building the Research and Development organization and programs targeting various nuclear hormone receptors. This work led to eight pharmaceutical partnerships and six marketed medicines, including two SERMs (Fablyn and Viviant), three novel retinoids (Panretin, Targetin gel and capsules) and Promacta, the small molecule Thrombopoietin mimetic.

After six years at Ligand, he became Executive Vice President, Research and Pre-clinical Development for DuPont-Merck and DuPont pharmaceuticals, leading to the registration of Sustiva and Innohep and the discovery and advancement of blockbuster Eliquis, subsequently registered by Bristol Myers Squibb Company. Following the acquisition of DuPont by Bristol Myers Squibb, Dr. Stein joined Incyte Pharmaceuticals as President, R&D and Chief Scientific Officer, spearheading the transition from genomics to drug discovery and development. Following Incyte, Dr. Stein became President of Roche Palo Alto LLC, where he built Roche's Translational Medicine capabilities, served on the Global Early Development Committee, Global Biologics Steering Committee, and Joint Roche-Genentech Steering Committee. Dr. Stein then joined Kinemed, a translational medicine company as Chief Executive Officer.

Following Kinemed, Dr. Stein served as President, R&D, for Agenus, an immuno-oncology company, with responsibility for the development of their R&D organization, and the advancement of four checkpoint modulatory antibodies and a personalized neo-epitope-directed cancer vaccine to Phase 1 trials. He also led the generation of a best-in-class TCR discovery and optimization effort. He served as a full-time Senior Advisor, R&D, to Agenus and AgenTus from March 2017 to October 2019. During this time, Agenus advanced 13 monoclonal antibodies into the clinic and formed significant partnerships with Incyte, Merck, UCB, and Gilead. The two most advanced Agenus products, AGEN2034 (PD-1 antagonist monoclonal antibody) and AGEN1884 (CTLA-4 antagonist monoclonal antibody) are on track for potential BLA submission in 2020.

Dr. Stein is deeply experienced in the lab, including in the areas of molecular and cellular biology, biochemistry, enzymology, animal pharmacology, virology, drug metabolism, and safety assessment. He also has extensive experience in Translational Medicine and Early Clinical Development. He has led groups of over 1,000 scientists and physicians for over 15 years, supervising work in all the major therapeutic areas. In addition, Dr. Stein serves on the board of directors for a number of private and public company boards, and acts as an advisor to multiple clients and academic institutions.

Risks

All investments contain an element of risk which reflects business uncertainty and opportunity. Some investments exhibit higher predictability, with current cash flows and established sales. These enterprises will have a lower level of perceived risk while other companies that are developing an undefined, new technology have a much higher level of perceived risk. MiMedx competes at both ends of the spectrum in the specialties of wound care and regenerative medicine, generating both revenues and funding development projects in these areas.

The wound-care space includes companies at both ends of the market capitalization spectrum, from multi-billion dollar powerhouses such as Wright Medical or Zimmer Biomet, to small, private operations with a handful of employees conducting pre-clinical studies. At approximately $1 billion in market capitalization, MiMedx is larger than most players in the space, especially in wound care. MiMedx has not been profitable in recent quarters, due to headwinds related to the pandemic and legacy liabilities attributable to the previous management team; however, many of the non-operating issues appear to be behind the company and management is now focused on growing the company's salesforce as well as invest in R&D. With a recent, considerable capital injection, liquidity risk is lowered, with development, commercialization and regulatory risk now in focus. We review the principal risk categories faced by MiMedx below.

Pandemic Risk

The pandemic has impacted MiMedx' operations in the sales function where quarantine has limited representatives' interaction with providers and payors and patient access to clinical studies. This has reduced revenues and extended the duration of clinical trials. COVID-19 cases continue to rise worldwide and may persist in their impact on company activities, although vaccinations and improved preventive behavior are slowing the virus' spread and future impact is likely to decline.

