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MiMedx Group, Inc. (MDXG - NASDAQ)

2020 Revenues Beat Our Estimates

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 (3/9/21)	$8.95
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 has a development portfolio advancing assets in plantar fasciitis and knee osteoarthritis. Clinical trials were launched for 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	**$11.44**
52-Week Low	**$2.95**
One-Year Return (%)	**47.9**
Beta	**1.66**
Average Daily Volume (sh)	**1,026,266**
Shares Outstanding (mil)	**137**
Market Capitalization ($mil)	**1,226**
Short Interest Ratio (days)	**14.0**
Institutional Ownership (%)	**12.1**
Insider Ownership (%)	**6.4**
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)
2019	$66.6 A	$67.4 A	$88.9 A	$76.4 A	$299.2 A
2020	$61.7 A	$53.6 A	$64.3 A	$68.5 A	$248.2 A
2021					$240.5 E
2022					$274.1 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
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	-$0.15 A	-$0.46 A
2021					-$0.05 E
2022					$0.22 E

WHAT'S NEW

Full Year 2020 Financial and Operational Results

On March 8, 2021, MiMedx Group, Inc. (NASDAQ: MDXG) filed its 2020 form 10-K with the SEC and published a press release summarizing its financial and operational results for the year ending December 31, 2020. A conference call and webcast were held the following day to communicate additional detail to analysts and investors. Highlights for 2020 include relisting on the NASDAQ and completion of enrollment in multiple trials including the Phase III plantar fasciitis (PF), Phase III Achilles tendonitis (AT) and Phase IIb knee osteoarthritis (KOA) studies. The company also closed $150 million in private equity and debt financings, announced coverage by the largest US commercial payor for EpiFix, launched EpiCord Expandable and appointed multiple new executives. See our recent initiation on MiMedx for an in-depth discussion of these events.

Revenues of $248 million were reported for 2020, ahead of our $242 million estimate. This represents a 17% year over year decline attributable to COVID-related impacts, changes in revenue recognition, decreases in elective procedures and the side effect of cost savings implemented by hospitals related to the pandemic. Loss per share was ($0.46) compared with our estimate of ($0.35) with higher investigation and restatement expenses explaining the majority of the difference.[1]

For the fiscal year ending December 31, 2020, compared to the fiscal year ended December 31, 2019:

- Revenues were $248.2 million down 17% from $299.3 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 84.2% versus 85.6%, compressed by costs associated with cGMP compliance, mostly incurred in the second half of the year;
- SG&A was $181.0 million down 9% from $198.2 million, due to company response to the pandemic, temporarily reduced salaries, lower travel expenses and reduction in commissions;
- R&D expenses were $11.7 million increasing 5% from $11.1 million with the difference attributable to clinical research consulting fees;
- Investigation, restatement and related expenses decreased 11% to $59.5 million from $66.5 million as activities related to the investigation and restatement wind down;
- Interest expense was ($7.9) million representing amounts paid related to the BT Term Loan and the Hayfin Term Loan;
- Other expense included ($8.2) million loss on extinguishment of debt related to the repayment of the BT Term Loan
- Net loss was ($49.3) million versus ($25.6) million, or ($0.46) per share versus ($0.24) per share.

As of December 31, 2020, cash was $95.8 million compared to $69.1 million a year before. Debt, as carried on the balance sheet was $47.7 million and $65.7 million respectively as of year-end 2019 and 2020.

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 351 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 and could extend the period again. If enforcement discretion is withdrawn by the end of May, MiMedx' revenues could be impacted an estimated $20 to $25 million over the June to December period in 2021. We will maintain close watch on this developing situation and update our model as additional information becomes available. See our initiation for additional detail on items discussed in this section.

[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.

2021 Expectations

Absent the impact from the conclusion of enforcement discretion, MiMedx has guided for 10% topline growth. This will come from continued penetration of the core wound care business augmented by an increase in the sales force, potential expansion in to 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.

New Board Member

On March 8th, 2021, MiMedx announced the appointment of Phyllis Gardner, M.D. to the board of directors. Dr. Gardner is a professor of medicine at the Stanford University School of Medicine with 35 years' experience in a variety of business and academic roles. She has conducted research in cell biology and gene therapy and is widely published in the fields of cell biology and pharmacology. Dr. Gardner will help the company advance the scientific rigor of regenerative medicine that will improve the quality of treatment for patients.

