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MiMedx Group, Inc. (MDXG - NASDAQ)

Multiple Readouts This Summer

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 (4/29/21)	$10.18
Valuation	**$16.00**

OUTLOOK

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 is developing assets in plantar fasciitis and knee osteoarthritis. Clinical trials were launched for AmnioFix injectable which is subject to enforcement discretion.

Legal matters are near conclusion with a majority of 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	**$12.87**
52-Week Low	**$3.30**
One-Year Return (%)	**168**
Beta	**1.68**
Average Daily Volume (sh)	**548,672**
Shares Outstanding (mil)	**138.5**
Market Capitalization ($mil)	**1,410**
Short Interest Ratio (days)	**10.4**
Institutional Ownership (%)	**44.7**
Insider Ownership (%)	**3.89**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**10.1**
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 $US)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	$61.7 A	$53.6 A	$64.3 A	$68.5 A	$248.2 A
2021	$60.0 A	$61.3 E	$59.0 E	$59.1 E	$239.4 E
2022					$273.0 E
2023					$322.1 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-$0.04 A	-$0.08 A	-$0.18 A	-$0.15 A	-$0.46 A
2021	-$0.08 A	-$0.02 E	-$0.04 E	-$0.04 E	-$0.18 E
2022					$0.20 E
2023					$0.50 E

WHAT'S NEW

First Quarter 2021 Financial and Operational Results

On April 28, 2021, MiMedx Group, Inc. (NASDAQ: MDXG) filed its 1Q:21 Form 10-Q with the SEC and published a press release summarizing its financial and operational results for the quarter ending March 31, 2021. A conference call and webcast were held the following morning to communicate additional detail to analysts and investors. Highlights for 1Q:21 and to date include completion of final clinical visits for Phase III trials in plantar fasciitis (PF) and Achilles tendonitis (AT), completion of clinical effectiveness endpoint for the Phase IIb knee osteoarthritis (KOA) trial, increased penetration into group purchasing organizations (GPOs) and commercial payors, and investigational new drug application clearance of AmnioFix Injectable in chronic cutaneous ulcers. Since the beginning of the year, MiMedx has added to its roster with a new board member and senior vice president. Looking ahead, there is now certainty regarding enforcement discretion, which will conclude on May 31 of this year. While we expect a step down in revenues as a result, continued growth in the sales force, new products and deeper relationships with existing partners are expected to offset the decline on a full-year basis.

See our recent initiation on MiMedx for an in-depth discussion of MiMedx' technologies and products, our investment thesis, and discussion of recent events and milestones.

Revenues for the quarter were $60.0 million, representing a 3% decline from 1Q:20. The difference was attributable to changes in revenue recognition, decreases in elective procedures and cost saving measures by hospitals in response to the pandemic. Net loss per share was ($0.08) and net loss per share to common stockholders, which recognizes the dividend paid to Series B convertible holders, was ($0.09). These results compare to net loss of ($0.04) per share at the end of the first quarter 2020.[1]

For the first quarter ending March 31, 2021, compared to the first quarter ended March 31, 2020:

- Reported revenues were $60.0 million, down 2.9% from $61.7 million, driven by changes in revenue recognition from cash-based to as-shipped, access restrictions, decreases in elective procedures and cost-saving measures employed by hospitals as a result of the pandemic;
- Gross margin was 83.9% versus 83.8%;
- SG&A decreased 3.3% to $45.4 million from $46.9 million due to decreases in travel expenses;
- R&D expenses were $4.3 million, increasing 59% from $2.7 million driven by higher consulting fees and increased head count to support clinical and preclinical efforts;
- Investigation, restatement and related expenses decreased 54% to $7.2 million from $15.6 million as restatement activities concluded mid-2020;
- EBITDA was ($5.5) million compared with ($12.0) million. Adjusted EBITDA, as calculated by MiMedx, which excludes investigation and restatement costs, the impact of the change in revenue recognition and share based compensation was $3.2 million vs. $3.3 million
- Interest expense was ($1.5) million versus ($2.4) million with the decrease due to lower outstanding principal, stated interest rate, and amortization of deferred financing costs;
- Net loss was ($8.4) million versus ($4.8) million, or ($0.08) per share versus ($0.04) per share.

As of March 31, 2021, cash stood at $84.7 million compared to $53.5 million on March 31, 2020. Debt was carried on the balance sheet at $47.8 million and $65.4 million at end of first quarter 2021 and 2020, respectively.

