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MiMedx Group, Inc. (MDXG - NASDAQ)

2Q:21 Update

Based on our multiple of earnings model and a 20% discount rate, MiMedx target price is approximately $17.00 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 (8/4/21)	$11.89
Valuation	**$17.00**

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 in these indications which was subject to enforcement discretion prior to June 2021.

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

We forecast 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 to determine reimbursement.

SUMMARY DATA

52-Week High	**$13.02**
52-Week Low	**$5.32**
One-Year Return (%)	**108**
Beta	**1.62**
Average Daily Volume (sh)	**826,134**
Shares Outstanding (mil)	**138.7**
Market Capitalization ($mil)	**1,650**
Short Interest Ratio (days)	**5.37**
Institutional Ownership (%)	**51.2**
Insider Ownership (%)	**2.85**
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	$68.2 A	$60.0 E	$60.1 E	$248.3 E
2022					$283.1 E
2023					$334.0 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	-$0.01 A	-$0.07 E	-$0.06 E	-$0.22 E
2022					$0.26 E
2023					$0.57 E

WHAT'S NEW

Second Quarter 2021 Financial and Operational Results

On August 3, 2021, MiMedx Group, Inc. (NASDAQ: MDXG) filed its 2Q:21 Form 10-Q with the SEC and issued a press release summarizing its financial and operational results for the quarter ending June 30, 2021. A conference call and webcast were held the following morning to communicate additional detail to analysts and investors.

Highlights for the second quarter, ended June 30th, and to-date include:

- Last patient visits for MSK trials - April 2021
- Dirk Stevens, Ph.D. appointed SVP, Quality Assurance and Regulatory Affairs - April 2021
- Collaborative agreement with Wake Forest Institute - May 2021
- Regulatory approval for EpiFix in Japan - June 2021
- Study demonstrating dHACM ability to modulate scar tissue formation - June 2021
- Addition to Russell 3000 and 2000 indices - June 2021
- Cato Laurencin, MD, Ph.D., receives NAACP Spingarn Medal - July 2021

With the FDA's confirmation that enforcement discretion would conclude on May 31, 2021, we expect a negative year over year impact from June onward that will be largely offset by organic growth of advanced wound care products and new launches such as EpiCord Expandable. Continued growth in the sales force and deeper relationships with existing partners are also expected to temper a decline on a full-year basis.

Revenues and net loss for the quarter were $68.2 million and ($1.78) million and net loss available to common stockholders was ($3.28) million. Net loss per share was ($0.01) and net loss per share to common stockholders, which recognizes the dividend paid to Series B convertible holders, was ($0.03). These results compare to net loss of ($0.08) per common share at the end of the first quarter 2020.[1]

For the second quarter ending June 30, 2021, compared to the same ending June 30, 2020:

- Reported revenues were $68.2 million, up 27% from $53.6 million, driven by easing of pandemic related restrictions that were in place in 2Q:20, positive impact from EpiCord Expandable which was launched in 3Q:20, growth in EpiFix sheet product and increases in Section 351 product;
- Gross margin decreased to 81.3% from 84.7% as a result of writedowns related to Section 351 product and higher manufacturing labor costs from overtime and additional contract work;
- SG&A increased 44% to $53.6 million from $37.3 million on $3.8 million in proxy contest costs, reinstatement of prior year executive salary reductions, higher commissions resulting from sales increases and increases in headcount for the sales team;
- R&D expenses were $4.06 million, increasing 80% from $2.26 million, rising on higher consulting fees, personnel costs, headcount and greater investment in preclinical studies;
- Investigation, restatement and related expenses were a benefit ($2.06) million vs $11.4 million. Director and officer insurance policies reimbursed company expenditures and negotiated reductions in previously-;
- Operating income was ($0.41) million vs ($5.86) million;
- Interest expense was ($1.37) million versus ($2.57) million;
- Net loss was ($1.78) million versus ($8.47) million, or ($0.02) per share versus ($0.08) per share;
- Net loss available to common stockholders was ($3.28) million vs ($8.47) million or ($0.03) and ($0.08).

