



May 24, 2024

VIA EDGAR

United States Securities and Exchange Commission
Division of Corporation Finance, Office of Industrial Applications and Services
100 F Street, NE
Washington, DC 20549

Attention: Julie Sherman
Michael Fay

Re: MIMEDX GROUP, INC.
Form 10-K for the Fiscal Year Ended December 31, 2023
Filed February 28, 2024
Form 10-Q for the Quarterly Period Ended March 31, 2024
Filed April 30, 2024
File No. 001-35887

Ladies and Gentlemen:

This letter is submitted by MiMedx Group, Inc. (the “Company” or “MiMedx”) in response to your letter dated May 10, 2024, regarding the Company’s Annual Report on Form 10-K for the year ended December 31, 2023 (the “Annual Report”) and its Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 (the “Quarterly Report”). For ease of reference, the text of the Staff’s comments is included in bold, italicized text below, followed in each case by the Company’s response. Capitalized items used herein, if not otherwise defined herein, refer to the definitions of such terms in the Annual Report or Quarterly Report, as applicable.

Form 10-Q For the Quarterly Period Ended March 31, 2024

TELA and Regenity Agreements, page 17

1. ***You disclose the Company entered into an Asset Purchase Agreement with TELA to obtain exclusive rights to sell and market a 510(k)-cleared collagen particulate xenograft product in the United States pursuant to a pre-existing Manufacturing and Supply Agreement between TELA and Regenity, which retains all intellectual property rights and regulatory clearances related to the product. Simultaneously with entry into the TELA APA, the Company executed a new Manufacturing and Supply Agreement with Regenity, replacing the previous TELA-Regenity Supply Agreement. Please clarify for us, and in future filings as appropriate, your accounting and disclosure as it relates to the following:***
- ***Since you entered into a new supply agreement that replaced the pre-existing supply agreement, clarify why you do not consider the \$7.6 million as a transaction cost to enter into the new agreement;***

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The Company acknowledges the Staff's comment and respectfully advises the Staff that, in evaluating the structure of the transaction, it should be noted that it was the Company's belief that the acquisition of TELA's exclusive rights to sell and market an FDA-approved, 510(k)-cleared, collagen particulate xenograft product (the "Xenograft Product") pursuant to the original TELA-Regenity Supply Agreement was more economically beneficial than a potential multi-year investment towards developing its own, organic xenograft product. Currently, all of the Company's products are derived from donated human placenta and umbilical cords; the Company does not currently have an animal-derived product as part of its portfolio. In addition, the regulatory pathways for xenograft products differ from those available to the Company's existing placenta-based allograft products. Acquiring this right fulfilled a strategic priority for the Company, as noted by the Company's CEO in a press release announcing the transaction, by diversifying the Company's product offering beyond human-derived skin substitutes and by accelerating the addition of potential future xenograft products to the Company's portfolio.

The Company considered the appropriate accounting treatment for this transaction pursuant to Accounting Standards Codification ("ASC") 805. While there were certain other immaterial assets acquired pursuant to the TELA Asset Purchase Agreement (the "TELA APA"), including small amounts of inventory, the Company concluded that substantially all of the fair value of the assets acquired was concentrated in an intangible asset consisting of the exclusive rights acquired from TELA under the TELA-Regenity Supply Agreement. Consequently, the acquisition did not meet the definition of a business, as prescribed by ASC 805-10-55-5A, and was accounted for instead as an acquisition of assets under ASC 805-50. In light of this treatment, because the consideration was paid to TELA in exchange for the exclusive rights, the consideration conveyed as part of the TELA APA was capitalized amongst the various assets acquired, pro rata, based on the relative fair value of the assets acquired.

The TELA APA was executed by and between TELA and MiMedx alone. However, while negotiating the assignment of TELA's rights under the TELA-Regenity Supply Agreement to MiMedx, MiMedx re-negotiated certain of the terms of that agreement with Regenity and executed a revised Supply Agreement immediately following the execution of the TELA APA. MiMedx would not have executed the TELA APA if there had been no assurance that Regenity would agree to the revised terms of the Supply Agreement with MiMedx. That said, no consideration was paid by MiMedx to Regenity to revise the original terms of the TELA-Regenity Supply Agreement; and because no consideration was paid to Regenity and no expenses were incurred related to the revisions to the Supply Agreement, the Company assigned all consideration transferred to TELA to the assets acquired (primarily the intangible asset consisting of the exclusive rights under the Supply Agreement) in accordance with ASC 805-50.