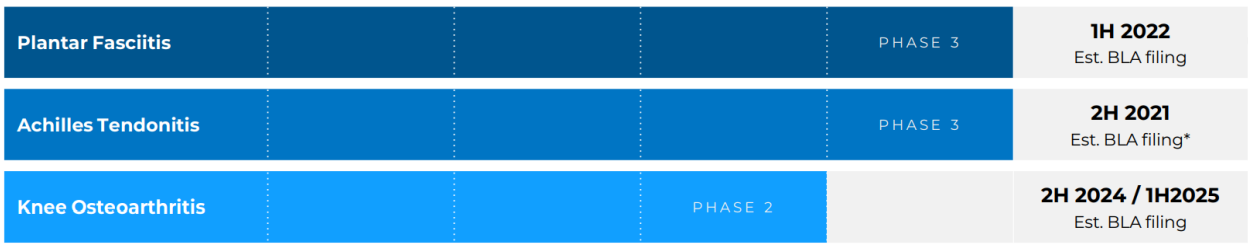
$150 Million Financing

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. 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% rate is eligible to decrease to 6.5% or 6.0% after December 31, 2020 if MiMedx is able to achieve certain leverage targets. It is accompanied by a one-year delayed draw term loan facility totaling $25 million that has not been drawn.

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.

Exhibit I - MiMedx Clinical Pipeline[2]



We anticipate that the Phase III PF and AT programs 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 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.

[2] MiMedx Corporate Presentation - February 2021

Upcoming Milestones

- Last patient visit, Phase III AT trial – 1H:21
- IND / IDE submission for multiple wound care indications – 1H:21
- Completion of primary and secondary observation visits, Phase II KOA trial - April 2021
- Anticipated conclusion of enforcement discretion – May 2021
- Last patient out, PF trial – 2Q:21
- 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 – 2022
- BLA submission for KOA – 2H:24 / 1H:25

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, 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 expecting to file investigational new drug (IND) and/or 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**
  - **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**
- **Investigation and expenses related to prior management misconduct are largely complete**

PROJECTED FINANCIALS

MiMedx Group, Inc. - Income Statement

MiMedx Group, Inc.	2019 A	Q1 A	Q2 A	Q3 A	Q4 A	2020 A	2021 E	2022 E
Total Revenues ($US '000)	**$299,255**	**$61,736**	**$53,647**	**$64,303**	**$68,548**	**$248,234**	**$240,470**	**$274,136**
YOY Growth	-17%	-7%	-20%	-28%	-10%	-17%	-3%	14%
Cost of Goods Sold	$43,081	$10,025	$8,198	$10,289	$10,818	$39,330	$38,475	$43,862
Product Gross Margin	85.6%	83.8%	84.7%	84.0%	84.0%	84.2%	84.0%	84.0%
Selling, general & administrative	$198,205	$46,942	$37,329	$48,046	$48,705	$181,022	$166,000	$170,000
Investigation, restatement etc.	$66,504	$15,592	$11,446	$12,027	$20,400	$59,465	$12,000	$0
Research & development	$11,140	$2,650	$2,259	$3,372	$3,434	$11,715	$37,955	$25,000
Amortization of intangible assets	$1,039	$271	$271	$276	$255	$1,073	$1,088	$1,088
Impairment of intangible assets	$446	$0	$0	$0	$1,027	$1,027	$0	$0
Income from operations	($21,160)	($13,744)	($5,856)	($9,707)	($16,091)	($45,398)	($1,960)	$35,274
Operating Margin	-7.1%	-22%	-11%	-15%	-23%	-18%	-1%	13%
Interest income, net	($4,708)	($2,387)	($2,574)	($1,472)	($1,508)	($7,941)	($3,500)	($3,500)
Other income, net	$283	$6	($9)	($8,200)	($1)	($8,204)	$0	$0
Pre-Tax Income	($25,585)	($16,125)	($8,439)	($19,379)	($17,600)	($61,543)	($5,460)	$31,774
Provision for Income Tax	$5	$11,304	($27)	($38)	$1,020	$12,259	$0	$0
Tax Rate	0.0%	-70.1%	0.3%	0.2%	-5.8%	-19.9%	0.0%	0.0%
Net Income	**($25,580)**	**($4,821)**	**($8,466)**	**($19,417)**	**($16,580)**	**($49,284)**	**($5,460)**	**$31,774**
Net Margin	-9%	-8%	-16%	-30%	-24%	-20%	-2%	12%
Reported EPS	**($0.24)**	**($0.04)**	**($0.08)**	**($0.18)**	**($0.15)**	**($0.46)**	**($0.05)**	**$0.22**
YOY Growth							-90%	-562%
Basic Shares Outstanding	106,946	107,539	108,119	108,493	108,868	108,257	116,130	120,243
Fully Diluted Shares	106,946	107,539	108,119	108,493	108,868	108,257	144,105	146,280

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

HISTORICAL STOCK PRICE

MiMedx Group, Inc. – Share Price Chart

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