As of June 30, 2021, cash stood at $85.0 million compared to $48.2 million on June 30, 2020. Debt was carried on the balance sheet at $47.9 million and $61.5 million at end of second quarter 2021 and 2020, respectively. Due to addbacks for share based compensation, depreciation, and builds in accounts payable and accrued compensation, cash of $2.9 million was generated from operations during the second quarter.

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

Cato T. Laurencin, MD. Ph.D., to Receive Historic NAACP Spingarn Medal

On July 14, 2021, MiMedx announced that the NAACP would present Dr. Cato Laurencin, member of MiMedx' Board, with its most prestigious honor, the Spingarn Medal. Dr. Laurencin is the Van Dusen Distinguished Endowed Professor at the University of Connecticut. Dr. Laurencin will be honored for his accomplishments in the fields of tissue regeneration, biomaterials, nanotechnology and regenerative engineering, a field that he founded. He received the Spingarn Medal at the NAACP's 112th Annual Convention. Dr. Laurencin is an International Fellow in Biomaterials Science and Engineering, received the Founders Award from the Society for Biomaterials, is the first surgeon in history to be elected to all four national academies[2] and has over 500 publications and patents. Dr. Laurencin also received the National Medal of Technology and Innovation.

dHACM Study - Scar Tissue Formation Modulation

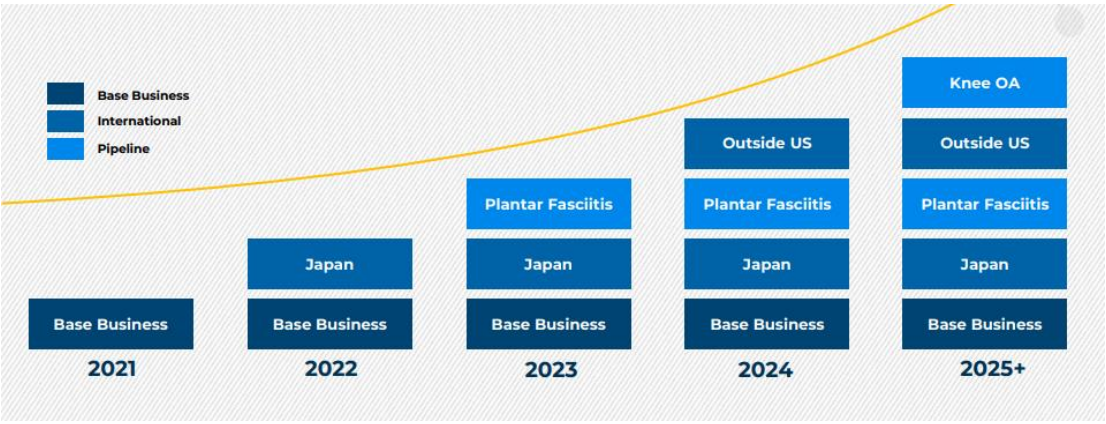
In a press release on June 15th, MiMedx announced the publication of a peer-reviewed study, "Dehydrated Human Amniotic Membrane Inhibits Myofibroblast Contraction through the Regulation of the TGFβ–SMAD Pathway In Vitro," by Moreno, Massee and Koob (2021). The paper was published in the *Journal of Investigative Dermatology* (JID) *Innovations*. The study addressed MiMedx' dHACM effect on complications resulting from excess fibrosis, which is central to a number of pathologies with unmet medical needs including hypertrophic and keloid scar formation. dHACM has been used for the treatment of wounds and has been associated with reduced scar tissue formation. The purpose of the study was to elucidate the underlying mechanism.