Liquidity, Financing & Trading

Securing funding may be difficult especially during a period of economic volatility. During periods of confidence, capital may be easy to obtain; however, during a liquidity crisis or a period of heightened risk perception, even companies with bright prospects may be in trouble if they are dependent on the financial markets to fund their work. Pre-revenue firms or those with in-development technologies rely heavily on equity issuance to fund their operations. The timeline for drug and device development is considerable and long periods can pass before a product is sold. Funds can be sourced through debt or equity issuances; however, these sources may reduce the flexibility of the company and can dilute existing shareholders.

If capital is required to sustain operations and it is not readily available, a company may be forced to suspend research and development, sell equity at a substantial discount to previous valuations and dilute earlier shareholders. A lack of funding may leave potentially promising therapies without a viable route forward or force a company to accept onerous terms. MiMedx raised $150 million midway through FY:20 which should sustain the firm until it is able to generate positive free cash flow. However, another raise may be required if our cash flow targets are not achieved. The conditions for favorable capital markets may not persist, which may result in difficult terms in subsequent financings.

Trading volumes are frequently low for smaller firms or firms with heightened uncertainty, creating liquidity risk where large transactions may have a material impact on share price. During periods of risk aversion, share price may be suppressed as investors await further clarity.

MiMedx has been the target of short-sellers, who borrow shares from shareholders and resell them in the market. The short-sellers frequently make public their rationale for selling the shares short, encouraging other investors to divest of their holdings. Short selling and short squeezes can lead to price volatility in both directions.

Market Risk

Once granted marketing authorization, the commercialization of a candidate relies on an experienced salesforce, key opinion leaders and supportive clinical data. Success relies on product acceptance, adoption and continued safety during the post-marketing period. Lack of marketing effort, exclusion from formularies and lack of product acceptance by the medical community may prevent material penetration of an approved product. New and improved competing therapies may siphon off market share.

MiMedx has commercialized products and candidates that are in clinical development. Current products may not gain or sustain market share in the future. The wound-care space is sizable and is a persistent need; however, there is substantial competition. In-development products may not be approved or be successfully commercialized if they are approved.

Management has plans to expand internationally into Japan, the UK and Germany. While the expansion is expected to accelerate revenue growth, the effort requires material investments which may be written down if the desired growth is not realized.

Regulatory Risk

As medicine continues to evolve and novel therapies come to market, the lines are often blurred between regulatory classifications. In 2017, the FDA issued guidance entitled "*Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue–Based Products: Minimal Manipulation and Homologous Use – Guidance for Industry and Food and Drug Administration Staff.*" The document provided an updated framework for the FDA's regulation and oversight of cellular and tissue-based products, signaling increased oversight in the space. In response, MiMedx launched several clinical trials to obtain approval for several of its products and to comply with the FDA's mandate.

The FDA guidance provided clarification on which tissue products the FDA would regulate under Section 361 and which would be regulated under Section 351. The difference in regulation will require clinical trials to be successfully conducted for identified products to comply with Section 351. Amniotic membrane in sheet form, like MiMedx' AminoFix, will continue to be regulated solely under Section 361, which does not require pre-market clearance or approval by FDA. Management expects EpiFix, EpiBurn, EpiXL, EpiCord and AminoCord products to also continue to be regulated under Section 361.

MiMedx' micronized products, such as AminoFix Injectable, EpiFix Micronized and AminoFill, undergo additional processing, thus not qualifying as "minimally manipulated," and are expected to be regulated under Section 351. These products are currently at risk following the end of enforcement discretion, which could materially impact MiMedx' revenues. The FDA initially withheld enforcement through November 2020 and has now extended the period until May 31, 2021. The discretionary period is intended to give sponsors time to evaluate their products, conduct a dialogue with the agency, begin clinical trials and file the appropriate pre-market applications.