- ***Clarify why you have not recorded the maximum profit share amount, how you will account for any future payments, and when you will record any future amounts due;***

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The Profit Share Payments under the TELA APA can be bifurcated into two components: (1) the \$3 million “Floor”, and (2) the \$4 million potential Profit Share Payments over and above the Floor. The Profit Share Payments are payable quarterly for two years following the first quarter of MiMedx’s first sale of the Xenograft Product. Profit Share Payments for each quarter are based on MiMedx’s net sales of the Xenograft Product during that quarter.

The Company evaluated each of these components against the GAAP definition of contingent consideration to determine the appropriate accounting treatment. Contingent consideration is defined as an obligation of the acquirer to transfer additional assets based on the resolution of specified future events.

With respect to the Floor, the payment of \$3 million is not contingent upon the resolution of future events as MiMedx has no practical ability to avoid the payment of \$3 million to TELA. Consequently, this \$3 million is reflected as a liability created on the transaction date, the fair value of which was calculated and added to the basis of the assets on the acquisition date.

With respect to the remaining \$4 million of potential Profit Share Payments, these payments will be made to TELA only to the extent that MiMedx generates sufficient sales of the Xenograft Product over the relevant period, as specified in the TELA APA. Because payment is contingent upon the occurrence of these sales, the Company concluded that this represents contingent consideration.

ASC 805-50 does not provide explicit guidance on the accounting for contingent consideration arrangements for an asset acquisition. Therefore, the Company plans to capitalize the contingent consideration payments when the contingency is resolved and the actual costs are known (i.e. when such payments are due and payable), similar to previous guidance that existed in Financial Accounting Standards Board (“FASB”) Statement 141, Paragraph 27.

Accordingly, the Company will reflect the liabilities incurred as these payments become due and payable with an associated increase in the value of the acquired assets. As of the acquisition date and the balance sheet date, these additional payments were not yet due and payable and, therefore, no liability has been recognized.

- ***Clarify the term of the TELA APA and your methodology for amortizing the \$7.6 million assigned cost; and***

MiMedx acquired rights under the TELA APA that were transferred to MiMedx immediately upon closing. While the term of the Company’s Supply Agreement with Regenity is through December 31, 2034, the Company is amortizing the \$7.6 million of contract asset over a five-year period, reflecting the period over which it expects future cash flows to be generated by the asset. The Company intends to disclose this in future filings.

- ***Clarify when you anticipate commercialization of the xenograft product to commence and whether you evaluated the recorded costs for recoverability before recording them as an asset.***

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The Company plans to begin sales of its version of the Xenograft Product by the third quarter of 2024 given that TELA had previously sold its version of the Xenograft Product in the United States prior to the execution of the TELA APA.

The remaining steps the Company is taking towards commercialization generally relate to product re-branding, including pricing, packaging and finalization of commercial strategy. The Company does not view these as being substantial hurdles prior to commercialization of the product (i.e., the technology is already commercially viable).

As noted above, the Company assessed the fair value of all assets acquired pursuant to the TELA APA. With respect to the exclusive rights, the Company used a discounted cash flow approach. On an undiscounted basis, these cash flows were sufficient to substantiate the recorded asset as required by the recoverability test in ASC 360-10-35-17.

In response to your comments, in future filings, the Company intends to enhance the previous disclosures in the footnotes to the consolidated financial statements regarding the acquisition of the exclusive distribution rights as follows:

On March 15, 2024, the Company entered into an Asset Purchase Agreement (the "TELA APA") with TELA Bio, Inc. ("TELA") to obtain exclusive rights to sell and market a 510(k)-cleared collagen particulate xenograft product in the United States. TELA held these rights pursuant to a Manufacturing and Supply Agreement (the "TELA-Regenity Supply Agreement") between TELA and Regenity Biosciences, Inc. ("Regenity"), which retains all intellectual property rights and regulatory clearances related to the product. Pursuant to the TELA APA, the Company paid \$5.0 million of initial consideration to TELA; additionally, the Company paid \$0.4 million to acquire TELA's remaining product inventory, and will be required to make additional payments (the "Profit Share Payments") of between a minimum of \$3.0 million and a maximum of \$7.0 million based on MIMEDX's net sales of the product over the two years following its commercialization of the product, which is expected to begin by the third quarter of 2024.