A common trait of fibrotic diseases is activation of ECM[3]- producing myofibroblasts that mediate fibrotic remodeling. An *in vitro* model of fibrosis was developed through stimulation of human dermal fibroblasts with TGF-β1, a profibrotic cytokine, to induce differentiation into myofibroblasts. Differentiation was confirmed by concomitant expression of alpha Smooth Muscle Actin and increased ECM deposition. These features are part of the normal healing cascade; however, prolonged TGF-β1 stimulation leads to pathological scarring. Introduction of dHACM into an *in vitro* model of sustained TGF-β1 resulted in the disruption of the TGF-β1 pathway, reducing expression of fibrotic factors and ECM components, implying myofibroblast activity modulation. Similar effects were also observed in an *ex vivo* model for cellular contraction where dHACM treatment reduced contractile capacity of stimulated fibroblasts embedded in collagen matrix down to near basal levels. The results from the study merit additional investigation in an *in vivo* study.

Regulatory Approval for EpiFix in Japan

EpiFix is MiMedx' dHACM allograft available in sheet configuration for the treatment of chronic wounds including diabetic foot ulcers, venous foot ulcers, pressure ulcers, and burns. On June 8th, MiMedx announced that EpiFix had received regulatory approval for commercialization in Japan from the Japanese Ministry of Health, Labor and Welfare (JMHLW), a milestone for MiMedx as it begins to look globally.[4] Pricing negotiations are expected to take place and conclude at the latest by mid-2022 after which first sales are expected.

Exhibit I - MiMedx Global Expansion[5]



[2] National Academy of Sciences, National Academy of Engineering, National Academy of Medicine and National Academy of Inventors
[3] Extracellular matrix
[4] MiMedx is currently targeting Japan and select countries in Europe, Asia Pacific and the Middle East in geographical expansion
[5] MiMedx Corporate Presentation June 2021.

In mid-2020, MiMedx submitted a pre-market approval (Shonin) to the JMHLW and an independent administrative agency the Pharmaceutical and Medical Device Agency (PMDA) that works with the JMHLW to ensure safety and quality of drugs and medical devices. In Japan, EpiFix is approved for hard-to-heal chronic wounds, such as diabetic foot ulcers, and venous leg ulcers that do not respond to conventional therapy, and will be classified as a Class IV medical device and Specified Biological Product under JMHLW guidelines.

MiMedx is now working with JMHLW to establish reimbursement pricing, which is expected to take up to six months. Once reimbursement pricing is approved and the reimbursement rate is listed, MiMedx may begin offering EpiFix to patients and providers in Japan.

Collaboration with Wake Forest Institute

MiMedx announced a collaboration with Wake Forest Institute for Regenerative Medicine (WFIRM) with focus on advancing regenerative science and developing innovative biologics that are safe and effective centered on MiMedx' amniotic tissue platform.

The WFIRM is an international leader in translating research and discovery into clinical therapies. WFIRM boasts many of the world's firsts including the first engineered organ implanted in a patient. The institute comprises over 400 people working on over 40 tissues and organs. WFIRM research has successfully produced engineered flat structures, tubular tissues, hollow organs and solid organs. The Institute's technology has been utilized in 15 different applications such as skin, urethra, cartilage, bladder, muscle, kidney and vaginal organs in human patients. In addition to the recently minted collaboration with MiMedx, WFIRM features collaborations with over 400 entities across the globe including government, academic, industry, and start-up entities.

Dirk Stevens, Ph.D. Appointed SVP, QA and Regulatory Affairs

Announced on April 28, 2021, MiMedx appointed Dirk Stevens its Senior Vice President, Quality Assurance and Regulatory Affairs, effective May 3, 2021. Dr. Stevens brings more than 35 years of strategic leadership experience in quality management and regulatory compliance, having served with multiple pharmaceutical and medical device companies. Stevens will apply his experience to quality improvement initiatives to MiMedx' late-stage pipeline. Among the companies that Stevens has worked with are Smith & Nephew, Fresenius Medical Care, Johnson & Johnson, Baxter Healthcare and Covidien. He earned his associate's at New Mexico Military Institute, his bachelor's in civil engineering at United States Military Academy, his MBA at Keller Graduate School of Management and his Ph.D. at Walden University. Dr. Stevens actively served in the US Army.