MiMedx is at risk of being required to withdraw its unapproved micronized products from the market in order to comply with FDA mandate, impacting sales and profits. Management has guided that net sales in 2021 could be reduced by as much as $20 million for the seven months following the May 31 enforcement date. Regulatory risks also apply to MiMedx' international expansion. In Japan, MiMedx' products would be the first amniotic tissue to be approved. There may also be risk of delays or uncertainty related to new regulatory environments.

Clinical Trials

Regardless of company size, investing in product development is a lengthy process. MiMedx management has guided toward increased investment in R&D in 2021 to advance its preclinical and clinical assets. The company has one clinical stage asset in plantar fasciitis, which is expected to conclude its Phase III trials near the end of 2021. MiMedx is also advancing a candidate in KOA which has completed enrollment with the goal of accelerating timelines where possible, including the filing for the Phase III KOA study.

Although MiMedx management has guided towards an acceleration in the pace of its pipeline development, the timeframe between conducting pre-clinical research to eventually commercializing a medical product can take from 3 to 7 years[86] or longer given market and company-specific conditions. There may be delays and setbacks to a company's anticipated timeline. The decision to allocate time, capital and personnel resources among multiple candidates requires a delicate balance to avoid exhausting limited resources. Trials involve many people and require coordination, organization and adherence to protocols. Third party contractors manage multiple trials and may not provide the required effort to produce success. Clinical trials must be designed to meet specific endpoints and generate statistically significant results in order to be considered by the FDA, which is one of the highest risk business propositions of any industry.

[86] Gail Van Norman, "Drugs, Devices, and the FDA: Part 2: An Overview of Approval Processes: FDA Approval of Medical Devices," *JACC: Basic to Translational Science* 01/04 June 2016, 277-287

VALUATION

MiMedx has a multi-year history of success in commercializing placental tissue allografts for wound care and orthopedic uses using its Purion® processing technology. While the company faced significant difficulties related to prior management behavior, the legacy liabilities are nearly resolved allowing the company to rebuild its reputation as a regenerative medicine leader. On the legal front, there are three outstanding matters, including a class action securities litigation and two defamation cases. The class action matter could be material and while there is some insurance protection, the company may also have to pay uncovered amounts upon resolution. The outcomes of class action lawsuits are highly uncertain and are frequently appealed or settled out of court. We capture the risk of these outstanding items in our discount rate and believe that they will be one-time items addressable with cash on hand. Over the last year, investigation and restatement costs have been approximately $60 million and we believe that the settlement amount for outstanding issues will fall below this level. However, we warn investors that outcomes can vary widely. MiMedx is also facing the end of enforcement discretion which could impact 2021 revenues by approximately $20 million beginning June 1. We assume the full $20 million impact from the action but do see alternatives that could temper or eliminate it. We will adjust our estimates as more information becomes available, likely in the next couple months. The new product launch of EpiCord Expandable in late 2020 is expected to offset some of the decline related to halting sales of product subject to enforcement discretion.

Despite the issues MiMedx has faced in the past, there is substantial opportunity in front of the amniotic tissue company. Sales over the trailing twelve months have been almost $260 million and we believe that the initiatives that the company has put into place for domestic and international expansion, further penetration into managed care and hospital contracts and increases in demand for wound care will drive growth in 2022 and beyond. We estimate that 2021 revenues will be down 1% due to the impact from enforcement discretion, with growth of EpiCord Expandable tempering the impact. After recovering from the initial impact of enforcement discretion, 2022 revenues are targeted to increase 14% on new international sales and underlying growth in the wound care market. International opportunities exist in Japan where approval of the company's AmnioFix product is expected to be approved this year. MiMedx products are already approved in the UK and Germany and reimbursement details are pending. The size of the wound care market in these three countries is estimated at over $1.5 billion.[87]

Along with the growth anticipated in the underlying business and in international expansion, 2023 is predicted to add another layer of sales with the potential approval of the BLA filing for Plantar Fasciitis (PF). PF is diagnosed with pain in 0.85% of the population[88] or 2.8 million individuals. Each 1% penetration into the PF market could generate $28 million in revenues.[89] 2024 is expected to receive a greater benefit of sales from a successful PF trial and we anticipate additional off-label use of AmnioFix after the FDA approves it in the first indication. We see a slight deceleration in 2025 sales growth as revenue increases are anticipated to be primarily driven by underlying trends in wound care, PF and continued international penetration rather than new launches or geographies.

