

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
**FORM 10-K**

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2022

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission file number 001-35887

**MIMEDX GROUP, INC.**

(Exact name of registrant as specified in its charter)

**Florida**

(State or other jurisdiction of incorporation or organization)

**26-2792552**

(I.R.S. Employer Identification No.)

**1775 West Oak Commons Court, NE, Marietta, GA**

(Address of principal executive offices)

**30062**

(Zip Code)

**(770) 651-9100**

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None.

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	MDXG	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§223.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered accounting firm that prepared or its audit report

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

The aggregate market value of the registrant's voting common equity held by non-affiliates of the registrant as of June 30, 2022 (the last business day of the registrant's most recently completed second quarter) was approximately \$388.1 million based upon the last sale price (\$3.47) of the shares as reported on The Nasdaq Stock Market LLC on such date.

There were 114,083,096 shares of the registrant's common stock, par value \$0.001 per share, outstanding as of February 24, 2023.

#### **Documents Incorporated By Reference**

Portions of the proxy statement relating to the 2023 Annual Meeting of Shareholders, to be filed within 120 days after the end of the fiscal year to which this report relates, are incorporated by reference in Part III of this Report.

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## Table of Contents

<b>Item</b>	<b>Description</b>	<b>Page</b>
Part I		
Item 1.	Business	<a href="#">6</a>
Item 1A.	Risk Factors	<a href="#">24</a>
Item 1B.	Unresolved Staff Comments	<a href="#">47</a>
Item 2.	Properties	<a href="#">47</a>
Item 3.	Legal Proceedings	<a href="#">47</a>
Item 4.	Mine Safety Disclosures	<a href="#">47</a>
Part II		
Item 5.	Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	<a href="#">47</a>
Item 6.	[Reserved]	<a href="#">50</a>
Item 7.	Management’s Discussion and Analysis of Financial Condition and Results of Operations	<a href="#">50</a>
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	<a href="#">64</a>
Item 8.	Financial Statements and Supplementary Data	<a href="#">F- 1</a>
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	<a href="#">79</a>
Item 9A.	Controls and Procedures	<a href="#">79</a>
Item 9B.	Other Information	<a href="#">80</a>
Item 9C.	Disclosures Regarding Foreign Jurisdictions that Prevent Inspections	<a href="#">80</a>
Part III		
Item 10.	Directors, Executive Officers and Corporate Governance	<a href="#">80</a>
Item 11.	Executive Compensation	<a href="#">81</a>
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	<a href="#">81</a>
Item 13.	Certain Relationships and Related Transactions, and Director Independence	<a href="#">81</a>
Item 14.	Principal Accounting Fees and Services	<a href="#">81</a>
Part IV		
Item 15.	Exhibits, Financial Statement Schedules	<a href="#">82</a>
Item 16.	Form 10-K Summary	<a href="#">85</a>
	Signatures	<a href="#">86</a>

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## PART I

### Explanatory Note and Important Cautionary Statement Regarding Forward-Looking Statements

As used herein, the terms “MIMEDX,” “the Company,” “we,” “our” and “us” refer to MiMedx Group, Inc., a Florida corporation, and its consolidated subsidiaries as a combined entity, except where it is clear that the terms mean only MiMedx Group, Inc.

The following discussion should be read in conjunction with the financial statements and related notes contained elsewhere in this Annual Report. Certain statements made in this Annual Report are “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “**Securities Act**”), and Section 21E of the Securities Exchange Act of 1934, as amended. All statements relating to events or results that may occur in the future are forward-looking statements, including, without limitation, statements regarding the following:

- our strategic focus and our current business priorities, and our ability to implement these priorities, including as a result of our no longer being able to market our micronized products and certain other products;
- our expectations regarding our ability to fund our ongoing operations and future operating costs and the sufficiency of our liquidity and existing capital resources to implement our current business priorities;
- the advantages of our products and development of new products;
- our expectations regarding the size of potential markets for our products and any growth in such markets;
- our expectations regarding the regulatory pathway for our products, including our existing and planned investigative new drug application and pre-market approval requirements; current plans, designs, expected timelines, and expectations for success of our clinical trials; and our expectations regarding timing and receipt of necessary regulatory approvals for certain of our products including Biological License Applications (“**BLAs**”);
- our expectations regarding ongoing regulatory obligations and oversight and the changing nature thereof impacting our products, research and clinical programs, and business, including those relating to patient privacy;
- our expectations regarding our ability to procure sufficient supplies of human tissue to manufacture and process our existing and future products;
- our expectations regarding our ability to manufacture certain of our products in compliance with Current Good Manufacturing Practices (“**CGMP**”) in sufficient quantities to meet current and potential demand;
- our expectations regarding costs relating to compliance with regulatory requirements, including those arising from our clinical trials, pursuit of Investigational New Drug applications and BLAs, and CGMP compliance;
- the likelihood, timing, and scope of possible regulatory approval and commercial launch of our late-stage product candidates and new indications for our products.
- our expectations regarding government and other third-party coverage and reimbursement for our products;
- our expectations regarding future revenue growth;
- our belief in the sufficiency of our intellectual property rights in our technology;
- our expectations regarding future income tax liability;
- our expectations regarding the outcome of pending litigation and investigations;
- our expectations regarding the ongoing and future effects arising from the investigation conducted by the Audit Committee (the “**Audit Committee**”) of our Board of Directors (the “**Board**”) that concluded in May 2019 relating to allegations regarding certain sales and distribution practices at the Company and certain other matters (the “**Investigation**” or the “**Audit Committee Investigation**”), the restatement of our consolidated financial statements previously filed in our Annual Report for the year ended December 31, 2016, as well as selected unaudited condensed consolidated financial data as of and for the years ended December 31, 2015 (Restated) and 2014 (Restated), which reflected adjustments to our previously filed consolidated financial statements as of and for the years ended December 31, 2015 and 2014 (collectively, the “**Restatement**”), and related litigation;

- ongoing and future effects arising from the COVID-19 pandemic or other similar public health emergencies on our business, employees, suppliers and other third parties with whom we do business, and our responses intended to mitigate such effects;
- demographic and market trends; and
- our ability to compete effectively.

Forward-looking statements generally can be identified by words such as “expect,” “will,” “change,” “intend,” “seek,” “target,” “future,” “plan,” “continue,” “potential,” “possible,” “could,” “estimate,” “may,” “anticipate,” “to be” and similar expressions. These statements are based on numerous assumptions and involve known and unknown risks, uncertainties and other factors that could significantly affect our operations and may cause our actual actions, results, financial condition, performance or achievements to differ materially from any future actions, results, financial condition, performance or achievements expressed or implied by any such forward-looking statements. Factors that may cause such a difference include, without limitation, those discussed in Item 1A, *Risk Factors* in this Annual Report.

Unless required by law, the Company does not intend, and undertakes no obligation, to update or publicly release any revision to any forward-looking statements, whether as a result of the receipt of new information, the occurrence of subsequent events, a change in circumstances or otherwise. Each forward-looking statement contained in this Annual Report is specifically qualified in its entirety by the aforementioned factors. Readers are advised to carefully read this Annual Report in conjunction with the important disclaimers set forth above prior to reaching any conclusions or making any investment decisions and not to place undue reliance on forward-looking statements, which apply only as of the date of the filing of this Annual Report with the SEC.

### **Estimates and Projections**

This discussion includes certain estimates, projections and other statistical data. These estimates and projections reflect management’s best estimates based upon currently available information and certain assumptions we believe to be reasonable. These estimates are inherently uncertain, subject to risks and uncertainties, many of which are not within our control, have not been reviewed by our independent auditors and may be revised as a result of management’s further review. In addition, these estimates and projections are not a comprehensive statement of our financial results, and our actual results may differ materially from these estimates and projections due to developments that may arise between now and the time the results are final. There can be no assurance that the estimates will be realized, and our results may vary significantly from the estimates, including as a result of unexpected issues in our business and operations. Accordingly, you should not place undue reliance on such information. Projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk. See Item 1A, *Risk Factors* for further information.

## Item 1. Business

### Overview

MIMEDX is a pioneer and leader in placental biologics, developing and distributing placental tissue allografts with patent-protected, proprietary processes for multiple sectors of healthcare. The Company is focused on addressing unmet clinical needs in the areas of Advanced Wound Care (“**AWC**”), Surgical Recovery, and osteoarthritis. We derive our products primarily from human placental tissues and process these tissues using our proprietary methods, including the PURION® process. We employ Current Good Tissue Practices (“**CGTP**”), Current Good Manufacturing Practices (“**CGMP**”), and terminal sterilization to produce our allografts. MIMEDX provides products primarily for use in the wound care, burn, and Surgical Recovery sectors of healthcare. All of our products sold in the United States are regulated by the U.S. Food & Drug Administration (“**FDA**”), and to the extent we sell our products outside the United States, by other regulatory agencies in such international markets.

At MIMEDX, our vision is to advance regenerative science and innovative biologics that restore quality of life. Our mission is to improve people’s health and lives through innovation that makes healing possible. By advancing rigorous science and increasing access to evidence-based regenerative technologies, we elevate the standard of care. Our commitment to the highest quality standards maximizes our potential to reduce cost to the healthcare system and restore quality of life. Character, Customer Orientation, Innovation, Collaboration and Stewardship are our core values.

MIMEDX is a leading supplier of human placental allografts, which are human tissues that are derived from one person (the donor) and used to produce products that treat another person (the recipient). MIMEDX has supplied over two million allografts, through direct shipments. Our primary platform technologies include tissue allografts derived from human placental membrane (EPIFIX®, AMNIOFIX®, and AMNIOEFFECT®), tissue allografts derived from human umbilical cord (EPICORD® and AMNIOCORD®), and a particulate extracellular matrix derived from human placental disc (AXIOFILL®).

EPIFIX and EPICORD products are marketed for external use, such as in Advanced Wound Care applications, while our AMNIOFIX, AMNIOEFFECT, AXIOFILL, and AMNIOCORD products are positioned for use in Surgical Recovery applications, including lower extremity repair, plastic surgery, vascular surgery and multiple orthopedic repairs and reconstructions. We describe these in greater detail below under the heading “ - *Our Product Portfolio & Pipeline.*”

*2017 FDA Guidance.* The products we sell are regulated by the FDA. Generally, our products are regulated as Human Cells, Tissues and Cellular and Tissue – Based Products (“**HCT/Ps**”), which do not require pre-market clearance or approval by the FDA and are subject solely to Section 361 of the Public Health Service Act (“**Section 361**”) and related regulations. However, in November 2017 the FDA published a series of related guidance documents, including one 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*” (collectively, the “**Guidance**”), which established an updated framework for the FDA’s regulation of cellular and tissue-based products. Among other things, the Guidance clarified the FDA’s views about the criteria that differentiate those products subject to regulation solely under Section 361 (“**Section 361 HCT/Ps**”) from those cellular and tissue-based products considered to be drugs, devices, and/or biological products (“**Section 351 HCT/Ps**”) subject to licensure under Section 351 of the Public Health Service Act (“**Section 351**”) and related regulations.

*Effect of Guidance on Our Products.* Under the Guidance, we expect that the FDA will continue to regulate certain of our placental tissue products (EPIFIX, AMNIOFIX, EPICORD, AMNIOCORD, AMNIOBURN, AXIOFILL and AMNIOEFFECT) as Section 361 HCT/Ps so long as the claims we make for them are consistent with the Section 361 framework. Beginning in May 2021, the FDA began regulating certain of our other products, including our micronized dehydrated human amnion chorion membrane (“**mDHACM**”) products that we previously marketed in the United States as Section 351 HCT/Ps.

*Enforcement Discretion.* Under the Guidance, the FDA exercised enforcement discretion under limited conditions with respect to the Investigational New Drug (“**IND**”) application and pre-market approval requirements for certain HCT/Ps through May 31, 2021. We continued to market our micronized products (mDHACM) and our particulate product (AMNIOFILL) under this policy of enforcement discretion in the United States until May 31, 2021, while at the same time pursuing Biologics License Applications (“**BLAs**”) for certain of our micronized products in specific clinical applications. After May 31, 2021, we no longer sell our products that were impacted by enforcement discretion in the United States, and do not intend to sell such products in the United States until the FDA grants pre-market approval. As a result, we will only be able to market such products for indications that have been cleared or approved by the FDA. Similarly, we are engaged with the FDA regarding the classification of our umbilical cord products, EPICORD, EPICORD Expandable, and AMNIOCORD, which are tissue allografts derived from the structural, protective covering and extracellular matrix cushioning layers of the umbilical cord. If the FDA makes a final determination that our umbilical cord-derived products do not meet the requirements for regulation solely under Section 361, then, in order to continue to market the products, we would be required to obtain the appropriate FDA clearance or approval. In 2022, revenues from US sales of our umbilical cord-derived products were \$23.2 million. See discussion below in Item 1A, *Risk Factors* under the heading “*Certain of our products do not qualify for regulation as human cells, tissues and cellular and tissue-based products solely under Section 361 of the Public Health Service Act, which has*

resulted in removal of the applicable products from the market, made the introduction of some new tissue products more expensive, significantly delayed the expansion of our tissue product offerings and subjected us to additional post-market regulatory requirements. Additional regulatory requirements may be imposed in the future.”

## **Our History**

Our current business began on February 8, 2008 when Alynx, Co., our predecessor company, acquired MiMedx, Inc., a development-stage medical device company, the assets of which included licenses to two development-stage medical device technology platforms which we do not currently market. On March 31, 2008, Alynx, Co. merged into MiMedx Group, Inc., a Florida corporation and wholly-owned subsidiary that had been formed for purposes of the merger, with MiMedx Group, Inc. as the surviving corporation in the merger. In January 2011, we acquired all of the outstanding equity interests of Surgical Biologics, LLC (n/k/a MiMedx Tissue Services, LLC).

## **Current Business Priorities and Strategy**

We combine a large donor network developed over multiple years that sources donated birth tissue from consenting mothers, with our proprietary tissue manufacturing process and significant research and development expertise to develop innovative placental-derived products that address a wide range of chronic and acute health conditions affecting large patient populations.

Our core business delivers innovative products that help clinicians treat patients suffering from acute and chronic non-healing wounds. These wounds can be slow to respond or unresponsive to conventional treatments and may benefit from advanced treatments, such as our products, in order to support the healing process. The costs associated with treatment and management of patients with acute and chronic wounds is also high, with some estimates of the Medicare spend associated with such wounds approaching \$100 billion annually.

The treatment of chronic wounds is often referred to as wound care. Chronic wounds are defined and characterized as those that do not progress through the normal process of healing and remain open for over a month. Patients, typically in the elderly population, with conditions such as diabetes, obesity and other comorbidities, are among those with the highest risk of developing chronic wounds, which include diabetic foot ulcers (“*DFUs*”), venous leg ulcers (“*VLUs*”), and pressure ulcers, among others. Studies estimate that in 2022 roughly 2.1% of the U.S. population was affected by chronic wounds<sup>1</sup>. Complications from non-healing chronic wounds can result in significant, life-altering adverse outcomes, such as limb amputation. Today, up to one-fifth of diabetic patients who develop a DFU will require some form of amputation<sup>2</sup>. Further, patients who undergo a major lower extremity amputation have an increased five-year mortality rate that is comparable to and in some cases higher than many forms of cancer<sup>3</sup>.

Acute wounds are defined as those that are recent, are acquired from an incision or trauma and have yet to progress through the sequential stages of wound healing. Acute wounds can be caused accidentally or they can arise in the normal course of a wide-range of surgical procedures. When acute wounds present in patients with similar comorbidities to those of chronic wound patients, the risk of a slow or ineffective healing wound increases, and the risk of a surgical site infection or other similar complication increases for the patient. We refer to the combination of a wide variety of surgical procedures on patients with these comorbidities, who could thus see slow or ineffective healing, as the Surgical Recovery market.

Our strategy is to continue to deliver advanced products that serve patient needs within the Advanced Wound Care and Surgical Recovery markets and increase access to our products through clinical data generation and physician education. We estimate that the combined U.S. wound and surgical market for our products is currently \$2.0 billion (\$1.1 billion in wound; \$0.9 billion in surgical) and is largely under-penetrated<sup>4</sup>. We expect the U.S. wound and surgical market will grow at an annual rate of 7-10% over the next 3 to 5 years<sup>5</sup>.

The prevalence of both acute and chronic wounds has grown not only in the U.S. but also globally. While historically we have focused primarily on the U.S. market, we are now in the process of expanding our footprint internationally, most notably with the recent launch of our EPIFIX product in Japan. In 2021, we secured regulatory approval for EPIFIX in Japan followed by reimbursement approval in 2022. We also announced an exclusive distribution agreement with Gunze Medical Limited (“*Gunze Medical*”), a subsidiary of Gunze Limited, for sales of EPIFIX in the Japanese market, and expect to commence sales in the region in 2023. In Japan, EPIFIX is the first and currently the only amniotic tissue product approved for wound treatment across a broad range of conditions. We believe our first-mover advantage, favorable reimbursement rate, and strong distribution partner set us up for long-term success in this large and growing market.

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<sup>1</sup> GlobalData: 2022 Wound Care Management- Tissue Engineered Skin Subs U.S. Updated May 2022

<sup>2</sup> Five year mortality and direct costs of care for people with diabetic foot complications are comparable to cancer, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7092527/#CR1>

<sup>3</sup> Epidemiology and Risk of Amputation in Patients With Diabetes Mellitus and Peripheral Artery Disease, <https://www.ahajournals.org/doi/10.1161/ATVBAHA.120.314595>

<sup>4</sup> GlobalData Tissue Engineered-Skin Sub Data Model Wound Management Year 2020 – retrieved Sept 2021

<sup>5</sup> GlobalData Tissue Engineered-Skin Sub Data Model Wound Management Year 2020 – retrieved Sept 2021

Additionally, we have a regenerative medicine pipeline led by an injectable placental biologic product candidate, for which we are targeting an indication to help decrease pain and improve function in patients suffering from knee osteoarthritis (“*KOA*”), also known as degenerative joint disease of the knee. *KOA* is the most prevalent form of osteoarthritis and is a leading source of chronic pain and disability in the U.S. Our *KOA* program is in late-stage clinical trials and we are working toward the filing of a BLA in order to obtain regulatory approval for this product and a subsequent commercial launch in the U.S.