Enforcement Discretion

The FDA's enforcement discretion exemption had allowed manufacturers of certain Section 351 product to receive treatment similar to that of Section 361 product until May 31, 2021. MiMedx' AmnioFix Injectable and EpiFix Micronized fell into this category and were granted a dispensation under enforcement discretion. Following the end of the arrangement, marketing of these products is no longer allowed. AmnioFix Injectable and EpiFix Micronized are considered to be more than "minimally manipulated" and under the new guidelines require clinical studies and pre-market approval prior to sale.

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 on overall revenues, 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 a 10% topline increase and it was able to grow ongoing Advanced Would Care product by 29%, albeit off of a pandemic-impacted prior year quarter. 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. Based on the strong core revenue performance in 2Q:21, we increase our revenue estimates for 3Q:21 and 4Q:21 by approximately $1 million each.

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:

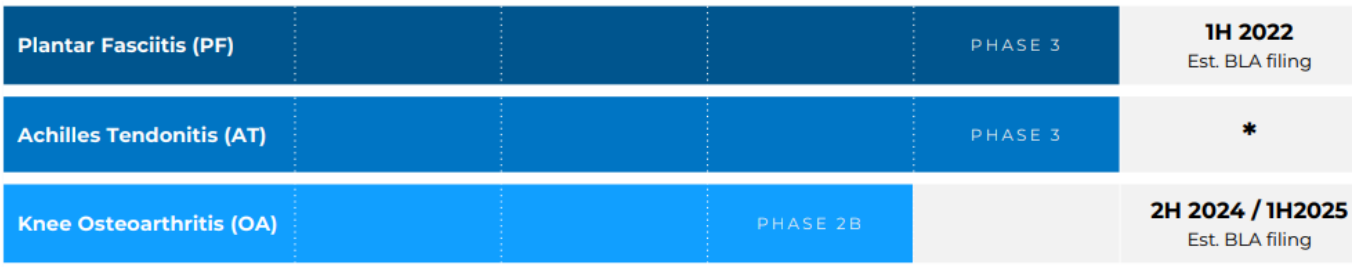
- Closing sites
- Cleaning the data
- Locking database
- Conducting statistical analysis
- Meeting with the FDA
- BLA submission

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.

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 ongoing studies. We note that management has stated that it does not expect to submit a BLA for AT due to inadequate trial design, patient selection and powering to capture all elements of a clinical response in that indication.

Exhibit II - MiMedx Clinical Pipeline[6]



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.

[6] Source: MiMedx Corporate Presentation, June 2021.

Company Milestones

- IND / IDE submission for multiple wound care indications – As of August 2021:
  - Chronic cutaneous ulcers (AmnioFix) - IND Cleared
  - Surgical incisions (AmnioFix) – IND Cleared
  - Soft tissue defects (AmnioFill) – IND Filed
- Appointment of Phyllis Gardner, MD to Board of Directors - March 2021
- Appointment of Dirk Stevens, Ph.D., SVP, Quality Assurance and Regulatory Affairs - April 2021
- Conclusion of enforcement discretion – May 31, 2021
- Regulatory approval for EpiFix in Japan – June 2021
- Spingarn Medal awarded to board member Dr. Cato T. Laurencin – July 2021
- Phase III PF trial completion – April 2021
  - Data validation, verification & database lock – June 2021
  - Final data analysis & generation of full data set – 2H:21
  - Pre-BLA meeting – following analysis in 2H:21
  - BLA filing – 1H:22
- Phase IIa KOA trial completion – April 2021
  - Final analysis & database lock – 2H:21
  - Final safety follow up – October 2021
  - Generation of full data set – 2H:21
  - End of Phase II meeting with FDA – 2H:21
- Analyst and investor R&D day – Late fall 2021
- Addition to NASDAQ Biotech Index – 4Q:21
- KOA Phase III trial initiation – 1H:22
- BLA submission for KOA – 2H:24 / 1H:25