The largest opportunity we see follows a successful trial in KOA, which may receive marketing approval in 2026. If AmnioFix injectable is found safe and effective and approved by the FDA, there is an addressable market of over 23 million individuals with KOA[90] that could benefit from AmnioFix. If we assume a penetration rate of 10% and $1,000 of revenue per injection and adjust this result by a 25% chance of success, this yields a $580 million opportunity for this product alone. If we assume a more optimistic 20% penetration, $2,000 of revenue per projection and an RMAT-driven 50% change of success, we estimate a probability adjusted $4.6 billion of opportunity. This excludes other OA areas such as elbow, foot and ankle. For reference, we review 2019 revenues from top products in the adjacent rheumatoid arthritis (RA) space of ~$28 billion, with the top eight drugs each generating well over $1 billion in revenues. RA has a materially lower prevalence vs. OA.[91] Furthermore, if the product provides a material benefit, both the penetration rate and revenue per treatment can easily exceed our conservative estimates. An important component of this initiative is the probability of success, which we believe is materially higher than other candidates in Phase II development. KOA has received the RMAT designation which lowers the hurdle required to gain approval. Expedited treatment is also possible and may help advance the timeline for marketing AmnioFix injectable

[87] Source: MiMedx corporate presentation which cited Global Data Tissue Engineered-Skin Sub Data Model Wound Management Japan, Germany and UK Year 2020. Information retrieved Sept 2020.
[88] Source: NIH, National Center for Complementary and Integrative Health. Analysis of Data on the Prevalence and Pharmacologic Treatment of Plantar Fasciitis Pain.
[89] Assuming $1,000 per treatment cost. A higher amount will likely be justified if clinical trial results are robust.
[90] 19% of those over 45 present knee OA (source: Wallace *et al*.) and according to the 2010 Census there were 122 million individuals over the age of 45.
[91] Hunter, T.M. *et al.* Prevalence of rheumatoid arthritis in the United States adult population in healthcare claims databases, 2004-2014. Rheumatol Int . 2017 Sep;37(9):1551-1557. doi: 10.1007/s00296-017-3726-1. Epub 2017 Apr 28. *RA prevalence is estimated to be approximately 0.5% of the commercially insured adult US population.

to KOA patients. These assumptions drive our estimate of continued 20%+ growth in total revenues over the next several years beyond 2027.

Gross margin is forecast at 84% over the duration of our model. This reflects both company guidance and recent performance. Sales, general and administrative expenses are forecast to fall to $166 million in 2021 as efforts related to many of the legacy issues are concluded and rise slightly in 2022 as sales efforts are reinforced. Modest inflation and SG&A leverage are expected over the remaining forecast period. Research and development will rise in 2021 and efforts to advance programs in PF, KOA and advanced wound care accelerate. Research and development will continue to grow in future years as further investment is made in clinical trials and product approvals over the next decade. We assume continued interest expense of approximately 7% per annum. We estimate that by 2024, MiMedx will have generated sufficient earnings to exhaust its net operating loss carryforwards and begin paying taxes at a 23% rate.

Share balance includes both basic shares outstanding and as-converted Series B Convertible Preferred Stock. We estimate approximately 26 million additional shares will be added to the basic share count over the next three years. The timing of the conversions is uncertain, but it is likely that all will be mandatorily convertible in mid-2023, which is reflected in our future share count. We will calculate loss per share using basic shares outstanding and net income per share using fully diluted shares which includes the mandatorily convertible shares and in the money options and warrants. We expect basic and diluted shares to be closer to equal in 2024.