By incorporating a strategy to advance the scientific and therapeutic potential of placental tissue and rigorously demonstrate the clinical and economic effectiveness of our products, we believe we can differentiate the value of our portfolio and address multiple areas of significant unmet clinical need. We have focused our priorities on initiatives across our organization that position us to realize our commercial ambitions over the long-term while also generating a profitable, cash flow positive business capable of self-funding our future growth objectives.

### **Business Segments**

Beginning in the third quarter of 2022, the Company manages itself as two reportable segments: Wound & Surgical and Regenerative Medicine. Wound & Surgical focuses on the Advanced Wound Care and Surgical Recovery markets through the sale of the Company’s existing product portfolio and product development to serve these end markets. Its platform technologies include tissue allografts derived from human placental membrane (EPIFIX, AMNIOFIX, and AMNIOEFFECT), tissue allografts derived from human umbilical cord (EPICORD and AMNIOCORD), and a particulate extracellular matrix derived from human placental disc (AXIOFILL). This segment is also responsible for the international sales of the Company’s Section 351 products.

The Regenerative Medicine business focuses solely on Regenerative Medicine technologies, specifically progressing the Company’s placental biologics platform towards registration as an FDA-approved biological drug. mDHACM is the lead product candidate in its late-stage pipeline targeted at achieving FDA approval for specific clinical indications, including degenerative musculoskeletal conditions, beginning with *KOA*.

### **Our Product Portfolio & Pipeline**

We sell our placenta-based allograft products primarily under our own brands. We maintain strict controls on quality at each step of the manufacturing process beginning at the time of procurement. Our Quality Management System is focused on compliance with the American Association of Tissue Banks’ (“*AATB*”) standards and the FDA’s CGTP and CGMP regulations.

#### *EPIFIX*

EPIFIX is a protective barrier allograft comprised of dehydrated human amnion/chorion membrane that may be used in the treatment of chronic wounds, including diabetic foot ulcers (DFUs), venous leg ulcers (VLUs), and pressure ulcers. EPIFIX is available in an assortment of sheet configurations and sizes to accommodate various wounds.

MIMEDX also has a micronized version of this product that it no longer markets or sells in the United States, but does sell outside the United States. As further discussed below under the heading “*Government Regulation - 2017 FDA Guidance and Transition Policy for HCT/Ps*,” the FDA clarified in its 2017 guidance that it regards micronized amniotic membrane products as subject to FDA licensure as biological products under Section 351.

#### *AMNIOFIX*

AMNIOFIX is a protective barrier allograft comprised of dehydrated human amnion/chorion membrane that may be used in Surgical Recovery applications. AMNIOFIX is available in an assortment of sheet configurations and sizes for internal use, including in the areas of lower extremity repair, spine, orthopedic, sports medicine, gastrointestinal, urologic, and other general surgery applications.

#### *mDHACM*

mDHACM is a micronized form of AMNIOFIX, and supplied in powder form, reconstituted with 0.9% sterile saline for injection. This product is our lead BLA candidate. We completed four late-stage randomized controlled studies under open INDs, evaluating mDHACM in plantar fasciitis, Achilles tendonitis and *KOA*. While the *KOA* Phase 2B trial did not meet its primary endpoints, we initiated a post-Phase 2B registrational clinical trial for *KOA* in February 2023. For further details, see “*-Clinical Trials*” below.

#### *AMNIOBURN*

AMNIOBURN is a protective barrier allograft comprised of dehydrated human amnion/chorion membrane that may be used in the treatment of partial-thickness and full-thickness burns.

#### *EPICORD and AMNIOCORD*

EPICORD and AMNIOCORD are dehydrated human umbilical cord allografts that may be used to provide a protective environment for the healing process and are used in the areas of Advanced Wound Care and Surgical Recovery, respectively. These products are thicker than our amniotic membrane allografts and can be applied in deeper wounds or in areas where suturing the allograft in place may be advantageous.

EPICORD Expandable is an allograft derived from the umbilical cord, and can expand to twice its size, conforming to uneven surfaces and deep wounds. The thickness of the product allows for suturing as needed to keep the graft in place, and it provides healthcare professionals a new option to support the Advanced Wound Care needs of their patients with larger, chronic, and hard-to-heal wounds.

#### *AXIOFILL*

The Company launched AXIOFILL during the third quarter of 2022. AXIOFILL is an extracellular matrix derived from human placental disc, and is designed to provide a cost-effective human collagen scaffold that is conducive for use in large, complex wounds and those of irregular geometries. Our AXIOFILL product has seen initial adoption by clinicians primarily focused on Surgical Recovery applications.

#### *AMNIOEFFECT*

The Company also launched AMNIOEFFECT during the third quarter of 2022. AMNIOEFFECT is a tri-layer placental tissue allograft that contains amnion, intermediate layer, and chorion membranes. This product is designed to meet the needs of surgeons performing procedures where a more robust allograft with expansive size offerings is desired.

#### *AMNIOFILL*

The Company ceased marketing and selling AMNIOFILL in the United States in May 2021, following the end of the FDA's period of enforcement discretion. We have not yet initiated any clinical trials in furtherance of any regulatory approvals for this product.

#### *Antimicrobial Wound & Surgical Products*

In December 2022, we announced an in-licensing and distribution agreement with Global Health Solutions, Inc. (d.b.a. Turn Therapeutics or "**Turn**"), providing us with worldwide exclusive rights to Turn's proprietary antimicrobial technology platform, PermaFusion®, for the development of future products focused on Advanced Wound Care and Surgical Recovery applications.

PermaFusion® is petrolatum-based, liquid-in-oil suspension technology that involves the creation of nanodroplets without binding agents or emulsifiers and also includes a process to coat materials with antimicrobial-infused petrolatum. Turn's intellectual property estate includes "mixing" and "coating" intellectual property and provides protection up to 20 years. MIMEDX expects this technology to be included in the creation of a number of new antimicrobial products for the Wound & Surgical markets.

In addition to the exclusive license obtained to Turn's intellectual property, MIMEDX will acquire the commercial rights to Turn's FleX™ Antimicrobial Collagen Matrix product, contingent upon its receipt of FDA 510(k) clearance and other conditions. FleX™ is a bovine collagen powder product that incorporates antimicrobial properties to aid in the management of partial and full thickness wounds.

Under the terms of the agreement, MIMEDX has exclusive rights to develop future products for the wound care, burn, and surgical fields using Turn's intellectual property. Turn received an upfront cash payment from MIMEDX and is entitled to future payments upon completion of regulatory and product commercial milestones, along with royalties on the sales of products covered by the licensed intellectual property.

#### *OEM Products*

We sell a selection of allografts on an Original Equipment Manufacturer ("**OEM**") basis pursuant to an agreement under which we have granted a third party an exclusive license to some of our technology for use in dental applications. This agreement is concluding during 2023, after which we do not anticipate generating sales of our allograft products on an OEM basis.

We continue to research new opportunities for amniotic and other placental tissue, and we have additional offerings in various stages of conceptualization and development.

### **Placenta Donation Program**

We partner with physicians and hospitals to recover donated placental tissue. Through our donor program, a mother who delivers a healthy baby via Caesarean section can donate her placenta and umbilical cord tissue in lieu of having it discarded as medical waste. After consent for donation is obtained, a blood sample from each donor is tested for communicable diseases, and the donor is screened for risk factors in order to determine eligibility in compliance with federal regulations and AATB standards. We operate a licensed tissue bank that is registered as a tissue establishment with the FDA, and we are an accredited member of the AATB. All donor records and test results are reviewed by our Medical Director and staff prior to the release of the tissue for distribution.

We have developed a large, geographically diverse, network of hospitals across the United States that participate in our placenta donation program, and we employ a dedicated staff that work with these hospitals. We also utilize third-party providers of placenta donations on an as-needed basis to mitigate business risk. We believe that we will be able to obtain an adequate supply of tissue to meet anticipated demand for the foreseeable future.

### **Processing (Manufacturing)**

The Company has developed and patented a unique and proprietary technique (PURION) for processing allografts from the donated placental tissue. This technique specifically focuses on preserving the tissue's natural growth factor content and regulatory proteins, and maintaining the structure and collagen matrix of the tissue. Our patented and proprietary processing method employs aseptic processing techniques in addition to terminal sterilization for increased product safety. Despite starting with similar placental tissues, all placental tissue products and processing methods are not the same – we believe that our proprietary process preserves more of the natural beneficial characteristics of the tissue than the processes used by many of our competitors.

The PURION process produces an allograft that retains the tissue's inherent biological properties and regulatory proteins (including cytokines, chemokines, and growth factors) found in the placental tissue and produces an allograft that is safe and easy for healthcare providers to use. The allograft can be stored at room temperature and has a five-year shelf life. Each sheet allograft incorporates specialized visual markings that assist the health care practitioner with allograft placement and orientation.

To ensure the safety of human tissue products, the FDA enforces CGTP manufacturing regulations. We believe that MIMEDX has developed robust systems to comply with, and is in compliance with, these regulations. As an important part of the Company's product safety compliance, MIMEDX products are terminally sterilized to an internationally recognized industry standard in addition to having been processed *via* the PURION process.

Our facilities are subject to periodic unannounced inspections by regulatory authorities and may undergo compliance inspections conducted by the FDA and corresponding state and foreign agencies. We are registered with the FDA as a tissue establishment and are subject to the FDA's CGTP quality program regulations, state regulations, and regulations promulgated by various regulatory authorities outside the United States. The Company's September 2018 FDA inspection for compliance with CGTP regulations resulted in no observations and a no action indicated ("NAI") rating, which is the most favorable designation the FDA provides after an inspection. In December 2019, the FDA conducted CGMP inspections at our Marietta, Georgia, and Kennesaw, Georgia, processing facilities. The FDA issued a Form FDA 483 ("483"), which is a list of inspectional observations, at the conclusion of each inspection. Specifically, the FDA issued a 483 consisting of nine observations at our Marietta, Georgia processing facility, and a 483 consisting of 14 observations at our Kennesaw, Georgia processing facility. MIMEDX timely responded to the FDA regarding each observation, providing substantive responses to all of the observations. The Company's response included completed and planned actions to address each observation, and all of these remedial actions have been completed. The FDA classified its December 2019 inspection of our Kennesaw, Georgia facility as voluntary action indicated ("VAI"), which means objectionable conditions or practices were found in their December 2019 inspection but the agency is not taking or recommending any administrative or regulatory actions. The FDA also categorized its December 2019 inspection of our Marietta, Georgia facility as VAI. The Company believes it has made progress in its CGMP compliance and continued to make quality improvements through its quality plan.

### **Intellectual Property**

Our intellectual property includes owned and licensed patents, owned and licensed patent applications and patents pending, proprietary manufacturing processes and trade secrets, and trademarks associated with our technology. We believe that our patents, proprietary manufacturing processes, trade secrets, trademarks, and technology licensing rights provide us with important competitive advantages.

## *Patents and Patent Applications*

Due to the substantial expertise and investment of time, effort and financial resources required to bring new regenerative biomaterial products and implants to the market, the importance of obtaining and maintaining patent protection for significant new technologies, products and processes cannot be underestimated. As of the date of the filing of this Annual Report, in addition to international patents and patent applications, we own 68 U.S. patents related to our amniotic tissue technology and products, and 30 additional patent applications covering aspects of this technology are pending at the United States Patent and Trademark Office. The vast majority of our domestic patents covering our core amniotic tissue technology and products will not begin to expire until August 2027. Globally, the Company has over 200 issued and pending patents.

## **Market Overview**

Domestic sales currently account for substantially all of our revenue, and we are actively pursuing international expansion, primarily targeting Japan and select countries in Europe, Asia Pacific, and the Middle East. In the United States, our primary areas of clinical use include Advanced Wound Care and Surgical Recovery applications.

### *Advanced Wound Care*

The Advanced Wound Care market is comprised of products such as medical devices, advanced dressings, xenografts, biological products, and HCT/Ps, which are used as skin substitutes to treat severe wounds or chronic wounds that have not appropriately closed after four weeks of treatment with traditional or standard of care dressings. Not included in Advanced Wound Care are traditional wound care dressings, such as bandages, gauzes and ointments, which typically are used in the treatment of non-severe or non-chronic wounds.

In the United States, estimates indicate that in 2022 the prevalence of chronic wounds was 2.1% of the total U.S. population, or approximately 6.9 million people suffering from chronic wounds. Of these chronic wounds, approximately 58% or 4.0 million are categorized as chronic leg ulcers (which include DFUs and VLUs), with 47% treated with Advanced Wound Care dressings such as skin substitutes<sup>6</sup>. MIMEDX is a leader in the cellular tissue products/skin substitute segment of the Advanced Wound Care category and the amniotic tissue allograft sub-category. We expect these markets will continue to grow due to certain demographic trends, including an aging population, increasing incidence of obesity and diabetes and the associated higher susceptibility to non-healing chronic wounds. Furthermore, the increasing number of patients requiring advanced treatment represents a significant cost burden on the healthcare system. The overall cost of treating chronic wounds is rising sharply, and the current annual estimated cost in the United States exceeds \$28 billion<sup>7</sup>.

Traditional dressings such as bandages, gauzes and ointments, along with treatment of active infection and debridement, currently represent the “standard of care” for treating chronic wounds such as DFUs and VLUs. If, after four weeks of standard of care therapy, the wound has not responded appropriately or improved, clinical research has shown that advanced therapy such as a skin substitute can be beneficial as part of the patient’s treatment plan. However, often times advanced therapies are not employed due to current treatment guidelines, product access, or medical education around the clinical and economic benefits of advanced skin substitutes. We believe this represents a large opportunity for us to expand the market and drive initiatives resulting in market growth. According to data provided by BioMedGPS, MIMEDX’s EPIFIX is the current product of choice for physicians choosing to use an amniotic skin substitute product as a barrier or cover. Our EPIFIX and EPICORD products can be stored at room temperature for up to five years compared to certain other skin substitutes currently on the market that require cryogenic freezer storage, have limited shelf life, and may not be human-derived. In addition, we market multiple sizes of EPIFIX and EPICORD sheets for use as protective barriers, which enables a healthcare provider to select an appropriate size graft based on the size of the wound to reduce product waste. Our EPICORD and EPICORD Expandable product lines also offer an alternative treatment option to address larger, deeper wounds in a cost-effective way earlier in the treatment algorithm.

### *Surgical Recovery*

We are expanding beyond Advanced Wound Care into areas where the use of our tissue products could help reduce complications across several surgical specialties, including plastic surgery, general surgery, gynecology, urology, orthopedics, spinal surgery, lower extremity repair and sports medicine procedures. Collectively, we refer to these areas as the Surgical Recovery segment of the market. Certain surgical procedures can have an increased likelihood of complications such as dehiscence, adhesions, and others that may affect both the recovery of the patient and the outcome of the surgery. The rate of complications can depend on a number of factors, including the complexity of the procedure and patient specific issues, such as obesity, diabetes or advanced age.

In the Surgical Recovery setting, applications of our products are used to augment tissue, serve as a barrier membrane in procedures where scar tissue formation may be problematic or where a second surgery may be required, or aid in incisional

<sup>6</sup> GlobalData: 2022 Wound Care Management- Tissue Engineered Skin Subs U.S. Updated May 2022

<sup>7</sup> Chronic Wounds: Economic Impact & Costs to Medicare, <https://www.woundcareholders.org/news/studies-and-publications/chronic-wounds-economic-impact-costs-to-medicare>

closure with the goal of preventing or reducing procedural complications. Following a thorough review of surgical procedures and potential clinical applications across several specialties, we have identified those areas where we believe our tissue products could be incorporated. We are targeting certain procedures for use of our products based on unmet clinical need, potential procedural complication rate, clinical relevance, economic factors and overall business priorities. As in Advanced Wound Care, we believe this market is expanding as a result of demographic trends, including an aging population, increasing incidence of obesity and diabetes and the associated higher susceptibility to non-healing chronic wounds.

#### *AXIOFILL*

The Company launched AXIOFILL during the third quarter of 2022. AXIOFILL is an extracellular matrix derived from human placental disc, and is designed to provide a cost-effective human collagen scaffold that is conducive for use in large, complex wounds and those of irregular geometries. Our AXIOFILL product has seen initial adoption by clinicians primarily focused on Surgical Recovery applications.

#### *AMNIOEFFECT*

The Company also launched AMNIOEFFECT during the third quarter of 2022. AMNIOEFFECT is a tri-layer placental tissue allograft that contains amnion, intermediate layer, and chorion membranes. This product is designed to meet the needs of surgeons performing procedures where a more robust allograft with expansive size offerings is desired.

#### *AMNIOFIX*

AMNIOFIX is a semi-permeable, protective barrier allograft comprised of dehydrated human amnion/chorion membrane that may be used in Surgical Recovery applications. AMNIOFIX is available in an assortment of sheet configurations and sizes for internal use, including in the areas of lower extremity repair, spine, orthopedic, sports medicine, gastrointestinal, urologic, and other general surgery applications.

#### *International*

The Company is actively pursuing international expansion, with an initial focus on Japan. Estimates for 2022 indicate that within a total Japanese population of approximately 126 million people, there are approximately 629,000 chronic leg ulcers, 100,000 of which are potential candidates for an Advanced Wound Care product<sup>8</sup>. The Japanese population has the largest proportion of people 65 or older in the world, estimated to be approximately 36.2 million (28.8%) in 2020, increasing the potential need for healthcare products and services<sup>9</sup>. We believe these demographic trends, along with an increasing incidence of obesity and diabetes and the associated higher susceptibility to non-healing chronic wounds, present a significant unmet patient need and underpenetrated market opportunity.