Valuation

We increase our target price for MiMedx based on better than expected core revenues in the second quarter which we expect will carry through for the rest of the year and form a higher base for future revenue growth. Our valuation model employs a 25x multiple of 2026 EPS and a 17x multiple of 2026 EBITDA and discounts a blend of the two values using a discount rate of 20% to generate a one-year target price of $17.00. Based on second quarter results and our adjustments to estimates, 2026 EPS rises from $1.40 to $1.47 and 2026 EBITDA increases from $288 to $303 million.

Summary

MiMedx has navigated a difficult period over the last several years with both endogenous and exogenous factors negatively impacting revenues and expenses. With the end of enforcement discretion, there are many positive factors that are expected to drive growth in 2022 and beyond. New indications and products, international expansion, and an increase in the sales force 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 if expedited treatment is granted. MiMedx is in the process of filing and receiving clearance for 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 coming quarters.

MiMedx holds sufficient cash on its balance sheet 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 increase our price target to $17.00 per share.

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.

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 – approved, reimbursement in process**
  - **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

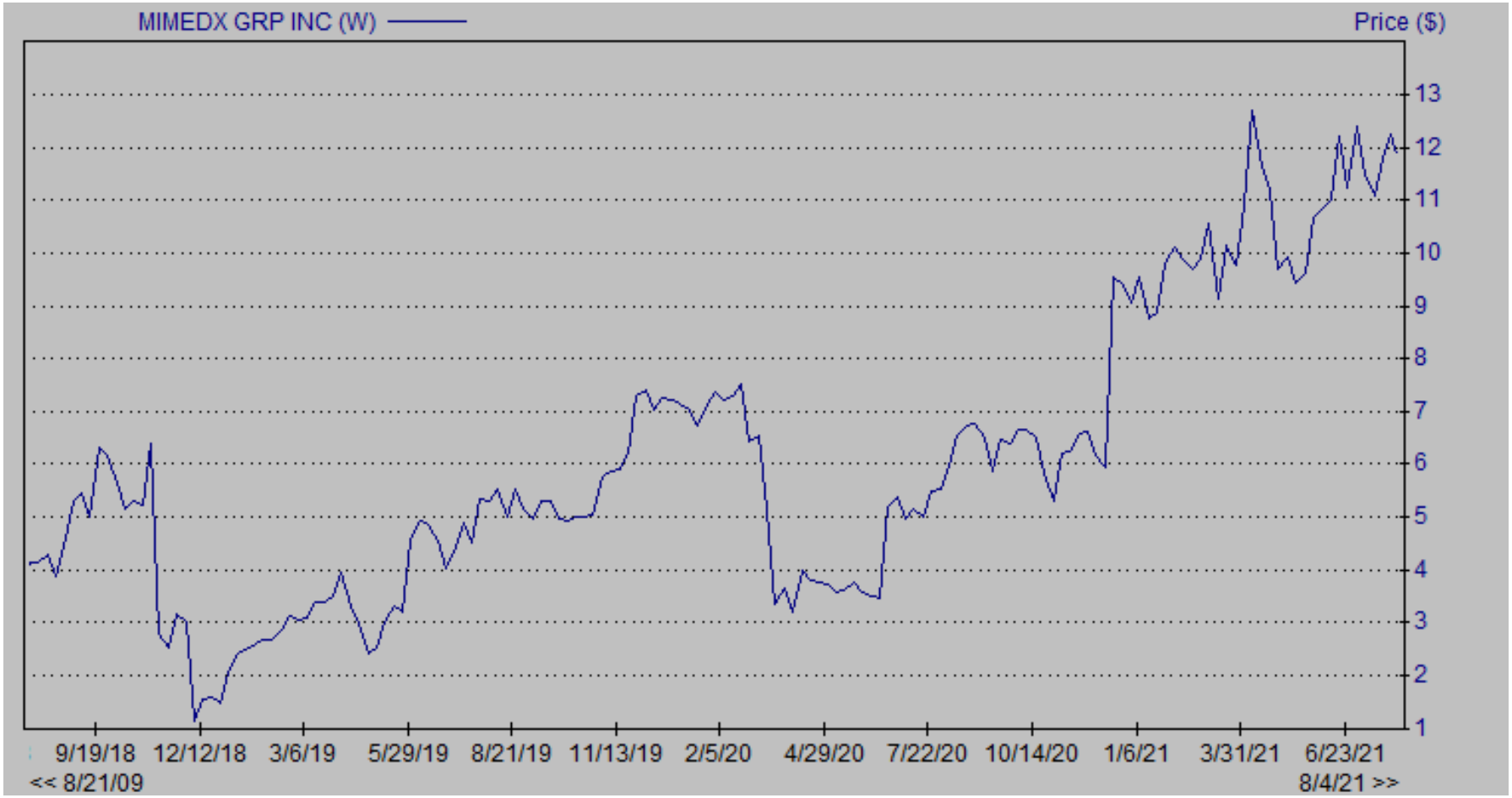
MiMedx Group, Inc. - Income Statement

MiMedx Group, Inc.	2020 A	Q1 A	Q2 A	Q3 E	Q4 E	2021 E	2022 E	2023 E