Enforcement Discretion

FDA Enforcement discretion has allowed manufacturers of certain Section 351 product to receive treatment similar to what Section 361 product receives until May 31, 2021. This product (AmnioFix Injectable and EpiFix Micronized) does not fall under Section 361 as it is considered more than "minimally manipulated" and therefore requires clinical studies and premarket approval prior to sale. The FDA has extended its period of enforcement discretion in the past, most recently as a result of the pandemic in July 2020. Until late April, it had been unclear if the FDA would provide another extension to manufacturers allowing marketing of the Section 351 product without FDA approval.

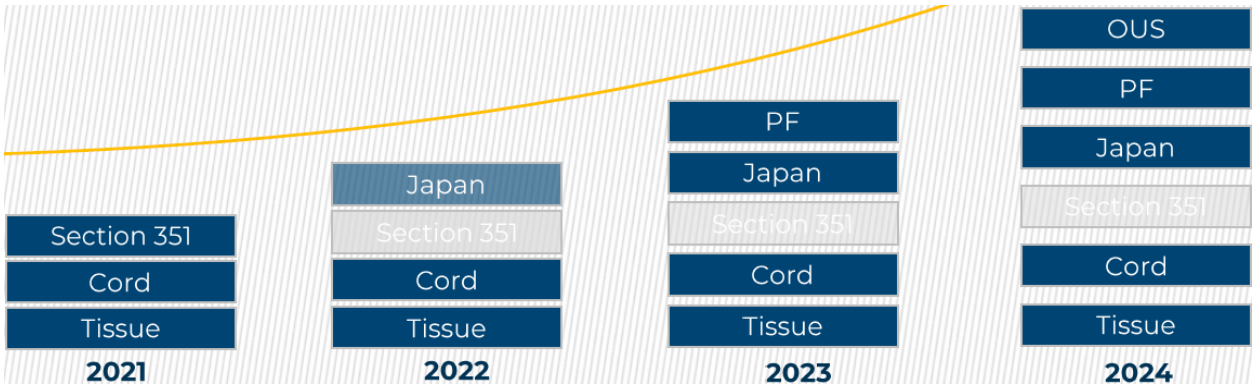
[1] Note that shares outstanding is calculated using shares provided on income statement whereas shares outstanding on page 1 include Series B convertible preferred stock as converted. Series B convertible preferred stock is only convertible into shares.

However, on April 21, 2021, the FDA communicated that the period of enforcement discretion would indeed cease on May 31st. Our initial estimates had already taken this into consideration.

2021 Expectations

With the additional clarity provided by the FDA's reaffirmation that enforcement discretion will cease, we anticipate near flat revenues in 2021 compared with the prior year levels. As we look at the impact to micronized products, there may be some pull forward of demand by physicians who want to complete treatment with existing patients and there may also be a shift in demand from the micronized products to sheet products tempering the anticipated decline. Counteracting the anticipated loss of this revenue component is increased penetration into existing GPOs and commercial payors. The sales team is adding personnel and demand for wound products, especially novel ones such as EpiCord expandable, is growing. Absent the impact from the conclusion of enforcement discretion, MiMedx has guided for 10% topline growth. In future years, we anticipate that growth will come from continued penetration of the core wound care business augmented by expansion into international markets including Japan and continued penetration into health plans and commercial payors. Research and development expenses will rise in 2021 to as much as 3x 2020 levels as efforts to advance the PF, KOA and early stage advanced wound care programs are expanded.

Exhibit I – Future Growth Drivers[2]



Last Patients, Last Visits

On April 19, 2021, MiMedx announced that three late stage trials in MiMedx' pipeline had achieved important milestones. All patients in the Phase III studies for AmnioFix Injectable in plantar fasciitis (PF) and Achilles tendonitis (AT) had completed their last clinical visits. The Phase IIb trial for AmnioFix Injectable in knee osteoarthritis (KOA) has completed all visits necessary to evaluate clinical effectiveness endpoints. Next steps for the programs include a planned review and statistical analysis of data for all three trials.