MIMEDX received regulatory approval from the Japanese Ministry of Health, Labor and Welfare (“*JMHLW*”) in June 2021 to market EPIFIX in Japan, as the first amniotic tissue approved for hard-to-heal chronic wounds, such as DFUs and VLUs, which do not respond to conventional therapy. We secured reimbursement approval in September 2022, and are putting in place the necessary structure, medical education programs, and market development initiatives to operationalize our commercial strategy. In December 2022, we announced an exclusive distribution agreement with Gunze Medical for sales of EPIFIX in the Japanese market. Under the terms of the agreement, Gunze Medical and its team of dedicated sales representatives will work to distribute EPIFIX for clinicians to treat patients with hard-to-heal DFUs and VLUs across Japan. MIMEDX will be responsible for the supply of EPIFIX to Gunze Medical, which will sell the products locally, pursuant to the indications for use and reimbursement rates secured for the product. The parties will collaborate to continue physician education activities and drive further key opinion leader engagement in-country.

The Company is also evaluating opportunities for geographic expansion in the United Kingdom and certain other countries in Europe and the Middle East. Current efforts are focused on the collection of real-world evidence to support the development of patient treatment guidelines, health economic analysis, and product reimbursement in core markets.

#### *Biologics License Application (BLA) Programs*

In 2017, the FDA released guidance clarifying its views that certain cellular and tissue-based products, including certain products marketed by MIMEDX, are considered drugs, devices, and/or biological products subject to Section 351 requirements under the federal Food, Drug and Cosmetic Act (the “*FD&C Act*”). In order to conform to this regulatory guidance, MIMEDX is pursuing an indication under the BLA pathway, although there can be no assurance that we will obtain a BLA and we may ultimately decide not to pursue a BLA for this product or indication.

<sup>8</sup> GlobalData: 2022 Wound Care Management – Tissue Engineered Skin Subs, Japan, updated May 2022; management estimates

<sup>9</sup> Statistics Bureau of Japan, <https://www.stat.go.jp/english/data/handbook/c0117.html>

mDHACM is our lead BLA product candidate and we are currently focused on conducting a post-Phase 2B registrational clinical trial for the KOA market, which we initiated in February 2023. See *Clinical Trials*, below, for more information.

After oral non-habit forming pain medication fails to adequately relieve a patient's joint, ligament or tendon pain, market available injections such as corticosteroids and hyaluronic acid are commonly used treatment options. However, a number of patients still do not get adequate relief from these injections, or do not want to use corticosteroids for a variety of reasons. Additionally, in light of the crisis with opioid abuse, non-surgical treatments and alternative approaches to musculoskeletal pain management are under consideration. Patients and physicians are searching for new products that are safe and effective for the management of chronic and degenerative musculoskeletal conditions.

Osteoarthritis (“**OA**”) is a disease characterized by progressive articular cartilage destruction, ultimately leading to disabling pain and joint dysfunction. The knee is the most commonly affected joint and knee OA represents the leading cause of disability in the adult population. Estimates indicate that approximately 18 million people suffered from symptomatic knee osteoarthritis in 2022<sup>10</sup>, and this number is expected to increase to 19 million people by 2025<sup>11</sup>. According to the Arthritis Foundation, more than half of knee osteoarthritis sufferers are younger than 65 years old. Current treatment options include analgesics, non-steroidal anti-inflammatory drugs (“**NSAIDs**”), injectable corticosteroids, viscosupplements, platelet rich plasma, and other emerging therapies. Approximately 80% of symptomatic knee OA patients fail conservative therapy<sup>12</sup>. When conservative and non-operative treatment options fail, patients often consider surgical intervention. According to estimates by Global Data's United States Knee Reconstruction Model, approximately one million people required knee reconstruction surgery in 2022 with 2% needing bilateral knee replacement. Costs for knee replacement procedures can exceed \$55,000, on average. We believe there is significant unmet need for a non-surgical treatment option to reduce pain and improve function in patients suffering from knee osteoarthritis. Current estimates of the potential addressable market for mDHACM are dependent on many factors, including the results of our clinical trial program, recommended place in the knee osteoarthritis treatment algorithm, anticipated dosing regimen, as well as the potential for our clinical trials to demonstrate disease modifying characteristics which could further amplify the market opportunity. However, mDHACM has not yet been approved by the FDA for any such use.

## Marketing and Sales

Our direct sales team includes field sales representatives and field sales management, who call on hospitals, wound care clinics, physician offices, and federal health care facilities such as the Department of Veterans Affairs (the “**VA**”) and Department of Defense (“**DoD**”) hospitals. Our direct sales force focuses on the Advanced Wound Care and Surgical Recovery categories through multiple sites of service. We also maintain a network of independent sales agents that focus on Surgical Recovery applications leveraging the complementary products in their portfolios, and provide access to certain customers, as well as sales coverage for areas where we do not have a full-time sales representative.

We also sell our products through distributors. Distributors purchase products from us at wholesale prices and resell products to providers and end users. For example, in Japan, our distribution partner, Gunze Medical, purchases products from us and is responsible for sales to the end users for the approved indications of use and at the prevailing reimbursement rate for the product. See Note 12, *Revenue* to our consolidated audited financial statements included in Item 8 of this Annual Report.

## Coverage and Reimbursement

With the exception of government accounts, most purchasers of our products include physicians, hospitals, or ambulatory surgery centers (“**ASCs**”) that rely on reimbursement by third-party payers. Accordingly, our growth substantially depends on adequate levels of third-party reimbursement for our products from these payers. Third-party payers are sensitive to the cost of products and services and are increasingly seeking to implement cost containment measures to control, restrict access to, or influence the purchase of health care products and services. In the U.S., such payers include U.S. federal healthcare programs (e.g., Medicare and Medicaid), private insurance plans, managed care programs, and workers' compensation plans. Federal healthcare programs have prescribed coverage criteria and reimbursement rates for medical products, services, and procedures. Similarly, private, third-party payers have their own coverage criteria and negotiate reimbursement amounts for medical products, services, and procedures with providers. In addition, in the U.S., an increasing percentage of insured individuals are receiving their medical care through managed care programs (including managed federal healthcare programs) which monitor and may require pre-approval of the products and services that a member receives. Ultimately, however, each third-party payer determines whether and on what conditions they will provide coverage for our products, and such decisions often include each payer's assessment of the science and efficacy of the applicable product.

A portion of our products is purchased by U.S. government accounts (e.g., the VA and the Public Health Service, including the Indian Health Service), which do not depend on reimbursement from third-party payers. In order for us to be eligible to have

<sup>10</sup> GlobalData: 2022 Orthopedic Devices — Knee Reconstruction – US – 2015-2030

<sup>11</sup> GlobalData: 2020 Orthopedic Devices – Knee Reconstruction – US – 2015-2030

<sup>12</sup> GlobalData: 2020 Orthopedic Devices – Viscosupplementation – US – 2015-2030

our products purchased by such federal agencies and paid for by the Medicaid program, federal law requires us to participate in the VA Federal Supply Schedule (“*FSS*”) pricing program.

### *Medicare Coverage*

The largest third-party payer in the United States is the Medicare program, which is a federally-funded program that provides healthcare coverage for senior citizens and certain disabled individuals. The Medicare program is administered by the Centers for Medicare and Medicaid Services (“*CMS*”), an agency within the U.S. Department of Health and Human Services (“*HHS*”). Medicare Administrative Contractors (“*MACs*”) are private insurance companies that serve as agents of *CMS* in the administration of the Medicare program and are responsible for making coverage decisions and paying claims for the designated Medicare jurisdiction. There are seven Part A/B *MACs* in the U.S., which cover 12 unique geographical jurisdictions. Each *MAC* also has its own standards and process for determining coverage and reimbursement for a procedure or product. Private payers often follow the lead of governmental payers in making coverage and reimbursement determinations. Therefore, achieving favorable Medicare coverage and reimbursement is usually a significant gating factor for successful adoption of a new product or clinical application by private payers.

The coverage and reimbursement framework for products under Medicare is determined in accordance with the Social Security Act and pursuant to regulations promulgated by *CMS*, as well as the agency’s coverage and reimbursement guidance. In some cases, *CMS* does not specify coverage, leaving each of the *MACs* to determine whether and on what conditions they will provide coverage for the product. Such decisions are based on each *MAC*’s assessments of the science and efficacy of the applicable product. As noted below under the heading “Research and Development,” we have devoted significant resources to clinical studies to provide data to the *MACs*, as well as other payers, in order to demonstrate the clinical efficacy and economic effectiveness of our tissue technologies. As of the date of this report, both *EPIFIX* and *EPICORD* allografts are eligible for coverage by all *MACs*. In January 2019, *EPIFIX* and *EPICORD* received separate *CMS* HCPCS Codes, Q4186 and Q4187, distinguishing each product in coverage and reimbursement policies.

For Medicare reimbursement purposes, our *EPIFIX* and *EPICORD* allografts are classified as “skin substitutes.” Current reimbursement methodology varies between the hospital outpatient department (“*HOPD*”) and ASC setting versus the physician office. Currently, within the *HOPD* and ASC places of service, skin substitutes are reimbursed under a “packaged” or “bundled” methodology that provides a single payment for both the application of the product as well as the product itself. *CMS* classifies skin substitutes into low cost or high cost groups, based on a geometric mean unit cost and per day cost. For 2022, the geometric mean unit cost threshold applicable to both our *EPIFIX* and *EPICORD* allograft products was \$48 per square centimeter, and the per day cost threshold was \$949. For 2023, the geometric mean unit cost threshold applicable to both our *EPIFIX* and *EPICORD* allograft products was \$47 per square centimeter, and the per day cost threshold was \$949. The national *HOPD* average packaged (“bundled”) rate for our *EPIFIX* and *EPICORD* allograft products was \$1,549 in 2019, \$1,623 in 2020, \$1,715 in 2021, \$1,749.26 in 2022, and is \$1,725 in 2023. *CMS* assigns lower national rates to the ASC to reflect a less resource-intensive place of service. Revenue in the ASC setting constitutes less than 1% of the Company’s annual net sales. Medicare payments for most items and services, including *EPIFIX* and *EPICORD* sheet products, have been subject to sequestration reductions of approximately 2% periodically from 2013.

Currently, providers that administer *EPIFIX* or *EPICORD* allografts and other skin substitutes in the physician office setting are reimbursed based on the size of the graft, computed on a per square centimeter basis. The payment rate is calculated using the manufacturer’s reported average sales price (“*ASP*”) submitted quarterly to *CMS*. This payment methodology applies to physician offices, as well as places of service such as patient home, assisted living and nursing home. The Medicare payment rates are updated quarterly based on this *ASP* information for many skin substitute products but not all. *EPIFIX* and *EPICORD* are included on the Medicare national *ASP* Drug Pricing File. The published skin substitute Medicare payment rate established by statute is *ASP* plus 6%. Reimbursement for products not included on the Medicare national *ASP* Drug Pricing File are at the discretion of each *MAC*, which typically is invoice cost or wholesale acquisition cost (“*WAC*”) plus 6%.

Recently, several wide-ranging proposals have been published for public comment, including relating to payment methodology within the physician office, and are under consideration by the *CMS*. In addition, three *MACs* have recently published for public comment changes to their Local Coverage Determinations (“*LCDs*”) that they are considering. If adopted, these proposals would significantly change Medicare policies governing the reimbursement of skin substitute products principally when used for wound treatment in the private physician office setting. The *LCDs* in the proposals could adopt a new standard of clinical evidence required as a prerequisite to coverage. In addition, the proposals all require a confirmation that the products are regulated solely under Section 361 of the Public Health Service Act as a prerequisite to continued coverage. We have the required confirmation for *EPIFIX*, but not currently for *EPICORD*. The proposed *LCDs* also include language that could lower the number of allowed applications of a product below what is commonly used in standard practice by physicians today (supported by clinical evidence) and reflected by *LCDs* currently in force with the *MACs*. The Company as well as stakeholders across the wound care industry do not support lowering the applications.

### *Private Payers*

We have devoted considerable resources to clinical trials to support coverage and reimbursement of our products. An increasing number of private payers reimburse for EPIFIX and EPICORD in the physician office, the HOPD and the ASC settings, and we have complete national commercial coverage for the use of EPIFIX in the treatment of DFUs. Coverage and reimbursement vary according to the patient's health plan and related benefits. The majority of health plans currently provide coverage for EPIFIX and EPICORD for the treatment of DFUs, and many include treatment of VLUs. MIMEDX has secured payer coverage for over 300 million covered lives, allowing a significant number of patients access to our products. Information contributing to the coverage determination included a third-party technical brief (by the Agency for Healthcare Research and Quality ("**AHRQ**")) that evaluated a number of skin substitutes for treating chronic wounds, in which EPIFIX was noted to have the most Randomized Controlled Trials, a low risk of overall study bias, and statistically significant findings.

We have established and continue to grow a reimbursement support group to educate providers and patients with regard to accurate coverage and reimbursement information regarding our products, and plan to continue investing in clinical data supportive of coverage for our products in additional clinical areas of use.

### *Hospital Use*

Products administered in the hospital inpatient setting are bundled when submitted as part of the hospital's claim under a diagnosis-related group ("**DRG**"). In these cases, we continue to educate the hospital that our products are cost-effective, and have the potential to improve patient outcomes and reduce the length of stay. We are working to develop additional health economic data to support this effort. As noted above, the ability to sell products in a hospital is dependent upon demonstrating to the hospital the product's efficacy and cost effectiveness.

### **Seasonality**

Revenues during our fourth quarter tend to be stronger than other quarters because many hospitals increase their purchases of our products during the fourth quarter to coincide with the end of their budget cycles in the United States. Satisfaction of patient deductibles through the course of the year also results in increased revenues later in the year. In general, our first quarter usually has lower revenues than the preceding fourth quarter, the second and third quarters have higher revenues than the first quarter, and the fourth quarter revenues are the highest in the year.

### **Customer Concentration**

For the years ended December 31, 2022, 2021, and 2020, our net sales to all U.S. government accounts comprised approximately 2%, 3% and 5% of our net sales, respectively. See discussion below in Item 1A, *Risk Factors* under the heading "*A portion of our revenues and accounts receivable come from government accounts.*"

### **Competition**

Due to lower barriers of entry in the Section 361 HCT/P regulated market, competition in the placenta-based and allograft tissue field is intense and subject to new entrants and evolving market dynamics. Companies within the industry compete on the basis of price, ease of handling, logistics and efficacy. Another important factor is third-party reimbursement, which is difficult to obtain as it is a time-consuming and expensive process. We believe our success in obtaining third-party reimbursement, our strong position with group purchasing organizations, capabilities and investments to apply CGMP, and established clinical evidence for our products are competitive advantages.

In February 2020, the AHRQ published a technology assessment analyzing Skin Substitutes for Treating Chronic Wounds. AHRQ conducted a literature search yielding 164 studies and 81 Supplemental Evidence and Data for Systematic Reviews ("**SEADs**") submissions. Only 22 randomized, controlled trials ("**RCTs**") met the inclusion criteria to be reviewed in the AHRQ analysis, and out of the 22 RCTs MIMEDX had six RCTs included in the final brief. Of the 22 studies reviewed, only 12 were assessed as low risk of bias, of which five were MIMEDX RCTs. This important government assessment highlights our commitment to providing unbiased level 1 clinical evidence in advanced wound treatment. This dedication to elevating the standard of care is further underscored by the fact that the AHRQ points out in its assessment that MIMEDX was the only entity to provide two studies out of the 22 evaluated that performed a subgroup analysis of patients with DFUs that received adequate debridement. Both studies reported an increase in wounds healed with adequate debridement.

Advanced Wound Care therapies employ technologies to aid in wound healing in cases where the wound is chronic and healing progress has stalled or stopped. The primary competitive products in the skin substitutes category include, among others, placental-tissue allografts, tissue-engineered living skin equivalents, porcine-, bovine- and fish skin-derived xenografts and collagen matrix products. Xenografts, or tissue transplants from non-human species, serve mainly as an extracellular matrix and have to undergo aggressive processing to remove immunogenic animal products from the tissue. In addition, challenges with xenografts include limited clinical published data, and some products may require suturing or stapling to the wound bed, making handling more difficult. Furthermore, other skin substitutes currently on the market require cryogenic freezer storage and have limited shelf life.

Our main competitors in the skin substitute market include Integra LifeSciences Holdings Corporation, Organogenesis, Inc., and Smith & Nephew plc, which sell a variety of Advanced Wound Care products, including skin substitutes and placental tissue allografts. In addition, the overall market is competitive, with a large number of other, smaller competitors that compete regionally and nationally.

Our Regenerative Medicine efforts around KOA are also subject to a wide range of potential future competitors. Based on published information from across the medical device and biotherapeutics industry, there are over 70 other active R&D programs currently developing potential treatments for KOA using a variety of different scientific approaches. The speed with which we can successfully develop our product, complete clinical trials, obtain regulatory clearance, and begin commercialization efforts for our KOA offering will influence our ability to succeed in this market.

## **Government Regulation**

The products manufactured and processed by the Company are derived from human tissue. As discussed below, our Section 361 HCT/Ps are tissue-based products that are regulated solely under Section 361 and do not require pre-market clearance or approval by the FDA. Our Section 351 HCT/Ps are also tissue products, but are regulated as biological products, and, in order to be lawfully marketed in the United States, require FDA pre-market approval.

### *Tissue Products*

In 1997, the FDA proposed a regulatory framework for cells and tissues. This framework was intended to provide adequate protection of public health while enabling the development of new therapies and products with limited regulatory burden. A key innovation in the system was that covered HCT/Ps would be regulated solely under Section 361 and would not be subject to pre-market clearance. The registration and listing rules were finalized in January 2001 in 21 CFR Part 1271. Additional rules regarding donor eligibility and good tissue practices were soon adopted. Together, these rules form a comprehensive system intended to encourage significant innovation.

The FDA requires each HCT/P establishment to register and establish that its product meets the requirements to qualify for regulation solely under Section 361. To be a Section 361 HCT/P, a cellular or tissue-based product generally must meet all four of the following criteria (fully set forth in 21 CFR Part 1271):

- it must be minimally manipulated;
- it must be intended for homologous use;
- its manufacture must not involve combination with another article, except for water, crystalloids or a sterilizing, preserving or storage agent; and
- it must not have a systemic effect and must not be dependent upon the metabolic activity of living cells for its primary function.