In connection with the execution of the TELA APA, the Company was able to renegotiate the terms of the TELA-Regenity Supply Agreement, ultimately replacing it with a new Manufacturing and Supply Agreement (the "Supply Agreement") with Regenity. The Supply Agreement maintains MIMEDX's exclusive right to sell and market the product in the United States.

The transaction was accounted for as an acquisition of assets, as substantially all the fair value of the acquired assets was concentrated in the acquired exclusive distribution rights. The cost to acquire the assets on the transaction date was \$8.1 million, reflecting the \$5.0 million of initial consideration, \$0.4 million to acquire inventory, and \$2.7 million, which represented the fair value of the minimum amount of the Profit Share Payments. These costs were allocated amongst the assets acquired. The Company assigned \$7.6 million to the distribution rights acquired and \$0.5 million to inventory. The amount ascribed to the distribution rights will be amortized over five years, generally reflective of the period of time over which the distribution rights are anticipated to contribute to cash flow generation.

Any Profit Share Payments exceeding the \$3.0 million minimum will be capitalized in the period incurred as part of the acquired assets and amortized over the remaining life of such assets.

Form 10-K for the fiscal year ended December 31, 2023

Financial Statements

13. Discontinued Operations, page 1

2. **Please provide us your analysis of how you determined that your disposal qualified as a strategic shift, as outlined in ASC 205-20-45-1B and 1C, in support of your discontinued operations accounting. Please identify and evaluate all relevant facts and circumstances. As part of your analysis, describe how you determined your Regenerative Medicine segment to be important to your operations and strategy, and a major part of your entity.**

The Company acknowledges the Staff's comment. ASC 205-20-45-1B and 1C stipulates that a disposal of a component of an entity shall be reported in discontinued operations if it reflects a strategic shift that has (or will have) a major effect on an entity's operations. The Company notes that there are no bright line tests for determining what represents a strategic shift and that this determination requires significant judgment.

The Company historically organized its business on the basis of two reportable segments: Wound & Surgical and Regenerative Medicine.

The Company's Wound & Surgical segment focused on the Advanced Wound Care and Surgical areas of healthcare through sales of the Company's existing product portfolio. Advanced Wound Care concerns the treatment of chronic wounds, defined and characterized as those that do not progress through the normal process of healing. Surgical applications range from involving the closure of an acute wound to those where our allografts are used inside the body to protect or reinforce tissues and/or regions of interest.

The Company's products that are used in these healthcare indications are generally regulated under Section 361 of the Public Health Services Act ("Section 361"). This regulatory pathway does not require any regulatory clearance from the FDA to sell products and, therefore, clinical trials are not conducted with the intention of achieving regulatory clearance. The Company actively sells these products in the United States.

The Company's Regenerative Medicine segment was singularly focused on research and development efforts associated with progressing the Company's micronized dehydrated human amnion chorion membrane ("mDHACM") in a specific indication of healthcare. Those indications of healthcare where the Company intended to sell mDHACM in the United States did not fall into either Advanced Wound Care or Surgical, as defined above; rather, the Company targeted degenerative musculoskeletal conditions as the primary use case for mDHACM, beginning with Knee Osteoarthritis. The Company believed that degenerative musculoskeletal conditions presented a significant potential source of value creation for the future.

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mDHACM did not meet all of the criteria for regulation solely under Section 361 and is regulated under Section 351 of the Public Health Services Act. This regulatory pathway required the Company to obtain a Biological License Application (“BLA”) with the FDA for a specific indication of health care. This required a series of clinical trials, which the Company was previously conducting. The Company was prohibited from selling and marketing mDHACM in the United States until a BLA was accepted by the FDA.

The Company does note that it had historically presented the activities of its Regenerative Medicine business prominently in various public filings. For example, in an October 26, 2017, press release, the Company announced that it had commenced clinical trials for its mDHACM product to advance its BLA initiative and indicated that the market opportunity for the use of its mDHACM product in General Tendonitis and Osteoarthritic Knee Pain exceeded \$12 billion. The status of these clinical trials and the status of the Company’s BLA efforts were given substantial discussion in the Company’s Annual Report on Form 10-K as of and for the year ended December 31, 2018, filed on March 17, 2020. In that same report, the Company indicated that FDA approval for mDHACM was a “strategic priority.” Slide presentations presented to investors and included in a Current Report on Form 8-K on September 21, 2020, included several pages providing updates to clinical trial timelines and indications as to the potential market for the Company’s mDHACM product.