The PF, AT and KOA trials are evaluating AminoFix Injectable, which uses MiMedx' micronized dehydrated Human Amnion Chorion Membrane (mdHACM). Following completion of the planned review and statistical analysis of data, MiMedx expects to share topline data this summer and will begin planning a Phase III in KOA assuming data are supportive. A BLA is expected to be submitted for PF in 1H:22; however, due to trial design, a BLA for AT is not expected. Data from the AT trial will be used to support safety of the product. Next steps for the PF program include:

- Closing sites
- Cleaning the data
- Locking database
- Conducting statistical analysis
- Meeting with the FDA
- BLA submission

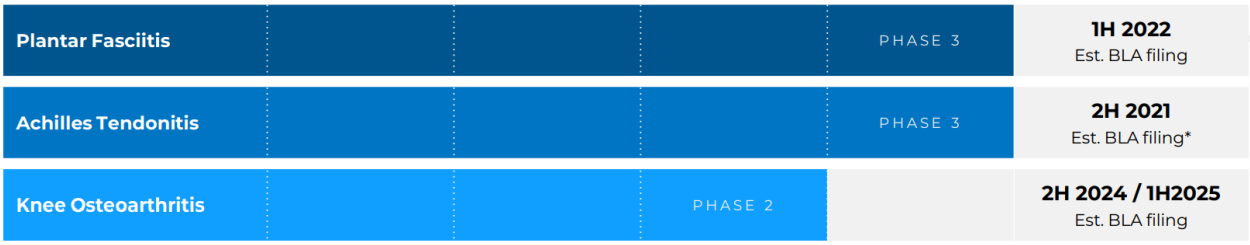
The KOA program is targeting a late 2024 or early 2025 BLA filing with the FDA. In parallel with regulatory submission in the US, we see similar efforts in other selected geographies, especially Japan, the United Kingdom and Germany.

[2] Source: MiMedx Corporate Presentation, March 2021.

Pipeline Summary

MiMedx has three clinical development programs underway in KOA, PF and AT. 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 on-going studies. We note that management has stated that it does not expect to submit a BLA for AT due to insufficient trial design, patient selection and powering to capture all elements of a clinical response in that indication.

Exhibit II - MiMedx Clinical Pipeline[3]



We anticipate seeing topline data for the PF, AT and KOA studies this summer. A BLA is expected in PF in about a year. Following an anticipated Phase III study, the KOA 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.

Premier's SURPASS Program

MiMedx was added to Premier Incorporated's Group Purchasing Agreement SURPASS (Synergizing for Unparalleled Results in Procurement and Strategic Sourcing) program in March. Members of the group are entitled to special pricing of MiMedx' placental-based tissue and wound products effective in the second quarter.

Company Milestones

- IND / IDE submission for multiple wound care indications – 1H:21
  - Chronic cutaneous ulcers (AmnioFix) – IND Cleared
  - Surgical incisions (AmnioFix)
  - Soft tissue defects (AmnioFill)
- Appointment of Phyllis Gardner, M.D. to Board of Directors – March 2021
- Last patient, last visit,
  - Phase III PF trial – April 2021
  - Phase III AT trial – April 2021
- Completion of primary and secondary observation visits, Phase II KOA trial - April 2021
- Appointment of Dirk Stevens, Ph.D., SVP, Quality Assurance and Regulatory Affairs – April 2021
- Anticipated conclusion of enforcement discretion – May 2021
- Completion of registration process in Japan – mid-2021
- FDA meeting on KOA – mid-2021
- Last patient visit for Phase II KOA trial – 2H:21
- BLA filing for PF – 1H:22
- KOA Phase III trial initiation – 1H:22
- BLA submission for KOA – 2H:24 / 1H:25

[3] Source: MiMedx Corporate Presentation, March 2021.

Prescience Point Capital Management Board Nominations

Prescience Point Capital Management recently announced that it will nominate four directors to the MiMedx board at the 2021 Annual Meeting. The Louisiana-based asset manager owns ~8.1% of the shares outstanding. When accounting for the Series B Convertibles and adjusting for their ultimate conversion to equity, ownership drops to ~6.6%. Prescience contends that EW Healthcare's interest may conflict with those of other shareholders and that MiMedx management has not provided sufficient information regarding the opportunities for AmnioFix in KOA.

We remind investors that data is not yet available for the Phase II study in KOA and that even if favorable information is generated and AmnioFix progresses to Phase III, there remain many hurdles to cross, including the approval of a BLA before commercialization may begin. Based on several independent studies that have been conducted on clinical trial success rates, only about half of products that enter Phase III are eventually approved, supporting a conservative stance by management at the current stage of development.

Prescience disagrees with other efforts and initiatives taken by management which can be found in a news release and letter to shareholders made public on April 16, 2021. If all four of Prescience's board members were added, they would hold four of nine seats (44% representation), compared with their 6% ownership adjusting for Series B conversion. MiMedx acknowledged the receipt of the director nominations in an April 16 press release.