Exhibit XIII – Our Model to 2027

MiMedx Group, Inc.	2021 E	2022 E	2023 E	2024 E	2025 E	2026 E	2027 E
Total Revenues ($US '000)	**$240,470**	**$274,136**	**$323,480**	**$388,176**	**$458,048**	**$572,560**	**$715,700**
YOY Growth	-1%	14%	18%	20%	18%	25%	25%
Cost of Goods Sold	$38,475	$43,862	$51,757	$62,108	$73,288	$91,610	$114,512
Product Gross Margin	84%	84%	84%	84%	84%	84%	84%
Income from operations	($1,960)	$35,274	$80,023	$130,222	$185,241	$279,231	$396,188
Operating Margin	-1%	13%	25%	34%	40%	49%	55%
Interest income, net	($3,500)	($3,500)	($3,500)	($3,500)	($3,500)	($3,500)	($3,500)
Other income, net	$0	$0	$0	$0	$0	$0	$0
Pre-Tax Income	($5,460)	$31,774	$76,523	$126,722	$181,741	$275,731	$399,688
Provision for Income Tax	$0	$0	$0	$0	$41,800	$63,418	$91,928
Tax Rate	0.0%	0.0%	0.0%	23.0%	23.0%	23.0%	23.0%
Net Income	**($5,460)**	**$31,774**	**$76,523**	**$126,722**	**$139,941**	**$212,313**	**$307,760**
Net Margin	-2%	12%	24%	33%	31%	37%	43%
Reported EPS	**($0.05)**	**$0.22**	**$0.52**	**$0.83**	**$0.92**	**$1.40**	**$2.01**
YOY Growth	-87%	-562%	138%	61%	10%	52%	44%
Basic Shares Outstanding	116,130	120,243	135,258	152,000	152,000	152,000	153,000
Fully Diluted Shares	144,105	146,280	148,193	152,000	152,000	152,000	153,000

Source: Company Filing // Zacks Investment Research, Inc. Estimates

Our valuation approach employs a discounted multiple of earnings per share (EPS) and multiple of enterprise value (EV) to EBITDA. We use 2026 forecasts to generate the underlying EPS and EBITDA values as we believe MiMedx will have achieved normalized margins by then. We anticipate continued topline growth above 20% for 2026 and beyond driven by success of the company's key product, AmnioFix injectable for use in joint osteoarthritis. Based on this growth rate we apply a 25x EPS multiple and a 17x EBITDA multiple to 2026 forecasts. The result is discounted at 20% by four years to yield our one-year target price.

Exhibit XIV – Valuation Under Various Discount Rate and EPS Multiple Assumptions[92]

P/E Multiple: 2026 EPS	Discount Rate (to 2022)				
	15.0%	17.5%	20.0%	22.5%	25.0%
20.0	$15.97	$14.66	$13.47	$12.41	$11.44
22.5	$17.97	$16.49	$15.16	$13.96	$12.87
25.0	$19.97	$18.32	$16.84	$15.51	$14.30
25.7	$20.52	$18.83	$17.31	$15.94	$14.70
30.0	$23.96	$21.98	$20.21	$18.61	$17.16

[92] Source: Zacks' analyst work

Exhibit XV – Valuation Under Various Discount Rate and EBITDA Multiple Assumptions[93]

2026 EV/EBITDA Multiple	Discount Rate (to 2022)				
	15.0%	17.5%	20.0%	22.5%	25.0%
15.0	$16.06	$14.74	$13.55	$12.48	$11.51
16.0	$17.15	$15.73	$14.46	$13.32	$12.28
17.0	$18.23	$16.73	$15.38	$14.16	$13.06
18.0	$19.31	$17.72	$16.29	$15.00	$13.84
19.0	$20.40	$18.71	$17.20	$15.84	$14.61

Based on the assumptions identified in our multiple of EPS and EBITDA approach, we generate a one-year target price of $16.00 per share. Our target price is equivalent to a 2021 EV to Sales of 7.6x which compares favorably to peers' trailing four quarter valuation summarized in the exhibit below.