The clinical trial results of mDHACM were material to the investing community and were summarized by the Company in a press release that was included in a Current Report on Form 8-K filed on September 13, 2021. The unfavorable trial results caused a significant reduction in the Company’s share price on the day of the announcement, evidencing the value that investors had placed on the Company’s execution of this strategy. This also led the Company to hold an Investor Day presentation and release a Letter to Shareholders on December 7, 2021, to analyze the root cause of the clinical trial results and to reaffirm the Company’s commitment to mDHACM as a significant element of the Company’s value creation.

Furthermore, the establishment of the Regenerative Medicine segment in 2022 reflected the strategic importance of these activities to the Company and the organization’s efforts to allow a division of the Company to singularly focus on advancing mDHACM, including through the oversight of a late-stage clinical trial to demonstrate safety and efficacy of the product. The establishment of the segment also led to the creation, for the first time, of an individual executive role, the head of the Regenerative Medicine business unit, reporting directly to the CEO, whose sole focus was to execute on the overall strategy of advancing mDHACM.

Between the creation of the Regenerative Medicine business unit and the subsequent decision to disband the Regenerative Medicine business unit, the Company announced a change in leadership. The Company separated from its previous CEO, as noted in a press release issued on September 6, 2022, and after a period of transition with an Interim CEO appointed a new, permanent CEO in January 2023, leading to a shift in strategic priorities and how management chose to pursue value creation.

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The Company's decision in the second quarter of 2023 to disband the Regenerative Medicine business unit reflects the abandonment of any effort to achieve regulatory clearance for mDHACM and any possibility of commercialization in the United States, and any potential value creation that could be derived from it. This decision enabled the Company to singularly focus on the portfolio of products which it currently has the ability to sell domestically and focus investment on products which could augment its existing portfolio. This was presented in a Current Report on Form 8-K filed on June 20, 2023, as a "strategic realignment," and it was noted that the change was intended to materially improve the Company's operating margins and free cash flow generation and provide much greater growth financing optionality. The Company also noted that the realignment provided it with the flexibility to explore opportunities to broaden its wound management offering, suggesting that the Company had formally pivoted toward wound care, indicating that investments which were previously earmarked toward research and development for mDHACM would be used for new product development and inorganic growth opportunities. This shift in strategy was further reinforced by the Company's TELA-Regenity transaction completed in March 2024.

The Company also notes that there are no bright line tests in determining whether the disposal of a component of the entity represents a "major effect." The Regenerative Medicine segment's results had historically represented a significant portion of the Company's overall net losses in 2022 and in the first quarter of 2023. The Company's loss from discontinued operations reflected 33.9% of the Company's overall net loss for the year ended December 31, 2022. For the six months ended June 30, 2023, loss from discontinued operations was \$11.1 million, compared to an overall net loss of \$3.8 million. Further, the research and development expenses incurred by the discontinued operations reflected 38.8%, 44.4%, and 42.7% of all of the Company's research and development expenses for the years ended December 31, 2023, 2022, and 2021, respectively.

The discontinued operation also contributed to cash outflows from operating activities, resulting in \$8.2 million and \$9.9 million of cash used in operating activities for the years ended December 31, 2023, and 2022, respectively. These outflows had a major effect on the consolidated cash provided by (used in) operating activities of \$26.8 million and \$(17.9 million) for the years ended December 31, 2023, and 2022, respectively.

As a result of the above factors, the Company concluded that the decision to disband Regenerative Medicine reflected a strategic shift which would have a major effect on its operations. In addition, the Company concluded that the run-off operations had materially ceased for Regenerative Medicine during the fourth quarter of 2023.

The Company intends to enhance its disclosures to include the following in future filings:

In the second quarter of 2023, the Company announced the disbanding of its Regenerative Medicine reportable segment and the suspension of its Knee Osteoarthritis clinical trial program. The announcement reflected the abandonment of the Company's efforts to pursue a Biological License Application for its micronized dehydrated human amnion chorion membrane product and a major definitive strategic shift in the Company's focus towards its continuing commercial pipeline as its primary source of value creation.

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The Company completed the regulatory obligations associated with the clinical trial during the fourth quarter of 2023, at which time material run-off operations had ceased and Regenerative Medicine met the criteria for presentation as a discontinued operation.