MiMedx' largest holder is Essex Woodlands Health Ventures (EW Healthcare), which, on an as converted basis owns about ~17% of shares outstanding. As a condition of their investment, they have secured the right to appoint two directors to the board as long as they hold in excess of 10% of the shares in equity or on an as-converted basis. The board members appointed by EW Healthcare are Martin P. Sutter and William A. Hawkins, III.

Excluding holdings by Vanguard, the only other holder above 2% is RTW Investments with a 2.4% interest (2.0% with Series B conversion). While Vanguard is reported to hold over half the shares outstanding, we believe this may be inflated by shares owned by individual investors held in Vanguard's name.

Summary

MiMedx has navigated a difficult period over the last several years with both endogenous and exogenous factors negatively impacting revenues and expenses. While we do expect one more hurdle to overcome related to the end of enforcement discretion, there are many positive factors that can drive growth in 2022. New indications and products, international expansion, an increase in the sales force, and fulfilling unmet need will all help increase penetration in wound care and other off-label indications.

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

There are numerous positive, near-term catalysts related to clinical studies taking place for PF, AT, KOA and advanced wound care indications. The company's largest opportunity in KOA is targeted to be approved by 2026, but could occur sooner due to the expedited treatment RMAT-designated projects receive. MiMedx is in the process of filing investigational new drug (IND) and investigational device exemption (IDE) packages in advanced wound care applications and we expect research and development efforts to increase in 2021.

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. We maintain our price target of $16.00 per share.

Key reasons to own MiMedx shares:

- **Existing high margin business in placental and umbilical cord tissue products**
- **Products recognized by payors**
  - **EpiFix on largest US health insurer formulary for diabetic foot ulcers (DFU)**
  - **EpiCord added as medically necessary option for DFU by large national commercial payor**
  - **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**
  - **Multiple preclinical advance would care development projects**
    - **First IND for chronic cutaneous ulcers cleared (AmnioFix)**
- **Investigation and expenses related to prior management misconduct are largely complete**