Exhibit XVI – Comparative Valuations[94]

Ticker	MktCap (MM)	EV (MM)	Revenues	EBITDA	EV/EBITDA	EV/Sales
ATHX	$532	$470	$0	($44)	NM	NM
AXGN	$775	$719	$108	($26)	NM	6.7
BIXT	$18	$18	$0	($2)	NM	NM
CRY	$969	$1,196	$253	$35	34.3	4.7
FLXN	$576	$599	$83	($123)	NM	7.2
IART	$5,827	$6,937	$1,378	$229	30.3	5.0
MDWD	$151	$126	$21	$6	20.4	6.1
MESO	$1,246	$1,194	$16	($70)	NM	72.7
MSON	$305	$313	$68	($15)	NM	4.6
OCC.AX	$106	$86	$0	($9)	NM	NM
OFIX	$835	$777	$410	$2	501.4	1.9
ORGO	$1,373	$1,437	$306	($22)	NM	4.7
PRED	$36	$42	$21	($86)	NM	2.0
PROMO	$98	$67	$2	($31)	NM	33.5
PSTI	$248	$205	$0	($28)	NM	NM
PTE	$102	$80	$8	($89)	NM	10.0
SNN	$19,311	$20,890	$4,690	$1,300	16.1	4.5
SNWV	$90	$95	$3	($9)	NM	37.6
SYK	$93,354	$103,560	$14,351	$2,766	37.4	7.2
VCEL	$2,302	$2,217	$118	($9)	NM	18.7
XTNT	$149	$226	$56	$1	285.1	4.0
ZBH	$33,451	$40,275	$7,025	$1,615	24.9	5.7
MDXG	$1,098	$1,036	$272	($17)	NM	3.8

[93] Source: Zacks' analyst work
[94] Source: Zacks' analyst work

CONCLUSION

MiMedx has navigated a difficult period over the last several years. In contrast to the mid-40% topline growth of the 2015 to 2017 period, by 2018, revenues fell precipitously and the company was embroiled in scandal related to the previous management's behavior. Since then, new management has been hired and has enacted a plan to resolve the outstanding legal issues against the company and improve the firm's reputation with product supported by clinical trials and high-grade manufacturing facilities. Some hurdles remain, such as the end of enforcement discretion, but there are numerous positive catalysts that can drive the company's shares substantially higher.

The company's primary market is in wound care which is only lightly penetrated. With physicians, managed care and hospitals recognizing AmnioFix' benefits and the cost savings it and related products can achieve, regenerative medicine is becoming more accepted. We anticipate this acceptance to grow as additional studies are conducted demonstrating safety and efficacy and after receiving regulatory approval in the United States and overseas.

Near term drivers for MiMedx' operational performance come from new product launches, such as EpiCord Expandable and wound care market growth. These may be offset by declines related to the cessation of product sales now allowed under enforcement discretion. Other drivers, including international expansion and successful clinical trials and FDA approval should support double digit growth over the longer term. The company's largest opportunity in knee osteoarthritis is targeted to be approved by 2026, but could occur sooner due to the expedited treatment RMAT-designated projects receive. MiMedx is progressing other development programs in advanced wound care and we expect future research and development efforts will increase in coming years.

MiMedx holds substantial cash on its balance sheet in sufficient amounts to reach positive cash flows and earnings without additional capital raises. We see full year positive earnings by 2022 and substantial growth over the next several years which will provide the firm substantial financial flexibility to optimize its capital structure.