Certain amniotic and other birth tissues are considered cellular and tissue-based articles and are therefore eligible for regulation solely as a Section 361 HCT/P depending on whether the specific product at issue and the claims made for it are consistent with the criteria set forth above. HCT/Ps that do not meet these criteria are subject to more extensive regulation as drugs, medical devices, biological products, or combination products.

### *Products Regulated Solely as Section 361 HCT/Ps*

The FDA has specific regulations governing HCT/Ps, including some regulations specific to Section 361 HCT/Ps, which are set forth in 21 CFR Part 1271. All establishments that manufacture Section 361 HCT/Ps must register and list their HCT/Ps with the FDA's Center for Biologics Evaluation and Research within five days after commencing operations. In addition, establishments are required to update their registration annually in December or within 30 days of certain changes and submit changes in HCT/P listing at the time of or within six months of such change.

The regulations in 21 CFR Part 1271 also require establishments to comply with donor screening, eligibility and testing requirements, and CGTP to prevent the introduction, transmission and spread of communicable diseases. The CGTP govern, as may be applicable, the facilities, controls, and methods used in the manufacture of all HCT/Ps, including processing, storage, recovery, labeling, packaging, and distribution of Section 361 HCT/Ps. CGTP require us, among other things, to maintain a quality program, train personnel, control, and monitor environmental conditions as appropriate, control and validate processes, properly store, handle and test our products and raw materials, maintain our facilities and equipment, keep records and comply with standards regarding recovery, pre-distribution, distribution, tracking and labeling of our products, and complaint handling. 21 CFR Part 1271 also mandates compliance with adverse reaction and CGTP deviation reporting and labeling requirements.

The FDA conducts periodic inspections of HCT/P manufacturing facilities, and contract manufacturers' facilities, to assess compliance with CGTP. Such inspections can occur at any time, with or without written notice, at such frequency as determined by the FDA in its sole discretion. To determine compliance with the applicable provisions, the inspection may include, but is not limited to, an assessment of the establishment's facilities, equipment, finished and unfinished materials, containers, processes, HCT/Ps, procedures, labeling, records, files, papers and controls required to be maintained under 21 CFR Part 1271.

If the FDA were to find serious non-compliant manufacturing or processing practices during such an inspection, it could take regulatory actions that could adversely affect our business, results of operations, financial condition, and cash flows.

#### *2017 FDA Guidance and Transition Policy for HCT/Ps*

In November 2017, the FDA released four guidance documents that, collectively, the agency described as a “comprehensive policy framework” for applying existing laws and regulations governing regenerative medicine products, including HCT/Ps. One guidance document in particular, “*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*,” offered important clarity.

The guidance documents confirmed that sheet forms of amniotic membrane generally are appropriately regulated as solely Section 361 HCT/Ps when intended for use as a barrier or covering. We continually evaluate our marketing materials for each of our products to align with FDA guidance.

Second, the guidance documents confirmed the FDA’s stance that all micronized amniotic membrane products are more than minimally manipulated, and therefore do not qualify as Section 361 HCT/Ps. However, the guidance documents also stated that the FDA intended to exercise enforcement discretion under limited conditions with respect to the IND application and pre-market approval requirements for certain HCT/Ps through November 2020, which was later extended through May 2021. This period of enforcement discretion was intended to give sponsors time to evaluate their products, have a dialogue with the agency and, if necessary, begin clinical trials and file the appropriate pre-market applications. The FDA’s approach was risk-based, and the guidance documents clarified that high-risk products and uses could be subject to immediate enforcement action.

This enforcement discretion applied across our industry, and during the period, the Company continued to market its products under this policy of enforcement discretion. After May 31, 2021, the Company no longer markets or sells its products that were impacted by enforcement discretion in the United States. We are pursuing the BLA pre-market approval process for certain uses of mDHACM. However, there is no assurance that the FDA will grant these approvals on a timely basis, or at all, or that we will not discontinue our pursuit of a BLA for certain products or indications. See “*Clinical Trials*” below for more information.

#### *Products Regulated as Biologics – The BLA Pathway*

The typical steps for obtaining FDA approval of a BLA to market a biological product in the United States include:

- Completion of preclinical laboratory tests, animal studies and formulations studies under the FDA’s Good Laboratory Practice regulations;
- Submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin and which must include independent Institutional Review Board approval at each clinical site before the trials may be initiated;
- Performance of adequate and well-controlled clinical trials in accordance with Good Clinical Practices to establish the safety and efficacy of the product and its dosage (as applicable) for each indication;
- Development of purity, potency and identity tests to demonstrate consistency and reliability of the manufacturing process through a chemistry, manufacturing and control program;
- Submission to the FDA of a BLA for marketing the product that includes, among other things, reports of the outcomes and full data sets of the clinical trials, and proposed labeling and packaging for the product;
- Satisfactory review of the contents of the BLA by the FDA, including the satisfactory resolution of any questions raised during the review;
- Satisfactory completion of an FDA Advisory Committee review, if applicable;
- Satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with FDA’s CGMP regulations, to assure that the facilities, methods and controls are adequate to ensure the product’s identity, potency, quality and purity; and
- FDA approval of the BLA, including agreement on post-marketing commitments, if applicable.

Generally, clinical trials are conducted in three phases, though the phases may overlap or be combined. Phase 1 trials typically involve a small number of healthy volunteers and are designed to provide information about the product safety and to evaluate the pattern of drug distribution and metabolism within the body. Phase 2 trials are conducted in a larger but limited group of patients afflicted with a particular disease or condition in order to determine preliminary efficacy, dosage tolerance and optimal dosing, and to identify possible adverse effects and safety risks. Dosage studies are typically designated as Phase 2A, and efficacy studies are designated as Phase 2B. Phase 3 clinical trials are generally large-scale, multi-center, comparative trials conducted with patients who have a particular disease or condition in order to provide statistically valid proof of efficacy, as well as safety and potency. In some cases, the FDA will require Phase 4, or post-marketing trials, to collect additional data after a product is on the market. All phases of clinical trials are subject to extensive record keeping, monitoring, auditing, and reporting requirements.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that the Company has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, such as issuing an FDA Form 483 notice of inspectional observations; sending a warning letter or untitled letter; issuing an order of retention,

destruction, or cessation of marketing; imposing civil money penalties; suspending or delaying issuance of approvals; requiring product recalls; imposing a total or partial shutdown of production; withdrawing approvals or clearances already granted; pursuing product seizures, consent decrees or other injunctive relief; and criminal prosecution through the Department of Justice (“*DOJ*”).

## Clinical Trials

### *Trial Overview*

The Company previously completed four IND studies investigating the use of mDHACM to reduce pain and increase function in patients with KOA, as well as plantar fasciitis and Achilles tendonitis. The Company is not currently pursuing the use of mDHACM to treat plantar fasciitis or Achilles tendonitis. The Company continues to pursue the use of mDHACM to treat KOA. The Company has instituted several actions with respect to its ongoing and anticipated clinical trials to address the resources, capabilities, and expertise needed for an effective dialogue with the FDA regarding our BLA progress. However, there can be no assurance that we will obtain BLA approval and we may ultimately decide not to pursue a BLA for this or for other products or indications.

### *Knee Osteoarthritis Trial Overview*

In March 2018, the FDA granted mDHACM the Regenerative Medicine Advanced Therapy (“*RMAT*”) designation for use in the treatment of osteoarthritis of the knee. *RMAT*-designated products are eligible for increased and earlier interactions with the FDA, similar to those interactions available to fast-track and breakthrough-designated therapies. In addition, these products may be eligible for rolling review and accelerated approval. The meetings with sponsors of *RMAT*-designated products may include discussions of whether accelerated approval would be appropriate based on surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit or reliance upon data obtained from a meaningful number of sites.

In March 2018, we initiated a Phase 2B prospective, double-blinded RCT investigating a single intra-articular injection of 40 mg of mDHACM as compared to a single injection of saline (placebo control) in the treatment of pain and functional impairment in patients with osteoarthritis of the knee. This trial was planned to enroll 318 patients, with an interim analysis to assess adequacy of this sample size built into the statistical plan. This blinded interim analysis was performed in July through August 2019 and revealed that while differences in the treatment groups were observed, the power to observe statistically and clinically significant results would be enhanced by increasing the sample size to 466 patients. Amendments to the protocol to allow this increase were subsequently approved. It should be noted that during the first half of 2020 in particular, study enrollment slowed considerably due to the ongoing COVID-19 pandemic, although this impact did begin to resolve in the third quarter of the year. Due to actual dropout rates observed in the study being lower than planned, in September 2020 we completed enrollment of 447 patients. We also amended the protocol to establish an open label extension to the trial and allow patients to receive a second injection of the active treatment at six months, nine months, or 12 months subsequent to their completion of study visits, if their pain has not resolved or responded, regardless of treatment arm. The study was still blinded to subjects, sites, and MIMEDX during this extension. The six months blinded efficacy visits in this study were completed during the second quarter of 2021, and analyses were completed during the third quarter of 2021. The final study visits occurred (open label extension) during the second quarter of 2022. The final endpoint of the study was at 12 months. All 12-month visits have now been completed, and data analysis has been accomplished. MIMEDX is currently evaluating these results and preparing a clinical report.

As previously announced, the trial did not meet its primary endpoints at six months. However, in a cohort of 190 subjects enrolled prior to a planned interim analysis performed for sample size correction in July through August 2019, a statistically significant and clinically meaningful difference in favor of mDHACM in WOMAC total scores and both the pain and function subscales compared to the placebo was observed. Subjects enrolled after this interim analysis did not show separation of results from the mDHACM treated from those of the placebo arm. Third-party biostatisticians validated the improvement in WOMAC Pain at three and six months, respectively ( $p=0.032$  and  $p=0.009$ ), WOMAC Function ( $p=0.046$  and  $p=0.009$ ), and WOMAC Total ( $p=0.038$  and  $p=0.008$ ) for the Pre-Interim Analysis Cohort of 190 patients. A root-cause analysis determined that the potency of the investigational product decreased as it aged, which we believe caused the study to fail to meet its primary endpoints. The Company’s proprietary biochemical and biological tests, along with the clinical observations, detected this reduced potency. Based on the clinically meaningful and statistically significant data from the Pre-Interim Analysis Cohort of 190 patients in the Phase 2B trial, published retrospective data, extensive real-world clinical use, and ongoing scientific mechanism of action research, the Company initiated the first of two registrational KOA trials in February 2023 and has been working closely with the FDA in advancing this program.

There can be no assurance, however, that our anticipated time frame for the registrational KOA trials and submitting a BLA will be achieved or that we will receive FDA approval for mDHACM and be able to commercialize this product, or that such approval will not be delayed for a variety of reasons, including failure of the studies to achieve their endpoints; the impact of the COVID-19 pandemic or other public health emergencies on study enrollment and FDA operations; the potential that the results of the clinical studies do not merit further investment; and the work required to achieve commercial and manufacturing readiness.

Prior to May 31, 2021, the date the FDA's period of enforcement discretion ended, we also filed investigational applications for additional indications for AMNIOFIX Injectable and EPIFIX Micronized. These two INDs were allowed to proceed for the injectable products, one in chronic wounds, another in surgical incisions. We have not yet initiated any clinical trials related to these applications, and have no immediate plans to advance these programs.

#### *BLA Process*

If study results support potential product approval and potential for commercialization, we intend to file a BLA as described above. The process of obtaining an approved BLA requires the expenditure of substantial time, effort and financial resources, and may take years to complete, including costs incurred on top of those fees incurred as part of conducting various clinical studies. The fee for filing a BLA and the annual user fees payable with respect to any establishment that manufactures biologics and with respect to each approved product are substantial. While there can be no assurance that we will ultimately obtain regulatory approval for our micronized products, we have already completed substantial work towards our BLA program, including engineering our manufacturing processes to conform to CGMP requirements.

#### **FDA Post-Market Regulation**

Tissue processors regulated solely under Section 361 are still required to register as a tissue establishment with the FDA. As a registered tissue establishment, we are required to comply with regulations regarding labeling, record keeping, donor eligibility, screening, and testing. We are also required to process the tissue in accordance with established CGTP, as well as report any deviations from core CGTP requirements or adverse reactions caused by a possible transmission of an infectious disease attributed to our tissue. Our facilities are also subject to periodic inspections to assess our compliance with the regulations.

Products covered by a BLA, New Drug Application, 510(k) clearance or a pre-market approval are subject to numerous additional regulatory requirements, which include, among others, compliance with CGMP (or, in the case of devices, with FDA's Quality System Regulation), which imposes certain procedural, substantive and record keeping requirements, and labeling regulations to ensure the product's identity, potency, quality, and purity. These products are also subject to the FDA's general prohibition against promoting products for unapproved or "off-label" uses, and additional adverse reaction reporting.

As part of our BLA development effort, we are updating our manufacturing establishments into maintaining application of CGMP for production of our injectable and other applicable Section 351 products. The process includes development and enhancement of production processes, procedures, tests, and assays, and it requires extensive validation work. It also involves the procurement and installation of new production and lab equipment. These efforts require human capital, expertise, and resources. We have made significant improvements over the last two years. We have engaged industry experts to assess our state of compliance and to provide guidance on the additional activities needed to maintain CGMP. Significant improvements include a newly built, validated processing suite applying CGMP that is utilized for processing of Section 351 products.

#### **Other Regulation Specific to Tissue Products**

##### *National Organ Transplant Act*

Procurement of certain human organs and tissue for transplantation is subject to the restrictions of the National Organ Transplant Act ("**NOTA**"), which prohibits the transfer of certain human organs, including skin and related tissue, for valuable consideration, but permits the reimbursement of reasonable expenses associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of human tissue and skin. Our wholly-owned subsidiary, MiMedx Tissue Services, LLC, is registered with the FDA as an establishment that manufactures human cells, tissues, and cellular and tissue-based products and is involved with the recovery and storage of donated human placental tissues. We reimburse tissue banks, hospitals, and physicians for their services associated with the recovery and storage of donated human tissue.

##### *Tissue Bank Laws, Regulations, and Related Accreditation*

As discussed above, we are required to register with the FDA as an establishment that manufactures human cells, tissues, and cellular and tissue-based products. We are licensed, registered, or permitted as a tissue bank in California, New York, Delaware, Illinois, Oregon, and Maryland. Additionally, we received and actively maintain AATB accreditation. The AATB has issued operating standards for tissue banking. Compliance with these standards is required in order to become an AATB-accredited tissue establishment. AATB standards include specific requirements for recovery, screening, testing, labeling, processing, and storing of birth tissue. We maintain compliance with AATB standards and our state licensure requirements.

To the extent we sell our products outside of the United States, we also are subject to laws and regulations of foreign countries.

##### *Other Healthcare Laws and Compliance Requirements*

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including CMS, other divisions of the HHS (e.g., the Office of Inspector General), the DOJ and individual United States Attorney offices within the DOJ, and state and local governments. These regulations include those described below.

- The federal Anti-Kickback Statute (“**AKS**”), which is a criminal law that prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward referrals, purchases or orders, or arranging for or recommending the purchase, order or referral of any item or service for which payment may be made in whole or in part by a federal healthcare program, such as the Medicare and Medicaid programs. The term “remuneration” has been broadly interpreted to include anything of value. The Patient Protection and Affordable Care Act amended the intent requirement of the federal AKS, so that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. A conviction for violation of the AKS results in criminal fines and requires mandatory exclusion from participation in federal health care programs. Although there are a number of statutory exceptions and regulatory safe harbors to the federal AKS that protect certain common industry practices from prosecution, the exceptions and safe harbors are drawn narrowly, and arrangements may be subject to scrutiny or penalty if they do not fully satisfy all elements of an available exception or safe harbor.
- The federal False Claims Act (“**FCA**”) imposes significant civil liability on any person or entity that knowingly presents, or causes to be presented, a claim for payment to the U.S. government, including the Medicare and Medicaid programs, that is false or fraudulent. The FCA also allows a private individual or entity as a whistleblower to sue on behalf of the government to recover civil penalties and treble damages. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of between \$11,181 and \$22,363 per false claim or statement for penalties assessed after January 29, 2018, with respect to violations occurring after November 2, 2015. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government.
- The federal Health Insurance Portability and Accountability Act of 1996 (“**HIPAA**”) fraud and abuse provisions prohibit executing a scheme to defraud any healthcare benefit program, willfully obstructing a criminal investigation of a health care offense, or making false statements or concealing a material fact relating to payment for healthcare benefits, items or services.
- While manufacturers of human cell and tissue products regulated solely under Section 361 are not subject to the federal Physician Payments Sunshine Act and its implementing regulations (together with the Act, the “**Sunshine Act**”), in the future, if we expand our product portfolio beyond those regulated solely under Section 361, this law will require us (with certain exceptions) to report information to CMS related to certain payments or other transfers of value we make to U.S.-licensed physicians and teaching hospitals, and for reports submitted on or after January 1, 2022, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives. If we receive a BLA approval, the Sunshine Act would also require us to report annually certain ownership and investment interests held by U.S.-licensed physicians and their immediate family members. Such information will subsequently be made publicly available by CMS on the Open Payments website. There is a risk that CMS or another government agency may take the position that our products are not human cell and tissue products regulated solely under Section 361, and thereby assert that we are currently subject to the Sunshine Act, which could subject us to civil penalties and the administrative burden of having to comply with the law.
- Federal conflicts of interest laws, the Standards of Ethical Conduct for Employees of the Executive Branch, and local site policies for each federal institution we call upon govern our interactions with federal employees at our various government accounts (e.g., DoD, VA, etc.) and impose a number of limitations on such interactions.
- There are state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payer, including commercial insurers, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“**HITECH**”) and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of protected health information. Among other things, HITECH made HIPAA’s privacy and security standards directly applicable to “business associates,” independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and possibly other persons and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

#### *International Regulation (Japan)*

MIMEDX received regulatory approval from the Japanese Ministry of Health, Labour and Welfare (JMHLW) to market EPIFIX in Japan. Under JMHLW guidelines, EPIFIX is classified as a Class IV Medical Device and “Specified Biological Product” and is approved for the treatment of refractory ulcers, such as DFUs and VLU that do not respond to conventional therapy. As a condition of the final approval, MIMEDX will conduct post-market surveillance, consisting of a limited study over 75 participants. The JMHLW has the ultimate responsibility of granting final approval on all Class III and IV Medical Devices and “Specified Biological Products.” All approved products in Japan, including EPIFIX, are regulated by the Pharmaceuticals and Medical Devices Agency (“PMDA”), which acts as the technical arm of the JMHLW. The PMDA serves in a similar function as the FDA in the United States, and is responsible for ensuring the safety, efficacy, and quality of pharmaceuticals and medical devices in Japan. The PMDA provides review and approval of medical devices, QMS/GLP/GCP inspections, and collection and analysis of adverse event reports.