PROJECTED FINANCIALS

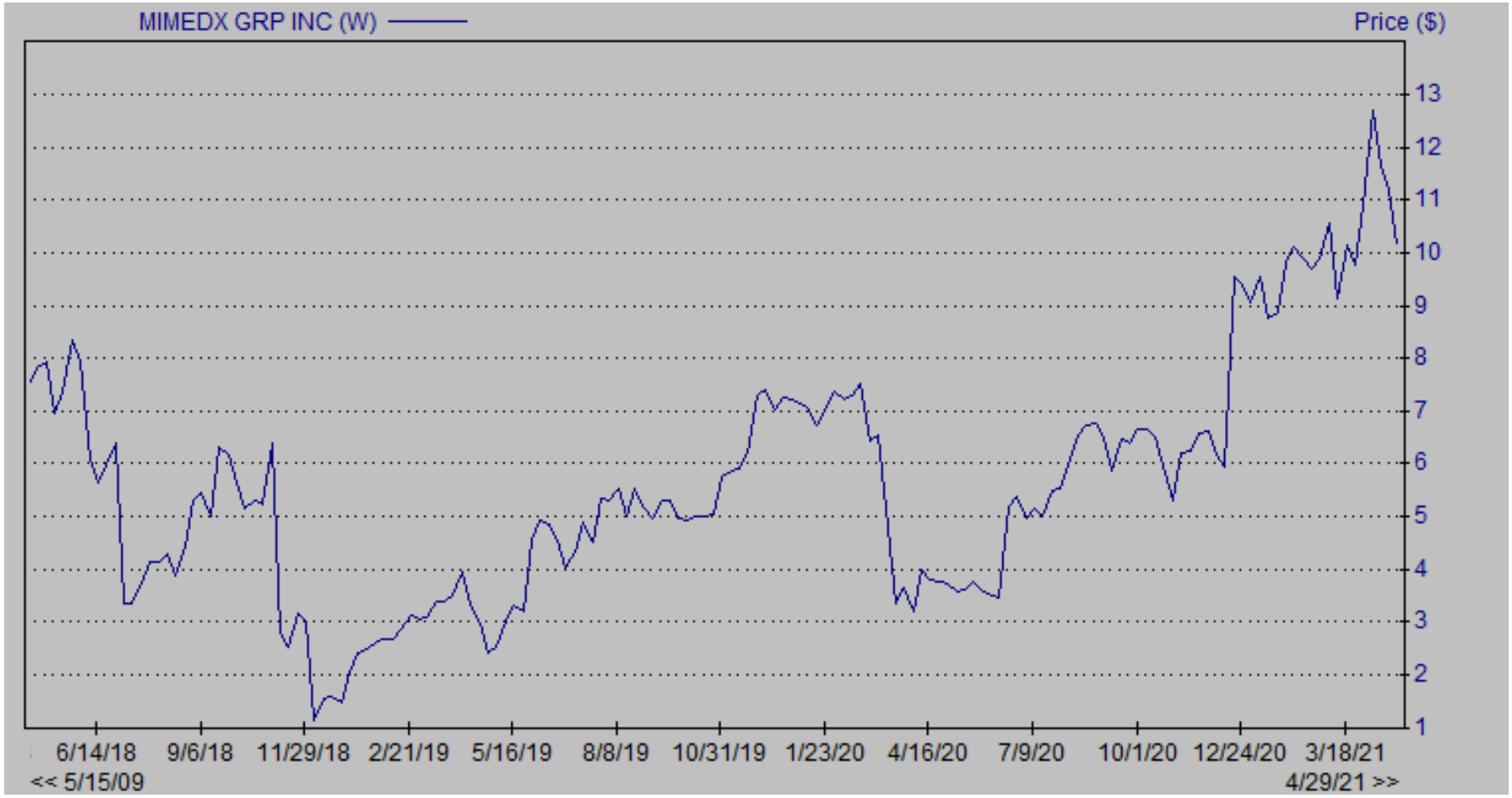
MiMedx Group, Inc. - Income Statement

MiMedx Group, Inc.	2020 A	Q1 A	Q2 E	Q3 E	Q4 E	2021 E	2022 E	2023 E
Total Revenues ($US '000)	**$248,234**	**$59,967**	**$61,300**	**$59,050**	**$59,120**	**$239,437**	**$272,958**	**$322,091**
YOY Growth	-17%	-3%	14%	-8%	-14%	-4%	14%	18%
Cost of Goods Sold	$39,330	$9,641	$9,808	$9,448	$9,459	$38,356	$43,673	$51,535
Product Gross Margin	84.2%	83.9%	84.0%	84.0%	84.0%	84.0%	84.0%	84.0%
Selling, general & administrative	$181,022	$45,404	$40,000	$41,000	$43,000	$169,404	$170,000	$171,700
Investigation, restatement etc.	$59,465	$7,196	$4,000	$2,000	$0	$13,196	$0	$0
Research & development	$11,715	$4,339	$9,250	$9,880	$10,325	$33,794	$25,000	$20,000
Amortization of intangible assets	$1,073	$239	$272	$272	$272	$1,055	$1,088	$1,088
Impairment of intangible assets	$1,027	$0	$0	$0	$0	$0	$0	$0
Income from operations	($45,398)	($6,852)	($2,030)	($3,550)	($3,936)	($16,368)	$33,197	$77,768
Operating Margin	-18%	-11%	-3%	-6%	-7%	-7%	12%	24%
Interest income, net	($7,941)	($1,472)	($875)	($875)	($875)	($4,097)	($3,500)	($3,500)
Other income, net	($8,204)	$0	$0	$0	$0	$0	$0	$0
Pre-Tax Income	($61,543)	($8,324)	($2,905)	($4,425)	($4,811)	($20,465)	$29,697	$74,268
Provision for Income Tax	$12,259	($58)	$0	$0	$0	($58)	$0	$0
Tax Rate	-19.9%	0.0%	0.0%	0.0%	0.0%	0.3%	0.0%	0.0%
Net Income	**($49,284)**	**($8,382)**	**($2,905)**	**($4,425)**	**($4,811)**	**($20,523)**	**$29,697**	**$74,268**
Net Margin	-20%	-14%	-5%	-7%	-8%	-9%	11%	23%
Reported EPS	**($0.46)**	**($0.08)**	**($0.02)**	**($0.04)**	**($0.04)**	**($0.18)**	**$0.20**	**$0.50**
YOY Growth		70.9%	-74.4%	-78.9%	-73.5%	-61%	-215%	147%
Basic Shares Outstanding	108,257	109,401	115,000	117,200	119,320	116,130	120,243	135,258
Fully Diluted Shares	108,257	141,924	145,000	147,200	149,320	145,861	146,280	148,193

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

HISTORICAL STOCK PRICE

MiMedx Group, Inc. – Share Price Chart



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