Total Revenues ($US '000)	**$248,234**	**$59,967**	**$68,165**	**$60,050**	**$60,120**	**$248,302**	**$283,064**	**$334,016**
YOY Growth	-17%	-3%	27%	-7%	-12%	0%	14%	18%
Cost of Goods Sold	$39,330	$9,641	$12,760	$10,809	$9,619	$42,829	$45,290	$53,443
Product Gross Margin	84.2%	83.9%	81.3%	82.0%	84.0%	82.8%	84.0%	84.0%
Selling, general & administrative	$181,022	$45,404	$53,599	$46,750	$46,820	$192,573	$170,000	$171,700
Investigation, restatement etc.	$59,465	$7,196	($2,062)	$1,000	$0	$6,134	$0	$0
Research & development	$11,715	$4,339	$4,063	$8,580	$9,325	$26,307	$25,000	$20,000
Amortization of intangible assets	$1,073	$239	$215	$272	$272	$998	$1,088	$1,088
Impairment of intangible assets	$1,027	$0	$0	$0	$0	$0	$0	$0
Income from operations	($45,398)	($6,852)	($410)	($7,361)	($5,916)	($20,539)	$41,686	$87,785
Operating Margin	-18%	-11%	-1%	-12%	-10%	-8%	15%	26%
Interest income, net	($7,941)	($1,472)	($1,371)	($875)	($875)	($4,593)	($3,500)	($3,500)
Other income, net	($8,204)	$0	($3)	$0	$0	($3)	$0	$0
Pre-Tax Income	($61,543)	($8,324)	($1,784)	($8,236)	($6,791)	($25,135)	$38,186	$84,285
Provision for Income Tax	$12,259	($58)	$5	$0	$0	($53)	$0	$0
Tax Rate	-19.9%	0.0%	0.0%	0.0%	0.0%	0.2%	0.0%	0.0%
Net Income	**($49,284)**	**($8,382)**	**($1,779)**	**($8,236)**	**($6,791)**	**($25,188)**	**$38,186**	**$84,285**
Net Margin	-20%	-14%	-3%	-14%	-11%	-10%	13%	25%
Reported EPS	**($0.46)**	**($0.08)**	**($0.01)**	**($0.07)**	**($0.06)**	**($0.22)**	**$0.26**	**$0.57**
YOY Growth		70.9%	-83.8%	-60.7%	-62.6%	-52%	-220%	118%
Basic Shares Outstanding	108,257	109,401	110,277	117,200	119,320	116,130	120,243	135,258
Fully Diluted Shares	108,257	141,924	140,277	147,200	149,320	144,680	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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