MIMEDX also secured reimbursement approval from JMHLW on September 1, 2022 with an awarded rate of 35,100 Yen/cm<sup>2</sup>, and subsequently entered into an exclusive distribution agreement with Gunze Medical for sales of EPIFIX in Japan. Insurance coverage for EPIFIX will provide doctors and patients in Japan with new treatment options and optimal wound care.

## **Research and Development**

Our research and development group has extensive experience in developing products for our target markets, and works to design products that are intended to improve patient outcomes, simplify techniques, shorten procedures, reduce hospitalization and rehabilitation times and, as a result, reduce costs. Our research and development group also works to establish scientific evidence in support of the use of our products. Clinical trials that demonstrate the safety, efficacy and cost effectiveness of our products are key to obtaining broader third-party reimbursement for our products. In addition to our internal staff, we contract with outside laboratories and physicians who aid us in our research and development process. See Part II, Item 7, below, for information regarding expenditures for research and development in each of the last three fiscal years.

## **Environmental, Social & Governance Matters (“ESG”)**

At MIMEDX, we are committed to improving people’s health and lives through innovation that makes healing possible. Our product offering is derived from donated human placental and umbilical cord tissue, which are processed into products used by health professionals to treat patients suffering from both acute and chronic hard-to-heal wounds. We are continuously looking to expand the breadth of our product offering, further leveraging birth tissue that would otherwise become medical waste, and have a product pipeline that includes innovations for wound and surgical end markets as well as a potential treatment option for other conditions such as knee osteoarthritis (KOA). Our Core Values define how we lead the field with rigorous science, help clinicians elevate the standard of care, provide a safe and healthy environment for our employees, and work and grow as a company.

In an effort to deliver long-term value to all of our stakeholders, we incorporate environmental, social, and governance (ESG) objectives that are relevant to our business. These ESG objectives are informed by a combination of feedback from our stakeholders as well as leading ESG frameworks, such as the Sustainability Accounting Standards Board (SASB) Medical Equipment & Supplies standards, under the oversight of our Board of Directors.

### *Environmental Matters*

Stewardship is a Core Value at MIMEDX. We are stewards of a precious, life-protecting and life-giving resource – human birth tissue – which currently represent the biological source material for all of our products. Without our placental donation and recovery program, this material would most likely be discarded as medical waste at the hospital. We do not produce a significant amount of emissions from our operations.

### Environmental Management

We recently worked with a third-party to conduct an environmental, health, and safety gap assessment in order to accurately benchmark our environmental impact. The review looked at several areas including:

- Air Pollution Control Management
- Battery Handling and Disposal
- Community Right-to-Know (Hazardous Material Reporting)
- Hazardous Waste Management
- SARA Title III (Release Reporting)
- Solid Waste Management
- Spill, Prevention, Control and Countermeasure
- State Pollutant Discharge Elimination System (SPDES)

- Storm Water Management
- Universal Waste Management
- Waste Oil Management

We are evaluating the results of this exercise in order to consider implementation of measures in support of our Environmental Management program.

### Waste Management

We work with waste removal providers to responsibly dispose of medical waste and biohazardous waste and have a program in place for the management of all medical and biohazardous waste processed in our facilities. In addition, we follow applicable packaging requirements for regulated medical waste, and conduct regular required training for all employees responsible for packaging medical waste for shipment. Our waste management initiatives also include the shredding and recycling of paper waste from our facilities, our transition to digital systems where possible to reduce print waste, and the distribution of electronic tablets to our sales teams to minimize printing needs, shipping costs, and printed materials.

Our facilities management team collects recyclable and reusable material when possible, including for cardboard, plastics, batteries, fluorescent lamps, and ballasts. We have significantly reduced the use of plastic and aluminum materials with the installation of filtered water and soda machines within our facilities. The packaging of our product cartons is recyclable and, since 2015, has been reduced in size by 50%.

### **Human Capital**

As of December 31, 2022, we had 867 full time employees. Generally, we consider our relationships with our employees to be good, and none of our employees are covered by a collective bargaining agreement. We conduct regular surveys of employees to monitor engagement levels and act on feedback received through this process.

#### *Our Diversity and Inclusion*

MIMEDX values the diversity of perspective, experience, and background within our Company. We have stated goals to promote diversity, inclusion, and equal opportunity regardless of race, gender, nationality, ethnic origin, religion, age, or sexual orientation. Intimidation or harassment of any kind are not acceptable in our workplace.

Our business requires a workforce with a wide range backgrounds, experiences, skills, and knowledge and a culture that blends this diversity into an effective team. In order for our employees to do their best work, and for us to achieve our mission, everyone at MIMEDX must feel respected, valued, and included. Comprised of employees across the company, our Inclusion and Diversity Council implements programs to create greater visibility to work environment challenges, champion diversity, and provide an intentional link for each employee to the company values and goals.

The table below provides an overview of MIMEDX’s diversity as of December 31, 2022:

Board of Directors	Women and minorities hold one-third of the seats on our Board, including the Chair of the Board.
Employee Gender Diversity	Women represented 57% of our workforce as of December 31, 2022. Women represented 61% of our new hires in 2022.
Employee Ethnic/Racial Diversity	Black or African American: 25% Hispanic or Latino: 8% Other Non-White (including American Indian, Alaskan Native, Asian, Native Hawaiian, or Other Pacific Islander): 6%

#### *Recruiting, Retaining, and Engaging Talent*

Talent is our greatest asset and we are dependent on being able to recruit, develop, and retain talent that share our Core Values. We use tools, such as an interview guide and a process reviewed by our Inclusion and Diversity Council, designed to prevent us from bias in our hiring decisions. We are currently in compliance with affirmative action reporting. As part of our Affirmative Action Plan, we leverage targeted outreach in our hiring process to ensure our postings reach underrepresented groups.

We are focused on retaining our talented professionals who we believe are key to the Company’s success. Our human resource group continuously monitors and benchmarks employee turnover and other trends in our industry and on a regional level to ensure MIMEDX is competitive and responsive to changes in the broader marketplace. Combining this data with feedback from exit interviews in any instances of voluntary employee turnover, we are able to use these actionable insights to improve

employee engagement, provide opportunities for career development, evolve our total rewards offering and evaluate implementation of additional resources to enhance the employee experience at MIMEDX.

#### *Training and Development*

We provide financial assistance to employees earning certifications through our Tuition Reimbursement Plan. Internally, we provide personal development and goal setting courses and counsel to help our employees understand how to grow their careers and learn new things.

#### *Compensation and Benefits*

We offer all full-time employees a comprehensive benefits package, including:

- Health coverage, including Medical, Dental, Vision insurance, a wellness incentive program and virtual and text-based healthcare
- Paid Parental and Caregiver leave
- Employee Assistance Program
- Paid company holidays, recently adding Juneteenth
- Tuition Reimbursement Program
- 401(k) plan, including Employer match
- Employee Stock Purchase Plan

#### **Available Information**

We are required to file proxy statements, annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K with the SEC. The SEC maintains an internet site, [www.sec.gov](http://www.sec.gov), where these reports are available free of charge. We also make these reports available free of charge on our website, [www.mimedx.com](http://www.mimedx.com), under the heading “*Investors–SEC Filings.*” In addition, our Audit Committee, Compensation Committee, Ethics and Compliance Committee, and Nominating and Corporate Governance Committee Charters as well as our Code of Business Conduct and Ethics, are on our website under the heading “*Investors–Corporate Governance.*” The reference to our website does not constitute incorporation by reference of any information contained on that site.

## Item 1A. Risk Factors

An investment in our Common Stock involves a substantial risk of loss. Set forth below is a summary of the risks and uncertainties affecting our business that we currently believe to be material. We caution you to read the following risk factors, which have affected, and/or in the future could affect, our business, prospects, operating results, and financial condition. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also affect our business, prospects, operating results, and financial condition. Additional risks and uncertainties are described under other captions in this report and should also be considered by our stockholders. If any of these risks materialize, our business, financial condition or operating results could suffer. In this case, the trading price of our Common Stock could decline, and you may lose part or all of your investment.

### Summary of Risk Factors

#### Risks Related to Our Business and Industry

- If we do not successfully execute our priorities, our business, operating results and financial condition could be adversely affected.
- We are in a highly competitive and evolving field and face competition from well-established tissue processors and medical device manufacturers, as well as new market entrants.
- Rapid technological change could cause our products to become obsolete.
- Our products depend on the availability of tissue from human donors, and any disruption in supply could adversely affect our business.
- Public health emergencies, such as the COVID-19 pandemic and the governmental and societal responses thereto have adversely affected our business in the past and future outbreaks could harm our business in the future.
- We depend on our senior leadership team and may not be able to retain or replace these employees or recruit additional qualified personnel.
- A portion of our revenues and accounts receivable come from government accounts.
- Our revenues depend on adequate reimbursement from public and private insurers and health systems and changes to the way in which our products are reimbursed in various sites of service could adversely impact our financial results.
- Our revenue, results of operations and cash flows may suffer upon the loss of a Group Purchasing Organization or Integrated Delivery Network.
- We contract with independent sales agents and distributors.
- Disruption of our processing could adversely affect our business, financial condition and results of operations.
- To be commercially successful, we must convince physicians, where appropriate, how and when our products are proper alternatives to existing treatments and that our products should be used in their procedures.
- If we cannot successfully address quality issues that may arise with our products, our brand reputation could suffer, and our business, financial condition, and results of operations could be adversely impacted.
- The formation of physician-owned distributorships could result in increased pricing pressure on our products or harm our ability to sell our products to physicians who own or are affiliated with those distributorships.
- We face the risk of product liability claims and may not be able to obtain or maintain adequate product liability insurance.
- The products we manufacture and process are derived from human tissue and therefore have the potential for disease transmission.
- We may implement a product recall or voluntary market withdrawal.
- A cyberattack or significant disruptions of information technology systems could adversely affect our business.
- We may expand or contract our business through acquisitions, divestitures, licenses, investments, and other commercial arrangements.
- New lines of business or new products and services may subject us to additional risks.
- Our international expansion and operations outside the U.S. expose us to risks.

#### Risks Related to Regulatory Approval of Our Products and Other Government Regulations

- Certain of our products no longer qualify for regulation as human cells, tissues and cellular and tissue-based products solely under Section 361 of the Public Health Service Act, which has resulted in removal of the applicable products from the market, made the introduction of some new tissue products more expensive, significantly delayed the expansion of our tissue product offerings and subjected us to additional post-market regulatory requirements. Additional regulatory requirements may be imposed in the future.
- If any of the BLAs are approved, the Company would be subject to additional regulation which will increase costs and could result in adverse sanctions for non-compliance. Obtaining and maintaining the necessary regulatory approvals for certain of our products will be expensive and time consuming and may impede our ability to fully exploit our technologies.

- If any of the BLAs are approved, we would be subject to additional regulation which will increase costs and could result in adverse sanctions for non-compliance.
- Obtaining and maintaining the necessary regulatory approvals for certain of our products will be expensive and time consuming and may impede our ability to fully exploit our technologies.
- Our business is subject to extensive regulation by the FDA and other authorities, which is costly.
- We may be subject to fines, penalties, injunctions and other sanctions if we are deemed to be promoting the use of our products for unapproved, or off-label, uses.
- We and our sales representatives must comply with various federal and state anti-kickback, self-referral, false claims and similar laws.
- Our results of operations may be adversely affected by current and potential future healthcare reforms.
- We may fail to obtain or maintain foreign regulatory approvals to market our products in other countries.
- Federal and state laws that protect the privacy and security of personal information may increase our costs and limit our ability to collect and use that information and subject us to liability if we are unable to fully comply with such laws.

#### Risks Related to Our Intellectual Property

- Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain and may be inadequate.
- We may become subject to claims of infringement of the intellectual property rights of others.
- We may be subject to damages resulting from claims that we, our employees, or our independent contractors have wrongfully used or disclosed alleged trade secrets, proprietary or confidential information of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

#### Risks Related to our Past Audit Committee Investigation, Consolidated Financial Statements, Internal Controls and Related Matters

- If we fail to maintain adequate internal control over financial reporting in the future, this could adversely affect our business, financial condition and operating results.
- Negative publicity, including publicity relating to or arising from the Restatement, the Audit Committee Investigation, or related matters, has had and could continue to have an adverse effect on our business, results of operations and financial condition.
- We are currently, in the past have been, and may in the future be, subject to substantial litigation and ongoing investigations that could cause us to incur significant legal expenses and result in harm to our business.

#### Risks Related to the Securities Markets and Ownership of Our Common Stock

- Our substantial indebtedness may adversely affect our financial health.
- Our variable rate indebtedness under the Hayfin Loan Agreement subjects us to interest rate risk.
- EW Healthcare Partners and its interests may conflict with those of our other shareholders.
- Holders of shares of our Series B Preferred Stock have rights, preferences and privileges that are not held by, and are preferential to, the rights of, our common shareholders.
- Our Series B Preferred Stock is convertible into shares of our Common Stock, and any such conversion may dilute the value of our Common Stock.
- The price of our Common Stock has been, and will likely continue to be, volatile.
- Securities analysts may elect not to report on our common stock or may issue negative reports that adversely affect the stock price.
- Fluctuations in revenue or results of operations could cause additional volatility in our stock price.
- We do not intend to pay cash dividends on our Common Stock.
- Certain provisions of Florida law and anti-takeover provisions in our organizational documents may discourage or prevent a change of control.

## Risks Related to Our Business and Industry

***If we do not successfully execute our priorities, our business, operating results and financial condition could be adversely affected.***

Our priorities in our Advanced Wound Care and Surgical Recovery Wound & Surgical business are to address large, underpenetrated market opportunities, domestically and internationally, including by launching new organic or inorganic products. We intend to implement and maintain rigorous CGMP standards throughout our entire supply chain and continue to advance the scientific body of evidence substantiating clinical efficacy, economic viability and the underlying mechanism of action for our PURION processed placental tissue platform through additional peer-reviewed publications, rigorous scientific research and clinical studies. We are also focused on pursuing FDA approval for mDHACM as a platform technology in our Regenerative Medicine segment to treat musculoskeletal degeneration across multiple indications, and initiated a post-Phase 2B registrational KOA program study in February 2023.

We have sought and may continue to seek capital to implement our priorities. In developing our priorities, we evaluated many factors including, without limitation, those related to developments in our industry, customer demand, competition, regulatory developments, and general economic conditions. Actual conditions may be different from our assumptions, and we may not be able to successfully execute our priorities. If we do not successfully execute our priorities, or if actual results vary significantly from our assumptions, our business, operating results and financial condition could be adversely impacted.

***We are in a highly competitive and evolving field and face competition from well-established tissue processors and medical device manufacturers, as well as new market entrants.***

Our business is in a very competitive and evolving field. Competition from other tissue processors, medical device companies, and biotherapeutic companies, and from research and academic institutions, is intense, expected to increase and subject to rapid change and could be significantly affected by new product introductions as well as changes in reimbursement that could favor certain products and competitors over others. Established competitors and newer market entrants are investing in additional clinical research that may allow them to gain further clinician usage, adoption and payer coverage of their products. In addition, consolidation and cost containment measures in the healthcare industry may cause hospitals to consolidate their purchases with suppliers that have a broad portfolio of products. This would continue to give rise to demands for price concessions, which could have an adverse effect on our business, results of operations and financial condition. Further, competitors may introduce placental-based membrane products in the future at lower prices, adding new features or gaining additional reimbursement coverage, or utilize sales and marketing practices that negatively impact the industry. Further, they may copy our products outside the United States. The presence of this competition may lead to pricing pressure, which could have an adverse effect on our business, results of operations and financial condition.

***Rapid technological change could cause our products to become obsolete and, if we do not enhance our product offerings through our research and development efforts, we may be unable to compete effectively.***

The technologies underlying our products are subject to rapid technological change. Competition intensifies as technical advances in each field are made and become more widely known. Others may develop services, products or processes with significant advantages over the products, services and processes that we offer or are seeking to develop. Any such occurrence could have an adverse effect on our business, results of operations and financial condition.

We plan to enhance and broaden our product offerings as part of a strategy that involves responding to changing customer demands and competitive pressure and technologies, among other factors. The success of any new product offering or enhancement to an existing product will depend on numerous factors, including our ability to:

- properly identify and anticipate physician and patient needs;
- acquire, through licensing, co-development or outright purchase, new technology developed outside of MIMEDX;
- develop and introduce new products or product enhancements in a timely manner;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;
- demonstrate the safety and efficacy of new products; and
- obtain the necessary regulatory clearances or approvals for new products or product enhancements.

If we do not develop and, when necessary, obtain regulatory clearance or approval for new products or product enhancements in time to meet market demand, or if there is insufficient demand for these products or enhancements, our results of operations and financial condition will suffer. Our research and development efforts may require a substantial investment of time and resources, including additional capital, before we are adequately able to determine the commercial viability of a new product, technology, material or other innovation. In addition, even if we are able to successfully develop enhancements or new generations of our products, these enhancements or new generations of products may not produce sales in excess of the costs

of development, or they may never receive required regulatory approval and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features.