- 3. In addition, we note research and development for your Regenerative Medicine segment was \$14,993 and \$11,480 for 2022 and 2021 per your prior year segment footnote, and the corresponding amounts in your Discontinued Operations footnote are \$10,128 and \$7,412. Please reconcile for use the difference between the amounts.***

The Company acknowledges the Staff's comment and respectfully advises the Staff that the Regenerative Medicine segment results historically reflected certain expenses which were incurred by certain support departments and individuals that the Company retained following the announcement of the disbanding of the Regenerative Medicine business unit and are, therefore, reflective of the Company's ongoing operations. The differences primarily reflect payroll and compensation expenses related to employees whose responsibilities were not solely dedicated toward the activities of the Regenerative Medicine business unit.

Note 14. Income Taxes, page 2

- 4. We note your change in the determination of the likelihood of the realizability of certain of the Company's deferred tax assets based on the disbanded Regenerative Medicine segment qualifying as a discontinued operation, in concert with the Company's operating results. We note, though, significant operating losses and losses from continuing operations before income tax provisions in 2022 and 2021 remain after the application of discontinued operations accounting. We also note a cumulative three year loss from continuing operations before income tax provision remains after the application of discontinued operations accounting. Please explain to us in further detail how you overcame this negative evidence to support your conclusion that a valuation allowance is not needed for most of your deferred tax asset and how your analysis is consistent with ASC 740-10-30-16 through 30-25.***

The Company acknowledges the Staff's comment and respectfully advises the Staff that the Company considered the guidance provided by ASC 740-10-30-17, which requires an evaluation of all available positive and negative evidence when assessing the realization of deferred tax assets. The Company considered the guidance provided by ASC 740-10-30-21, which indicates that it is difficult to form a conclusion that a valuation allowance is not needed when there is negative evidence such as "cumulative losses in recent years."

In determining if the Company has "cumulative losses in recent years," the Company notes that ASC 740-10-30 does not define "cumulative losses in recent years" and that there is no authoritative definition of this term. Therefore, it was necessary for management to use judgment in determining whether the Company has negative evidence in the form of cumulative losses. In making that determination, management considered the Company's income or loss before income tax for the current year and the previous two years, adjusted for recurring permanent differences.



While the Staff correctly notes that a loss from continuing operations before income tax for the current period ended December 31, 2023, and previous two years of approximately \$1.2 million exists, after adding back permanent book-tax differences of approximately \$17 million, mostly attributed to nondeductible expenses related to meals and entertainment and to share-based compensation, the Company would be in a cumulative income position over the prior three years of approximately \$15.8 million.

The Company also assessed and determined that it did not have other examples of negative evidence provided in ASC 740-10-30-21.

Future realization of the Company's deferred tax assets depends on the existence of sufficient taxable income of appropriate character within the carryback, carryforward period available under the tax law. Given that some of our tax attributes, such as tax credits and some state net operating loss carryforwards have definite carryforward periods, the Company considered all four sources of taxable income under ASC 740-10-30-18 and determined that taxable income from future reversals of existing taxable temporary differences and future taxable income exclusive of reversing temporary differences and carryforwards (the only two sources available) will result in the majority of the existing deferred tax assets being realized within the next ten years, before any tax attributes expire. The Company has an immaterial valuation allowance of approximately \$0.9 million related to certain state tax credits that will not be realized.

The Company also performed a separate benchmarking analysis whereby, instead of basing future income on management estimates and projections, it developed an estimate of future taxable income projections on the historical cumulative income of \$15.8 million as adjusted for other nonrecurring items, resulting in estimated future taxable income of \$11.8 million per year, which would allow the Company to realize a benefit for substantially all of its deferred tax assets within the next 16 years, also before any tax attributes expire.

Based on the weighing of all available evidence, positive and negative, the Company concluded that a valuation allowance is not required as of December 31, 2023, other than the valuation allowance noted above for certain state tax credits.

In future Management's Discussion and Analysis of Financial Condition and Results of Operations sections of its public filings and the footnotes of the included financial statements, the Company intends to include the following disclosures:

Our effective tax rate for the year ended December 31, 2023, was significantly impacted by the reversal of a valuation allowance. In the period, the Company noted that it was no longer in a cumulative three-year loss on a continuing operations basis, after excluding the effects of permanent book-tax differences. The absence of such negative evidence, coupled with our expectation for future taxable income generation, led to the change in our assessment of the realizability of our deferred tax assets.



Should you have any questions or comments, please feel free to call me at (214) 435-1889.

Sincerely,

/s/Doug Rice

Doug Rice
CFO

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