Key reasons to own MiMedx shares:

- **Existing high margin business in placental and umbilical cord tissue products**
  - **EpiFix**
  - **EpiCord**
  - **AmnioFix**
  - **AmnioFill**
  - **AmnioCord**
  - **EpiBurn**
- **Products recognized by payors**
  - **EpiFix on largest US health insurer formulary for diabetic foot ulcers**
  - **EpiFix and EpiCord allografts eligible for coverage by Medicare Administrative Contractors**
- **International growth opportunities**
  - **Japan – anticipated approval mid-2021**
  - **United Kingdom – approved, reimbursement in process**
  - **Germany – approved, reimbursement in process**
- **Development candidates**
  - **Plantar fasciitis – Phase III**
  - **Achilles tendonitis – Phase III**
  - **Knee Osteoarthritis – Phase II**
    - **Designated as a Regenerative Medicine Advanced Therapy (RMAT) by FDA**
  - **Multiple preclinical advance would care development projects**
  - **Investigation and expenses related to prior management misconduct are largely complete**

Based on the numerous opportunities and catalysts over the next several years, we are optimistic that near term hurdles in the legal arena and the conclusion of enforcement discretion will be decisively overcome. Our valuation work recognizes the multiple catalysts from international expansion, growth in the base business and approvals in new indications that can drive future topline. As we initiate on MiMedx Group our forecast and analysis generate a one year target price of $16.00 per share.

PROJECTED FINANCIALS

MiMedx Group, Inc. - Income Statement

MiMedx Group, Inc.	2019 A	Q1 A	Q2 A	Q3 A	Q4 E	2020 E	2021 E	2022 E
Total Revenues ($US '000)	**$299,255**	**$61,736**	**$53,647**	**$64,303**	**$62,000**	**$241,686**	**$240,470**	**$274,136**
YOY Growth	-17%	-7%	-20%	-28%	-19%	-19%	-1%	14%
Cost of Goods Sold	$43,081	$10,025	$8,198	$10,289	$9,920	$38,432	$38,475	$43,862
Product Gross Margin	85.6%	83.8%	84.7%	84.0%	84%	84%	84%	84%
Selling, general & administrative	$198,205	$46,942	$37,329	$48,046	$44,000	$176,317	$166,000	$170,000
Investigation, restatement etc.	$66,504	$15,592	$11,446	$12,027	$9,000	$48,065	$12,000	$0
Research & development	$11,140	$2,650	$2,259	$3,372	$3,600	$11,881	$37,955	$25,000
Amortization of intangible assets	$1,039	$271	$271	$276	$276	$1,094	$1,088	$1,088
Impairment of intangible assets	$446	$0	$0	$0	$0	$0	$0	$0
Income from operations	($21,160)	($13,744)	($5,856)	($9,707)	($4,796)	($34,103)	($1,960)	$35,274
Operating Margin	-7.1%	-22%	-11%	-15%	-8%	-14%	-1%	13%
Interest income, net	($4,708)	($2,387)	($2,574)	($1,472)	($875)	($7,308)	($3,500)	($3,500)
Other income, net	$283	$6	($9)	($8,200)	$0	($8,203)	$0	$0
Pre-Tax Income	($25,585)	($16,125)	($8,439)	($19,379)	($5,671)	($49,614)	($5,460)	$31,774
Provision for Income Tax	$5	$11,304	($27)	($38)	$0	$11,239	$0	$0
Tax Rate	0.0%	-70.1%	0.3%	0.2%	0.0%	-22.7%	0.0%	0.0%
Net Income	**($25,580)**	**($4,821)**	**($8,466)**	**($19,417)**	**($5,671)**	**($38,375)**	**($5,460)**	**$31,774**
Net Margin	-9%	-8%	-16%	-30%	-9%	-16%	-2%	12%
Reported EPS	**($0.24)**	**($0.04)**	**($0.08)**	**($0.18)**	**($0.05)**	**($0.35)**	**($0.05)**	**$0.22**
YOY Growth							-87%	-562%
Basic Shares Outstanding	106,946	107,539	108,119	108,493	111,125	108,819	116,130	120,243
Fully Diluted Shares	106,946	107,539	108,119	108,493	111,125	108,819	144,105	146,280

Source: Company Filing // Zacks Investment Research, Inc. Estimates

HISTORICAL STOCK PRICE

MiMedx Group, Inc. – Share Price Chart[95]

[95] Source: Zacks Research System

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