***Our products depend on the availability of tissue from human donors, and any disruption in supply could adversely affect our business.***

The success of our human tissue products depends upon, among other factors, the availability of tissue from human donors. Any failure to obtain tissue from our sources will interfere with our ability to effectively meet demand for our products incorporating human tissue. The availability of donated tissue could also be adversely impacted by regulatory changes, public opinion of the donor process and our own reputation in the industry. We may not be successful in our ability to scale tissue recovery efforts to meet the potential future demand of our pipeline. Obtaining adequate supplies of human tissue involves several risks, including limited control over availability (due to for example, access to hospital accounts and the number of consenting mothers), quality, delivery schedules, and eligibility requirements. In addition, any interruption in the supply of any human tissue component could harm our ability to manufacture our products until a new source of supply, if any, could be found. We also utilize third-party providers of placental donations on an as-needed basis to mitigate risks but there can be no assurance that these third parties will be able to provide donated tissues at all times. We may be unable to find a sufficient alternative supply channel in a reasonable time period or on commercially reasonable terms, if at all, which would have an adverse effect on our business, results of operations and financial condition.

***Public health emergencies, such as the COVID-19 pandemic and the governmental and societal responses thereto have adversely affected our business, results of operations and financial condition in the past, and future outbreaks could harm our business, results of operations, and financial condition in the future.***

The COVID-19 pandemic and governmental and societal responses thereto have adversely affected our business, results of operations and financial condition and future public health emergencies could have similar and wide-ranging impacts to our business. See Item 7, *Management's Discussion and Analysis - Results of Operations*. Public health emergencies such as these have the potential to adversely affect our operations and increase our costs and expenses in numerous ways. For example:

- We source raw materials for our products from donated placentas from scheduled C-section births via a large, geographically-diverse network of donor hospitals. We may experience shortages of donated placentas if donors or our recovery specialists are excluded from hospitals, or if other disruptions occur. We experienced interruptions from a portion of our hospitals in certain geographic areas in the first half of 2020, in late 2021 and in early 2022. To date, we have been successful in mitigating this disruption to our supply by adding additional donor hospitals, increasing efforts at hospitals that did not impose access limits, and using third-party providers of donated placentas (where necessary and in accordance with MIMEDX quality standards). However, there can be no assurance that our efforts to source raw materials for our products will continue to be successful, and we may experience shortages of raw materials, especially if the current pandemic, including further strains, or responses thereto intensify. Additionally, we may experience shortages of donated placentas if additional testing protocols are implemented for donated tissues based on guidance issued by the AATB, the FDA, or other standards, and are screened as ineligible.
- We process donated tissue using aseptic techniques in a controlled environment. However, the manufacturing space is a confined space area in which an infected employee may spread viruses such as the flu and COVID-19 to other employees despite the use of personal protective equipment required for all areas at MIMEDX. To date, we have been successful in mitigating these risks through a variety of measures, however, there can be no assurance that our efforts to prevent wide-scale infections among our processing staff will continue to be successful. If we experience wide-scale infections among our production staff, we may experience a shortage of finished goods.
- Our ability to sell our products was previously hampered by the COVID-19 pandemic. In many areas of the country, our sales force was excluded from hospitals and the offices of other health care providers for periods of time. Additionally, many patients stayed away from hospitals and other medical facilities. This had adverse effects on our revenues for periods of time in the past. We are not able to estimate the future effect of COVID-19 or other public health emergencies on patient behavior and, consequently, future demand or the ability of providers to pay for our products.
- Similarly, our clinical researchers, clinical study coordinators, and their patients have experienced restrictions in their access to hospitals and ability to access other healthcare providers, which has slowed enrollment in our clinical trials in the past. If such access were to be restricted again, it might again impair or delay the initiation, approval and launch of future products or additional clinical trials.

If our leadership, employees, sales agents, suppliers, medical professionals, or users of our products are impacted by an epidemic, by illness, or through social distancing, quarantine or other precautionary measures taken in connection therewith, then our manufacturing operations, sales, demand for our products, and clinical trials may be adversely affected.

Disruptions to the health care system generally, such as if patients are unable or unwilling to visit health care providers, or if health care providers prioritize treatment of acute or communicable illnesses over wound care, have affected and may continue to adversely affect our revenues and results of operations.

The ultimate impact of the COVID-19 pandemic remains uncertain and subject to change. We do not yet know the full extent of delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole, or how long such effects will endure. The effects of the COVID-19 pandemic or other public health emergencies could have an adverse impact on our business, results of operations and financial condition.

***We depend on our senior leadership team and may not be able to retain or replace these employees or recruit additional qualified personnel, which would harm our business, results of operations and financial condition.***

Our business and success are materially dependent on attracting and retaining members of our senior leadership team to formulate and execute the Company's business plans. Since June 2018, we have made significant changes to our senior leadership team, and hired several new senior leaders.

Leadership changes can be inherently difficult to manage and may cause material disruption to our business or management team. Changes in senior management could also lead to an environment that presents additional challenges in recruiting and retaining employees, which could have an adverse effect on our business, results of operations and financial condition. We experienced difficulties in recruiting due to legal and business uncertainties resulting from the issues that were the subject of the Audit Committee Investigation.

Our future success will also depend, in part, upon our ability to attract and retain skilled personnel, including sales, managerial and technical personnel. There can be no assurance that we will be able to continue to find and attract additional qualified employees to support our expected growth or retain any such personnel.

***A portion of our revenues and accounts receivable come from government accounts.***

Some of our revenues are derived from sales, both direct and through a distributor, to the government. Any disruption of our products on the FSS or any change in the way the government purchases products like ours or the price it is willing to pay for our products could adversely affect our business, results of operations and financial condition.

***Our revenues depend on adequate reimbursement from public and private insurers and health systems and changes to the ways in which our products are reimbursed in various sites of service could adversely impact our financial results.***

Our success depends on the extent to which our customers receive adequate reimbursement for the costs of our products and related treatments from third-party payers, including government healthcare programs, such as Medicare and Medicaid, as well as private insurers and health systems. Government and other third-party payers attempt to contain healthcare costs by limiting both coverage and the level of reimbursement of medical products, particularly new products. Therefore, significant uncertainty may exist as to the reimbursement status of new healthcare products by third-party payers. Although EPIFIX and EPICORD have coverage with the majority of large payers, a significant number of public and private insurers currently do not cover or reimburse our other products.

The reimbursement landscape for our products varies depending upon the site in which the products are administered. If we are not successful in obtaining adequate coverage and reimbursement for our products from these third-party payers in one or more of the sites of service where our products are used, it could have an adverse effect on market acceptance of our products. Inadequate reimbursement levels would likely also create downward price pressure on our products. Even if we do succeed in obtaining widespread coverage and reimbursement rates or policies for our products, future changes in coverage or reimbursement rates or policies could have a negative impact on our business, financial condition and results of operations.

Further, we have experienced some reluctance by payers to cover our products under certain circumstances, including for applications other than those for which we have published clinical efficacy data. Recently, several wide-ranging proposals have been published for public comment, including relating to payment methodology within the physician office, and are under consideration by the U.S. Centers for Medicare and Medicaid Services (CMS). In addition, three Medicare Administrative Contractors (MACs) have recently published for public comment changes to their Local Coverage Determinations (LCDs) that they are considering. If adopted, these proposals would significantly change Medicare policies

governing the reimbursement of skin substitute products principally when used for wound treatment in the private physician office setting. The LCDs in the proposals could adopt a new standard of clinical evidence required as a prerequisite to coverage. In addition, the proposals all require a confirmation that the products are regulated solely under Section 361 of the Public Health Service Act as a prerequisite to continued coverage. We have the required confirmation for EPIFIX, but not currently for EPICORD. The proposed LCDs also include language that could lower the number of allowed applications of a product below what is commonly used in standard practice by physicians today (supported by clinical evidence) and reflected by LCDs currently in force with the MACs. The Company as well as industry stakeholders across the wound care industry do not support lowering the applications.

Changes in the coverage and reimbursement environment as described above could result in declines in our revenue that would adversely affect our business, financial condition and results of operation.

***Our revenue, results of operations and cash flows may suffer upon the loss of a Group Purchasing Organization or Integrated Delivery Network.***

As with many manufacturers in the healthcare space, the Company contracts with Group Purchasing Organizations (“GPOs”) and Integrated Delivery Networks (“IDNs”) to establish contracted pricing and terms and conditions for the members of GPOs and IDNs. Approximately three-quarters of our sales in the year ended December 31, 2022 came from customers that are members of our primary GPOs or IDNs.

Our agreements with GPOs and IDNs allow us to sell our products efficiently to large groups of customers. Our agreements with GPOs and IDNs typically provide their members with favorable ordering terms and conditions and access to favorable product pricing. These customers purchase our product through GPO and IDN arrangements in part because of the favorable pricing and terms and conditions. If our agreement with any GPO or IDN is terminated or expires without being extended, renewed or renegotiated, this could adversely affect our revenue, results of operations and cash flows.

***We contract with and are dependent upon independent sales agents and distributors.***

In 2022, approximately 22% of our sales were through our relationships with independent agents, and we also use a small number of distributors, primarily outside the United States, and may use more in the future. (Sales agents act directly on behalf of MIMEDX to arrange sales, while distributors take title to product and may set their own prices.) See Note 12, *Revenue* to our audited consolidated financial statements included in Item 8, *Consolidated Financial Statements and Supplementary Data*.

If our relationships with our independent sales agents were terminated for any reason, it could materially and adversely affect our revenues and profits. Because the independent agent often controls the customer relationships within its territory, there is a risk that if our relationship with the agent ends, our relationship with the customer will be lost.

Because our agents and distributors are not employees, there is a risk we will be unable to ensure that our sales processes, compliance safeguards, and related policies will be adhered to despite our communication and training of agents and distributors regarding these requirements. Furthermore, if we fail to maintain relationships with our key independent agents, or fail to ensure that our independent agents adhere to our sales processes, compliance safeguards and related policies, there could be an adverse effect on our business, results of operations, and financial condition.

We may obtain the assistance of additional distributors and independent sales representatives to sell products in certain sales channels, particularly in territories and fields where agents are commonly used. Our success is partially dependent upon our ability to train, retain and motivate our independent sales agencies, distributors, and their representatives to appropriately and compliantly sell our products in certain territories or fields. They may not be successful in implementing our marketing plans or compliance safeguards. Some of our independent sales agencies and distributors do not sell our products exclusively and may offer similar products from other companies. Our independent sales agencies and distributors may terminate their contracts with us, may devote insufficient sales efforts to our products or may focus their sales efforts on other products that produce greater commissions for them, which could have an adverse effect on our business, results of operations and financial condition. We also may not be able to find additional independent sales agencies and distributors who will agree to appropriately and compliantly market or distribute our products on commercially reasonable terms, if at all. If we are unable to establish new independent sales representative and distribution relationships or renew current sales agency and distribution agreements on commercially acceptable terms, our business, financial condition, and results of operations could be materially and adversely affected.

***Disruption of our processing facilities could adversely affect our business, financial condition and results of operations.***

Our business depends upon the continued operation of our processing facilities in Marietta, Georgia and Kennesaw, Georgia. Risks that could impact our ability to use these facilities include the occurrence of natural and other disasters, the outbreak of pandemics, and the need to comply with the requirements of directives from government agencies, including the FDA. See above, for example, “ - *Public health emergencies, such as the COVID-19 pandemic and governmental and societal responses thereto have adversely affected our business, results of operations and financial condition in the past, and future outbreaks could harm our business, results of operations, and financial condition in the future.*”

Either of our two processing facilities can serve as a redundant processing facility for most of our Section 361 products in the event the other facility experiences a disaster event. For clinical trial requirements of our Section 351 products, we have transitioned manufacturing to our Kennesaw, Georgia facility to comply with CGMP standards, and implemented these standards for upstream and downstream supply chain activities at our Marietta, Georgia facility. However, if our processing facilities were to become unavailable, this could have a material adverse effect on our business, financial condition and results of operations during the period of such unavailability.

***To be commercially successful, we must educate physicians, where appropriate, how and when our products are proper alternatives to existing treatments and that our products should be used in their procedures.***

We believe physicians will only use our products if they determine, based on their independent medical judgment and experience, clinical data, and published peer reviewed journal articles, that the use of our products in a particular procedure is a favorable alternative to other treatments. Physicians may be hesitant to change their existing medical treatment practices for the following reasons, among others:

- their lack of experience with advanced therapeutics, such as our placenta-based allografts;
- lack of evidence supporting additional patient benefits of advanced therapeutics, such as our placenta-based allografts, over conventional methods in certain therapeutic applications;
- perceived liability risks generally associated with the use of new products and procedures;
- limited availability of reimbursement from third-party payers;
- more favorable reimbursement for other market-available products; and
- the time that must be dedicated to physician training in the use of our products.

***If we cannot successfully address quality issues that may arise with our products, our brand reputation could suffer, and our business, financial condition, and results of operations could be adversely impacted.***

In the course of conducting our business, we must adequately address quality issues that may arise with our products, as well as defects in third-party components included in our products, as any quality issues or defects may negatively impact physician use of our products. Although we have established internal procedures to minimize risks that may arise from quality issues, we may not be able to eliminate or mitigate occurrences of these issues and associated liabilities. If the quality of our products does not meet the expectations of physicians or patients, then our brand reputation could suffer and our business could be adversely impacted. We must also ensure any promotional claims made for our products comport with government regulations.

***The formation of physician-owned distributorships (“PODs”) could result in increased pricing pressure on our products or harm our ability to sell our products to physicians who own or are affiliated with those distributorships.***

PODs are medical product distributors that are owned, directly or indirectly, by physicians. These physicians derive a proportion of their revenue from selling or arranging for the sale of medical products for use in procedures they perform on their own patients at hospitals that agree to purchase from or through the POD, or that otherwise furnish ordering physicians with income that is based directly or indirectly on those orders of medical products. The Office of Inspector General (“OIG”) of the Department of Health & Human Services has issued a Special Fraud Alert on PODs, indicating that they are inherently suspect under the federal Anti-Kickback Statute.

Our commercial strategy emphasizes selling directly to healthcare providers and, to a limited extent, through distributors. To our knowledge, we do not directly sell to or distribute any of our products through PODs. The number and strength of PODs in the industry may continue to grow as economic pressures increase throughout the industry and hospitals, insurers and physicians search for ways to reduce costs, and, in the case of the physicians, identify additional sources to increase their incomes. These companies and the physicians who own, or partially own, PODs may have significant market knowledge, access to and influence on the physicians who use our products and the hospitals that purchase our products, and we may not be able to compete effectively for business from physicians who own PODs.

***We face the risk of product liability claims and may not be able to obtain or maintain adequate product liability insurance.***

Our business exposes us to the risk of product liability claims that are inherent in the manufacturing, processing and marketing of human tissue products. We may be subject to such claims if our products cause, or appear to have caused, an injury. Claims may be made by patients, healthcare providers or others selling our products. Product liability claims can be expensive to defend (regardless of merit), divert our management's attention, result in substantial damage awards against us, harm our reputation, and generate adverse publicity, which could result in the withdrawal of, or reduced acceptance of, our products in the market.

Although we have product liability insurance that we believe is adequate, this insurance is subject to deductibles and coverage limitations, and we may not be able to maintain this insurance at an acceptable cost or on acceptable terms or be able to secure increased coverage (if needed), nor can we be sure that existing or future claims against us will be covered by our product liability insurance. Moreover, the existing coverage of our insurance or any rights of indemnification and contribution that we may have may not be sufficient to offset existing or future claims. If we are unable to maintain product liability insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect ourselves against potential product liability claims or we underestimate the amount of insurance we need, we could be exposed to significant liabilities, which may harm our business. A product liability claim or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could result in significant costs and significant harm to our business. Even if a claim is not successful, defending such claim would be time-consuming and expensive, may damage our reputation in the marketplace, and would likely divert our management's attention.

***The products we process are derived from human tissue and therefore have the potential for disease transmission.***

The utilization of human tissue creates the potential for transmission of communicable disease, including, without limitation, human immunodeficiency virus, viral hepatitis, syphilis and other viral, fungal or bacterial pathogens. We are required to comply with federal and state regulations intended to prevent communicable disease transmission.

We maintain strict quality controls designed in accordance with CGTP to ensure the safe procurement and processing of our tissue, including terminal sterilization of our products. These controls are intended to prevent the transmission of communicable disease. However, risks exist with any human tissue implantation. We are also implementing and maintaining CGMP systems to comply with the regulations that will apply to our Section 351 HCT/Ps, and believe this provides an added level of quality throughout our manufacturing process. However, negative publicity concerning disease transmission from other companies' improperly processed donated tissue could have a negative impact on the demand for our products and adversely affect our business, financial condition and results of operations.

***We may implement a product recall or voluntary market withdrawal, which could significantly increase our costs, damage our reputation, disrupt our business and adversely affect our business, results of operations and financial condition.***

The processing and marketing of our tissue products involves an inherent risk that our tissue products or processes may not meet applicable quality standards and requirements. In the event that one or more of our products experiences a failure to meet such standards and requirements, we may voluntarily implement a recall or market withdrawal or may be required to do so by a regulatory authority.

A recall or market withdrawal of one of our products could be costly and may divert management resources. A recall or withdrawal of one of our products, or a similar product processed by another entity, also could impair sales of our products as a result of confusion concerning the scope of the recall or withdrawal, or as a result of the damage to our reputation for quality and safety.

***A cyberattack or significant disruptions of our information technology systems could adversely affect our business, results of operation and financial condition.***

A cyberattack, a disruption in availability, or the unauthorized alteration of systems or data could adversely affect our business, results of operations and financial condition. We rely on technology for day-to-day operations as well as positioning to enhance our stance in the market. We generate intellectual property that is central to the future success of the business and transmit large amounts of confidential information. Additionally, we collect, store and transmit confidential information of customers, patients, employees and third parties. We also have outsourced significant elements of our operations to third parties, including significant elements of our information technology infrastructure, and, as a result, we are managing many independent vendor relationships with third parties who may or could have access to our confidential information. The continually changing threat landscape of cybersecurity today makes our systems potentially vulnerable to service interruptions

or to security breaches from inadvertent or intentional actions by our employees, partners, and vendors, and from attacks by malicious third parties, including supply chain attacks originating at our third-party partners. Such attacks are of ever-increasing levels of sophistication. Attacks are made by individuals or groups that have varying levels of expertise, some of which are technologically advanced and well-funded including, without limitation, nation states, organized criminal groups and hacktivists organizations.

To ensure protection of our information, we have invested in cybersecurity and have implemented processes and procedural controls to maintain the confidentiality and integrity of such information. We measure these controls and their success through a cybersecurity framework that is based on industry standards. While we have invested in the protection of our data and technology, there can be no guarantees that our efforts will prevent all service interruptions or security breaches. Any such interruption or breach of our systems could adversely affect our business operations and result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal and reputational harm to our business, including legal claims and proceedings, liability under laws that protect the privacy of personal information, government enforcement actions and regulatory penalties, as well as remediation costs. We also maintain cyber liability insurance. However, this insurance may not be sufficient to cover the financial, legal or reputational losses that may result from an interruption or breach of our systems.

***We may expand or contract our business through acquisitions, divestitures, licenses, investments, and other commercial arrangements with other companies or technologies, which may adversely affect our business, results of operations and financial condition.***

We periodically evaluate opportunities to acquire companies or divest divisions, technologies, products, and rights through licenses, distribution agreements, investments, and outright acquisitions to grow our business. In connection with one or more of those transactions, we may, subject to the requirements and limitations set forth in our secured credit agreement (the "**Hayfin Loan Agreement**") with Hayfin Services, LLP ("**Hayfin**") an affiliate of Hayfin Capital Management LLP:

- issue additional equity securities that would dilute the value of equity currently held by our shareholders;
- divest or license existing products or technology;
- use cash that we may need in the future to operate our business;
- incur debt that could have terms unfavorable to us or that we might be unable to repay;
- structure the transaction in a manner that has unfavorable tax consequences, such as a stock purchase that does not permit a step-up in the tax basis for the assets acquired;
- be unable to realize the anticipated benefits, such as increased revenues, cost savings, or synergies from additional sales; and
- be unable to secure the services of key employees related to the transaction(s).

Any of these items could adversely affect our revenues, results of operations and financial condition. Business acquisitions also involve the risk of unknown liabilities associated with the acquired business, which could be material. Incurring unknown liabilities or the failure to realize the anticipated benefits of any transaction could adversely affect our business if we are unable to recover our initial investment. Inability to recover our investment, or any write off of such investment, associated goodwill or assets could have an adverse effect on our business, results of operations and financial condition.

***New lines of business or new products and services may subject us to additional risks.***

From time to time, we may implement or may acquire new lines of business or offer new products and services within existing lines of business. There are risks and uncertainties associated with these efforts, particularly in instances where the markets are not fully developed or are evolving. In developing and marketing new lines of business and new products and services, we may invest significant time and resources. External factors, such as regulatory compliance obligations, competitive alternatives, and shifting market preferences, may also impact the successful implementation of a new line of business or a new product or service. Failure to successfully manage these risks in the development and implementation of new lines of business or new products or services could have an adverse effect on our business, results of operations and financial condition.

***Our international expansion and operations outside the U.S. expose us to risks associated with international sales and operations.***

We are pursuing further expansion outside the U.S., including in Japan. Managing a global organization is difficult, time consuming and expensive. Our ability to conduct international operations is affected by many of the same risks we face in our U.S. operations, as well as unique costs and difficulties of managing international operations, including the relationships and

operations of distributors we elect to work with in these markets. Adoption of our products in new geographic regions could take longer and cost more than we anticipate. Risks inherent in international operations also include, among others, potential adverse tax consequences, greater difficulty in enforcing intellectual property rights, risks associated with the Foreign Corrupt Practices Act and local anti-bribery law compliance, and other international regulations. These regulations may limit our ability to market, sell, distribute or otherwise transfer our products to prohibited countries or persons. International regulations may also limit what promotional claims we may make for our products.

Compliance with these regulations and laws is costly, and failure to comply with applicable legal and regulatory obligations could adversely affect us in a variety of ways that include, without limitation, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments and restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities.

These risks may limit or disrupt our expansion, restrict the movement of funds or result in the deprivation of contractual rights or the taking of property by nationalization or expropriation without fair compensation. Operating outside of the U.S. also requires significant management attention and financial resources.

### **Risks Related to Regulatory Approval of Our Products and Other Government Regulations**

***Certain of our products no longer qualify for regulation as human cells, tissues and cellular and tissue-based products solely under Section 361 of the Public Health Service Act (“Section 361”), which has resulted in removal of the applicable products from the market, made the introduction of some new tissue products more expensive, significantly delayed the expansion of our tissue product offerings and subjected us to additional post-market regulatory requirements. Additional regulatory requirements may be imposed in the future.***

The products we manufacture and process are derived from human tissue. Amniotic and other birth tissue have in the past generally been regulated as HCT/P and were therefore eligible to be subject to regulation solely under Section 361 (“**Section 361 HCT/P**”) depending on whether the specific product at issue and the claims made for it were consistent with the applicable criteria. HCT/Ps that do not meet these criteria are subject to more extensive regulation as drugs, medical devices, biological products, or combination products. These HCT/Ps must comply with both the FDA’s requirements for HCT/Ps and the requirements applicable to biologics, devices or drugs, including pre-market clearance or approval from the FDA. Obtaining FDA pre-market clearance or approval involves significant time and investment by the Company.

In accordance with the FDA Guidance, as discussed above in “*Business – Government Regulation*,” after May 31, 2021, the Company no longer markets or sells its products that were impacted by enforcement discretion in the United States, has requested the return of unused consignment inventory as of that date, and does not intend to sell such products in the United States until the FDA grants pre-market approval. Our sales of such products for all uses was \$2.4 million, \$17.6 million, and \$31.8 million, respectively, in 2022, 2021, and 2020. Prior to May 31, 2021 these sales were primarily in the United States. However, we are pursuing the BLA pre-market approval process for certain use of mDHACM, as more fully discussed above in “*Business - Government Regulation*.” The loss of our ability to market and sell our micronized products has had an adverse impact on our revenues, business, financial condition and results of operations.

Also, the Company currently markets EPICORD and AMNIOCORD, tissue products derived from the protective covering and extracellular matrix cushioning layers of the human umbilical cord, as providing a protective environment or as a barrier. In warning letters to several companies marketing human umbilical cord derived products for a variety of uses, the FDA has stated that those products fail to meet one or more of the Section 361 criteria, including the minimal manipulation criterion, the dependence on the metabolic activity of living cells for their primary function criterion, and the homologous use criterion, as “the product is not intended to perform the same basic function or functions of umbilical cord in the recipient as in the donor, such as serving as a conduit.” We are engaged with the FDA regarding the classification of our umbilical cord-derived products. If the FDA makes a final determination that our umbilical cord products do not meet the requirements for regulation solely under Section 361, in order to continue to market the products, we would be required to obtain the appropriate FDA approval or clearance. The loss of our ability to market and sell our umbilical cord derived products would have an adverse impact on our revenues, business, financial condition and results of operations. Included in net sales were sales of umbilical cord-derived products totaling \$23.2 million, \$23.6 million, and \$16.1 million, respectively, in 2022, 2021, and 2020, almost entirely in the United States.

Any future regulatory changes could also have adverse consequences for us and make it more difficult or expensive for us to conduct our business by requiring pre-market clearance or approval and compliance with additional post-market regulatory requirements with respect to those products. For example, the FDA may in the future impose conditions, such as labeling restrictions, and the requirement that a product be manufactured in compliance with CGMP. Although the Company is

preparing for these requirements in connection with its pursuit of a BLA for certain of its products, earlier compliance with these conditions would require significant additional time and cost investments by the Company. Moreover, increased regulatory scrutiny within the industry in which we operate could lead to increased regulation of HCT/Ps, including Section 361 HCT/Ps, which could ultimately increase our costs and adversely impact our business, results of operations and financial condition. If the FDA approves the BLAs we seek, we will incur increased compliance costs on an ongoing basis. See “ - *If any of the BLAs are approved, the Company would be subject to additional regulation which will increase costs and could result in adverse sanctions for non-compliance*” below.

***If any of the BLAs are approved, the Company would be subject to additional regulation which will increase costs and could result in adverse sanctions for non-compliance.***

Products subject to the FDA’s BLA requirements must comply with a range of pre- and post-market provisions. Pre-market compliance includes the conduct of clinical trials in support of BLA approval, the development and submission of a BLA, and the production of product for use in the clinical trials that meets FDA’s quality expectations. We have been making enhancements in our fixed plant as well as incurring costs and reduced product yields due to testing against CGMP drug requirements to ensure quality, identity, purity, and potency. Post-approval requirements for BLA products include: compliance with CGMP, which will require us to comply with promotional and labeling requirements, which limit our ability to make claims about regulated products; submission of annual reports in appropriate circumstances; compliance with the FDA’s “Biological Product Deviation Reporting System,” when applicable; submission of adverse events; reporting and correcting product problems within established timeframes; recalling or stopping the manufacture of a product if a significant problem is detected; complying with the appropriate laws and regulations relevant to the biologics licensed and identifying any changes needed to help ensure product quality. In some instances, the FDA can also require that applicants conduct post-market studies or trials of the product. This additional compliance burden may increase costs, and failure to comply with such requirements may subject the Company to sanctions that would have an adverse impact on our business, results of operations and financial condition.

***Obtaining and maintaining the necessary regulatory approvals for certain of our products will be expensive and time consuming and may impede our ability to fully exploit our technologies.***

The process of obtaining regulatory clearances or approvals to market a biological product or medical device from the FDA or similar regulatory authorities outside of the U.S. may be costly and time consuming, and such clearances or approvals may not be granted on a timely basis, or at all. We are pursuing approval of BLAs for certain of our micronized products, but have not yet submitted a BLA for review. Additionally, the FDA may take the position that some of the other products that we currently market require a BLA as well. Some of the future products and enhancements to our current products that we expect to develop or may acquire and market may require marketing clearance or approval from the FDA. However, clearance or approval may not be granted with respect to any of our products or enhancements and further FDA review may add delays that could adversely affect our ability to market such products or enhancements.

The process of obtaining an approved BLA, including clinical trial development and execution as well as manufacturing processes, requires the expenditure of substantial time, effort and financial resources and may take years to complete, including costs incurred on top of those fees incurred as part of conducting various clinical studies. The fee for filing a BLA and program fees payable with respect to any establishment that manufactures biologics are substantial. Additionally, there are significant costs associated with clinical trials that can be difficult to accurately estimate until a BLA is approved. Clinical trials may not be successful or may return results that do not support approval. Moreover, data obtained from clinical trials are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all, or we may decide not to pursue a BLA for certain products or indications, or need to conduct additional trials for a given indication. Additionally, the FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of the products. If we do receive approval, some types of changes to the approved product, such as adding new indications or doses, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval. Our revenues will be adversely affected if we fail to obtain BLA approvals on a timely basis or at all, or if the FDA limits the indications for use or requires other conditions that restrict the commercial application of our products.

***Clinical trials will be necessary to support future BLA submissions and potential product approvals by the FDA. The clinical trial process is lengthy and expensive with uncertain outcomes, and often requires the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Delays or failures in our clinical trials could prevent us from commercializing any modified or new products and would adversely affect our business, operating results and prospects.***

The results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials. Our interpretation of data and results from our clinical trials does not ensure that we will achieve similar results in future clinical trials. In addition, clinical data are often susceptible to various

interpretations and analyses, and many companies that have believed their products performed satisfactorily in earlier clinical trials or retrospective studies have nonetheless failed to replicate results in later clinical trials. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials and retrospective studies, and such failures can occur at any stage of clinical testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned.

The initiation and completion of a trial may be prevented, delayed, or halted for numerous reasons, including, but not limited to, the following:

- regulatory authorities do not approve a clinical study protocol, force us to modify a previously approved protocol, or place a clinical study on hold;
- patients do not enroll in, or enroll at a lower rate than we expect or need, or do not complete a clinical study;
- patients or investigators do not comply with study protocols;
- the FDA may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials;
- patients do not return for post-treatment follow-up at the expected rate;
- patients may experience serious or unexpected adverse side effects for a variety of reasons that may or may not be related to our product causing a clinical trial study to be put on hold;
- we may be unable to recruit a sufficient number of clinical trial sites;
- sites participating in an ongoing clinical study may withdraw, requiring us to engage new sites;
- third-party clinical investigators decline to participate in our clinical studies, do not perform the clinical studies on the anticipated schedule, or act in ways inconsistent with the investigator agreement, clinical study protocol, good clinical practices, or other regulatory requirements;
- third-party entities do not perform data collection and analysis in a timely or accurate manner;
- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to regulatory authorities for approval;
- the cost of clinical trials may be greater than we anticipate; and
- regulators or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities, the supply of materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply.

Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of certification or regulatory approval of our product candidates.

***Our ability to consistently and reliably manufacture our biologic products will be key to the marketing of any future Section 351 products. Also, our current manufacturing facilities may be inadequate to produce sufficient quantities if our planned BLA program is approved.***

The manufacture of biologic products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the approval of BLAs require one to demonstrate the ability to manufacture pursuant to specified chemistry and manufacturing controls. Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up initial production as would be the case at any new facility. These problems can include difficulties with production costs and yields, quality control (including stability of the product candidate and quality assurance testing), shortages of qualified personnel, and compliance with strictly enforced federal, state and foreign regulations. If we were to encounter any of these difficulties, or otherwise fail to comply with our obligations under applicable regulations, then our ability to provide product candidates to patients in our clinical trials or commercially would be jeopardized, and any delay or interruption in the supply of product could delay the commercial launch of the product or impair our ability to meet demand for the product.

Our products can be manufactured only in a facility that has undergone a satisfactory inspection by the FDA and other relevant regulatory authorities. We may not be able to replace manufacturing capacity for our products quickly if we were unable to use our manufacturing facilities as a result of a fire, natural disaster (including an earthquake), equipment failure, or other difficulty, or if such facilities were deemed not in compliance with the regulatory requirements and such non-compliance could not be rapidly rectified. An inability or reduced capacity to manufacture our products could have a material adverse effect on our business, financial condition, and results of operations.

Our existing manufacturing facilities have been adequate for the products we currently sell, but may become inadequate for future products if our planned BLA for mDHACM is approved or if our sales of current and future Wound & Surgical products ramps at a rate faster than we are able to manufacture. Therefore, we have begun planning changes to our processes to increase manufacturing capacity. Failure to adequately expand capacity could delay commercialization of our current or

future product candidates, depriving us of potential product revenue. Any manufacturing problem could be disruptive to our operations and result in lost sales.

***Our business is subject to extensive regulation by the FDA and other authorities, which is costly, and our failure to comply could result in negative effects on our business, results of operations and financial condition.***

As discussed above, the FDA has specific regulations governing our tissue-based products, or HCT/Ps. The FDA has broad post-market and regulatory and enforcement powers, even for Section 361 HCT/Ps. The FDA's regulation of HCT/Ps includes requirements for registration and listing of products, donor screening and testing, processing and distribution, labeling, record keeping and adverse-reaction reporting, and inspection and enforcement.

HCT/Ps that are regulated as drugs, biological products or medical devices are subject to even more stringent regulation by the FDA. Even if pre-market clearance or approval is obtained, the approval or clearance may place substantial restrictions on the indications for which the product may be marketed or to whom it may be marketed, may require warnings to accompany the product or impose additional restrictions on the sale or use of the product. In addition, regulatory approval is subject to continuing compliance with regulatory standards, including the FDA's quality system regulations.

If we fail to comply with the FDA regulations regarding our tissue products, the FDA could take enforcement action, including, without limitation, any of the following sanctions and the manufacture of our products or processing of our tissue could be delayed or terminated:

- untitled letters, warning letters, cease and desist orders, fines, injunctions, and civil penalties;
- recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our requests for clearance or approval of new products;
- withdrawing or suspending current applications for approval or approvals already granted;
- refusal to grant export approval for our products; and
- criminal prosecution.

The FDA's regulation of HCT/Ps may continue to evolve. Complying with any such new regulatory requirements may entail significant time delays and expense, which could have an adverse effect on our business, results of operations and financial condition.

The AATB has issued operating standards for tissue banking. Compliance with these standards is a requirement in order to become an accredited tissue bank. In addition, some states have their own tissue banking regulations.

In addition, procurement of certain human organs and tissue for transplantation is subject to the restrictions of the NOTA, which prohibits the transfer of certain human organs, including skin and related tissue for valuable consideration, but permits the reasonable payment associated with the removal, transportation, implantation, processing, preservation, quality control and storage of human tissue and skin. We reimburse tissue banks, hospitals and physicians for their services associated with the recovery and storage of donated human tissue. Although we have independent third party appraisals that confirm the reasonableness of the service fees we pay, if we were to be found to have violated NOTA's prohibition on the sale or transfer of human tissue for valuable consideration, we could potentially be subject to criminal enforcement sanctions, which could adversely affect our results of operations.

Finally, we and other manufacturers of skin substitutes are required to provide average ASP information to CMS on a quarterly basis. The Medicare payment rates are updated quarterly based on this ASP information. If a manufacturer is found to have made a misrepresentation in the reporting of ASP, such manufacturer is subject to civil monetary penalties of up to \$10,000 for each misrepresentation for each day in which the misrepresentation was applied, and potential False Claims Act liability. See *"We and our sales representatives, whether employees or independent contractors, must comply with various federal and state anti-kickback, self-referral, false claims and similar laws, any breach of which could cause an adverse effect on our business, results of operations and financial condition."*

***We may be subject to fines, penalties, injunctions and other sanctions if we are deemed to be promoting the use of our products for unapproved, or off-label, uses.***

As a general rule, FDA regulations require that the marketing of 361 HCT/Ps only be for appropriate homologous uses, and that the promotion of pre-approved biological products or devices only be for FDA-approved indications. Generally, unless the products are approved by the FDA for alternative uses, the FDA contends that we may not make claims about the safety or

effectiveness of our products, or promote them as safe or effective for uses other than those specifically approved by the FDA. Such limitations present a risk that the FDA or other federal or state law enforcement authorities could determine that the nature and scope of our sales, marketing and support activities, though designed to comply with all FDA requirements, constitute the promotion of our products for an unapproved use in violation of the federal FD&C Act. We also face the risk that the FDA or other governmental authorities might pursue enforcement based on past activities that we have discontinued or changed, including sales activities, prior marketing materials, arrangements with institutions and doctors, educational and training programs and other activities.

Investigations concerning the promotion of unapproved product uses and related issues are typically expensive, disruptive and burdensome and generate negative publicity. If our promotional activities are found to be in violation of the law, we may face significant legal action, fines, penalties, and even criminal liability and may be required to substantially change our sales, promotion, grant and educational activities. There is also a possibility that we could be enjoined from selling some or all of our products for any unapproved use. In addition, as a result of an enforcement action against us or any of our executive officers, we could be excluded from participation in government healthcare programs such as Medicare and Medicaid.

However, under the Guidance, as discussed above in “*Business – Government Regulation*,” after May 31, 2021, the Company no longer markets or sells its products that were impacted by enforcement discretion in the United States, and does not intend to sell such products in the United States until the FDA grants pre-market approval. We will ultimately only be able to market such products for indications that have been cleared or approved by the FDA.

Nevertheless, while we believe we are fully in compliance with the FDA’s Guidance on HCT/Ps, there can be no assurance that we have correctly interpreted the FDA Guidance, or that we will not need to discontinue marketing a product and/or may be subject to fines, penalties, injunctions, and other sanctions if we are deemed to be promoting the use of our products for unapproved uses. Such regulatory penalties by the FDA could adversely affect our business and results of operations.

***We and our sales representatives, whether employees or independent contractors, must comply with various federal and state anti-kickback, self-referral, false claims and similar laws, any breach of which could cause an adverse effect on our business, results of operations and financial condition.***

Our relationships with physicians, hospitals and other healthcare providers are subject to various federal and state healthcare fraud and abuse laws. Healthcare fraud and abuse laws are complex and, in some instances, even minor or inadvertent violations can give rise to liability. Possible sanctions for violation of the healthcare fraud and abuse laws include, without limitation, monetary fines, civil and criminal penalties, exclusion from participating in the federal and state healthcare programs, including, without limitation, Medicare, Medicaid, the VA health programs and TRICARE (the healthcare program administered by or on behalf of the U.S. Department of Defense for uniformed service members, including both those in active duty and retirees, as well as their dependents), and forfeiture of amounts collected in violation of such prohibitions. Many states have similar fraud and abuse laws, imposing substantial penalties for violations. A finding of a violation of one or more of these laws, or even a government investigation or inquiry into the same, would likely result in a material adverse effect on the market price of our Common Stock, as well as on our business, results of operations, and financial condition.

The federal Anti-Kickback Statute (AKS) is a criminal law that prohibits, among other things, any person from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or in kind, to induce or reward referrals, purchases or orders or arranging for or recommending the purchase, order or referral of any item or service for which payment may be made in whole or in part by a federal healthcare program, such as the Medicare and Medicaid programs. The term “remuneration” has been broadly interpreted to include anything of value. The Patient Protection and Affordable Care Act (the “*PPACA*”) amended the federal AKS to clarify the intent that is required to prove a violation. Under the federal AKS as amended, a person or entity need not have actual knowledge of this statute or specific intent to violate it. The PPACA also amended the federal AKS to provide that any claims for items or services resulting from a violation of the federal AKS are considered false or fraudulent for purposes of the federal FCA. A conviction for violation of the AKS results in criminal fines and requires mandatory exclusion from participation in federal health care programs. Although there are a number of statutory exceptions and regulatory safe harbors to the federal AKS that protect certain common industry practices from prosecution, the exceptions and safe harbors are drawn narrowly, and arrangements may be subject to scrutiny or penalty if they do not fully satisfy all elements of an available exception or safe harbor. We have entered into consulting agreements, speaker agreements, research agreements and product development agreements with physicians, including some who may order or recommend our products or make decisions to use them. In addition, some of these physicians own our stock, which they purchased in arm’s-length transactions on terms identical to those offered to non-physicians, or received stock awards from us in the past as consideration for services performed by them. While we believe these transactions generally meet the requirements of applicable laws, including the federal AKS and analogous state laws, it is possible that our arrangements with physicians and other providers may be questioned by regulatory or enforcement authorities under such laws, which could lead us to redesign

the arrangements and subject us to significant civil or criminal penalties. We have designed our policies and procedures to comply with the federal AKS, FCA, and industry best practices. In addition, we have conducted training sessions on these principles. If, however, regulatory or enforcement authorities were to view these arrangements as non-compliant with applicable laws, there would be risk of government investigations/inquiries or penalties. There is also risk that one or more of our employees or agents will disregard the rules we have established. Because our strategy relies on the involvement of physicians who consult with us on the design of our products, perform clinical research on our behalf or educate other health care professionals about the efficacy and uses of our products, we could be materially impacted if regulatory or enforcement agencies or courts interpret our financial relationships with physicians who refer or order our products to be in violation of applicable laws. This could harm our reputation and the reputations of the physicians we engage to provide services on our behalf. In addition, the cost of noncompliance with these laws could be substantial since we could be subject to monetary fines and civil or criminal penalties, and we could also be excluded from federally-funded healthcare programs, including Medicare, Medicaid, VA and TRICARE.

The FCA imposes civil liability on any person or entity that knowingly submits, or causes the submission of, a false or fraudulent claim to the U.S. government. Damages under the FCA can be significant and consist of the imposition of fines and penalties. The FCA also allows a private individual or entity to sue on behalf of the government to recover civil penalties and treble damages as a whistleblower. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of between \$11,181 and \$22,363 per false claim or statement for penalties assessed after January 29, 2018, with respect to violations occurring after November 2, 2015.

Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payers if they are deemed to “cause” the submission of false or fraudulent claims. The PPACA provides that claims tainted by a violation of the federal AKS are false for purposes of the FCA. The DOJ on behalf of the government has previously alleged that the marketing and promotional practices of pharmaceutical and medical device manufacturers, including the off-label promotion of products or the payment of prohibited kickbacks to doctors, violated the FCA, resulting in the submission of improper claims to federal and state healthcare programs such as Medicare and Medicaid. In certain cases, manufacturers have entered into criminal and civil settlements with the federal government under which they entered into plea agreements, paid substantial monetary amounts and entered into onerous corporate integrity agreements with the government that require, among other things, substantial reporting and remedial actions, as well as oversight and review by an outside entity, an Independent Review Organization (“IRO”), at substantial expense to the Company.

Under the HIPAA criminal federal healthcare fraud statute, it is a crime to knowingly and willfully execute, or attempt to execute, a scheme or artifice to defraud any health care benefit program or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, in connection with the delivery of or payment for health care benefits, items or services.

There are federal and state laws requiring detailed reporting of manufacturer interactions with and payments to healthcare providers, such as the federal Physician Payments Sunshine Act (Sunshine Act). The Sunshine Act requires, among others, “applicable manufacturers” of drugs, devices, biological products, and medical supplies reimbursed under Medicare, Medicaid or the Children’s Health Insurance Program to annually report to CMS information related to payments and other transfers of value provided to “covered recipients.” The term covered recipients includes U.S.-licensed physicians and teaching hospitals, and, for reports submitted on or after January 1, 2022, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives. While manufacturers of human cell and tissue products regulated solely under Section 361 are not subject to the Sunshine Act, in the future, if we receive a BLA, we will be subject to this law. There is the risk that CMS or another government agency may take the position that our products are not human cell and tissue products regulated solely under Section 361, and thereby assert that we are currently subject to the Sunshine Act, which could subject us to civil penalties and the administrative burden of having to comply with the law.

There are state law equivalents to the AKS and FCA. There are also so-called state “all-payer” anti-kickback laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, as well as when no insurer is involved (*i.e.* cash-pay patients).

The enforcement of all of these laws is uncertain and subject to rapid change. Federal or state regulatory or enforcement authorities may investigate or challenge our current or future activities under these laws. Any investigation or challenge could have a material adverse effect on our business, financial condition and results of operations. Any state or federal regulatory or enforcement review of us, regardless of the outcome, would be costly and time consuming. Additionally, we cannot predict the impact of any changes in these laws, whether these changes are retroactive or will have effect on a going-forward basis only.

***Our results of operations may be adversely affected by current and potential future healthcare reforms.***

In response to perceived increases in healthcare costs in recent years, there have been and continue to be proposals by the U.S. federal government, state governments, regulators and third-party payers to control these costs and, more generally, to reform the U.S. healthcare system. In the U.S., the PPACA was enacted in 2010 with a goal of reducing the cost of healthcare and substantially changing the way healthcare is financed by both government and private insurers.

In addition, other legislative changes have been proposed and adopted in the U.S. since the PPACA was enacted. The Budget Control Act of 2011 created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013. In January 2013, the American Taxpayer Relief Act was signed into law, which, among other things, further reduced Medicare payments to several provider types, including hospitals.

In addition to the ACA, the Medicare Access and CHIP Reauthorization Act of 2015 ("**MACRA**") repealed the Sustainable Growth Rate formula used to calculate Medicare payment updates for physicians providing services to Medicare beneficiaries. In its place, MACRA introduced the Quality Payment Program ("**QPP**"), which is a value-based program that focuses on quality and outcomes as a metric for physician reimbursement. The Centers for Medicare and Medicaid Services released its final rules for the QPP in October 2016. The QPP, which impacts more than 600,000 physicians and other practice-based clinicians, represents a fundamental change in physician reimbursement, transitioning from a system that solely rewards volume of care to one that also rewards quality and value of care. The rule may have an impact on our revenue in the future. The program's increased emphasis on quality and cost of care may encourage physicians to merge practices or seek direct employment with hospitals. In addition, the ACA encourages hospitals and physicians to work collaboratively through shared savings programs as well as other bundled payment initiatives. These shifts could lead to a consolidation of hospital providers into larger delivery networks with increased price negotiation strength resulting in downward pressure on our selling prices. Although we believe that we are well positioned to minimize any such impact on our business, our inability to address the consolidation trend could materially and adversely affect our business and results of operations.

There is uncertainty with respect to the impact the U.S. Administration, the executive order, and the attempted legislation may have, if any, and any changes will likely take time to unfold and could have an impact on coverage and reimbursement for healthcare items and services, including our products. We believe that substantial uncertainty remains regarding the net effect of the PPACA, or its repeal and potential replacement, on our business, including uncertainty over how benefit plans purchased on exchanges will cover our products, how the expansion or contraction of the Medicaid program will affect access to our products, the effect of risk-sharing payment models such as Accountable Care Organizations and other value-based purchasing programs on coverage for our product, and the effect of the general increase or decrease in federal oversight of healthcare payers. The taxes imposed and the expansion in government's role in the U.S. healthcare industry under the PPACA, if unchanged, may result in decreased revenues, lower reimbursements by payers for our products and reduced medical procedure volumes, all of which could have a material adverse effect on our business, results of operations and financial condition.

***We may fail to obtain or maintain foreign regulatory approvals to market our products in other countries.***

We currently market our products in a small number of foreign countries, and are actively pursuing international expansion, including in Japan. Foreign jurisdictions require separate regulatory approvals and compliance with numerous and varying regulatory requirements. The approval procedures vary among countries and may involve requirements for additional testing. Certain of our products require clearance or approval by the FDA. However, such clearance or approval does not ensure approval or certification by regulatory authorities in other countries or jurisdictions, and approval or certification by one foreign regulatory authority does not ensure approval or certification by regulatory authorities in other foreign countries or by the FDA. The foreign regulatory approval or certification process may include all of the risks associated with obtaining FDA clearance or approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals or certifications and may not receive necessary approvals to commercialize our products in any foreign jurisdiction. Furthermore, many foreign jurisdictions operate under socialized medical care, and obtaining reimbursement for our products under that construct may also prove difficult. If we fail to receive necessary approvals, certifications, or reimbursements necessary to commercialize our products in foreign jurisdictions such as Japan on a timely basis, or at all, our business, results of operations and financial condition could be adversely affected. Further, governmental authorities outside the U.S. have become increasingly stringent in their regulation of medical devices, and our products may become subject to more rigorous regulation by non-U.S. governmental authorities in the future. U.S. or non-U.S. government regulations may be imposed in the future that may have a material adverse effect on our business and operations.

***Federal and state laws that protect the privacy and security of personal information may increase our costs and limit our ability to collect and use that information and subject us to liability if we are unable to fully comply with such laws.***

Numerous federal and state laws, rules and regulations govern the collection, dissemination, use, security and confidentiality of personal information, including protected health information and individually identifiable health information. These laws include:

- provisions of HIPAA that limit how covered entities and business associates may use and disclose protected health information, provide certain rights to individuals with respect to that information and impose certain security requirements;
- HITECH, which strengthened and expanded the HIPAA Privacy Rule and Security Rules, imposed data breach notification obligations, created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- other federal and state laws restricting the use and protecting the privacy and security of personal information, including health information, many of which are not preempted by HIPAA;
- federal and state consumer protection laws; and
- federal and state laws regulating the conduct of research with human subjects.

The California Consumer Protection Act ("**CCPA**"), which became effective on January 1, 2020, is a privacy law that requires certain companies doing business in California to disclose information regarding the collection and use of a consumer's personal data and to delete a consumer's data upon request. The Act also permits the imposition of civil penalties and expands existing state security laws by providing a private right of action for consumers in certain circumstances where consumer data is subject to a breach. We are still evaluating whether and how this rule will impact our U.S. operations and/or limit the ways in which we can provide services or use personal data collected while providing services.

As part of our business operations, including our medical record keeping, third-party billing and reimbursement and research and development activities, we collect and maintain protected health information in paper and electronic format. Standards related to collecting and maintaining health information, whether implemented pursuant to HIPAA, HITECH, state laws, federal or state action or otherwise, could have a significant effect on the manner in which we handle personal information, including healthcare-related data, and communicate with payers, providers, patients, donors and others, and compliance with these standards could impose significant costs on us or limit our ability to offer services, thereby negatively impacting the business opportunities available to us.

If we are alleged to have not complied with existing or new laws, rules and regulations related to personal information, we could be subject to litigation and to sanctions that include monetary fines, civil or administrative penalties, civil damage awards or criminal penalties.

#### **Risks Related to Our Intellectual Property**

***Our ability to protect our intellectual property and proprietary technology through patents and other means is uncertain and may be inadequate, which could have an adverse effect on our business, results of operations and financial condition.***

Our success depends significantly on our ability to protect our proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology, including our licensed technology. These legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. In addition, our pending patent applications include claims to material aspects of our products and procedures that are not currently protected by issued patents. The patent application process can be time consuming and expensive. Our pending patent applications might not result in issued patents. Competitors may be able to design around our patents or develop products that provide outcomes that are comparable or even superior to ours. Although we have taken steps to protect our intellectual property and proprietary technology, including entering into confidentiality agreements and intellectual property assignment agreements with some of our officers, employees, consultants and advisors, such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements.

The failure to obtain and maintain patents or protect our intellectual property rights could have an adverse effect on our business, results of operations, and financial condition. Whether a patent claim is valid is a complex matter of science, facts and law, and therefore we cannot be certain that, if challenged, our patent claims would be upheld. If any of those patent claims are invalidated, our competitive advantage may be reduced or eliminated.

In the event a competitor infringes upon our licensed patents, issued patents, pending patent applications or other intellectual property rights, enforcing those rights may be costly, uncertain, difficult and time consuming. Even if successful, litigation to enforce or defend our intellectual property rights could be expensive and time consuming and could divert our management's attention. Further, bringing litigation to enforce our patents subjects us to the potential for counterclaims. Other companies or entities also have commenced, and may again commence, actions seeking to establish the invalidity of our patents and certain related claims. In the event that any of our patent claims are challenged, a court, the United States Patent and Trademark Office ("**USPTO**"), or the Patent Trial and Appeal Board ("**PTAB**") of the USPTO may invalidate one or more challenged patent claims or determine that the patent is unenforceable, which could harm our competitive position. If the USPTO or the PTAB ultimately cancels or narrows the claim scope of any of our patents through these proceedings, it could prevent or hinder us from being able to enforce them against competitors. Such adverse decisions could negatively impact our business, results of operations, and financial condition.

In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in enforcing and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in some countries may be inadequate.

***We may become subject to claims of infringement of the intellectual property rights of others, which could prohibit us from developing our products, require us to obtain licenses from third parties or to develop non-infringing alternatives, and subject us to substantial monetary damages.***

Third parties could assert that our products infringe their patents or other intellectual property rights. Whether a product infringes a patent claim or other intellectual property right involves a complex combination of legal and factual issues, the determination of which is often uncertain. Therefore, we cannot be certain that we have not infringed the intellectual property rights of others. Because patent applications may take years to issue, there also may be applications now pending of which we are unaware that may later result in issued patent claims that our products or processes infringe. There also may be existing patents or pending patent applications of which we are unaware that our products or processes may inadvertently infringe.

Any infringement claim could cause us to incur significant costs, place significant strain on our financial resources, divert management's attention from our business and harm our reputation. If the relevant patent claims at issue in such a dispute were upheld as valid and enforceable and we were found to infringe, we could be prohibited from selling any product that is found to infringe those claims unless we could obtain licenses to use the technology covered by the asserted patent claims or other intellectual property, or are able to design around the patent claim or claims at issue or other intellectual property. We may be unable to obtain such a license on terms acceptable to us, if at all, and we may not be able to redesign our products to avoid infringement. A court could also order us to pay compensatory damages for such infringement, plus prejudgment interest and could, in addition, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily or permanently enjoin us and our customers from making, using, or selling products, and could enter an order mandating that we undertake certain remedial measures. Depending on the nature of the relief ordered by the court, we could become liable for additional damages to third parties. Further, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our trade secrets or other confidential information could be compromised by inadvertent or court-ordered disclosure during this type of litigation.

***We may be subject to damages resulting from claims that we, our employees, or our independent contractors have wrongfully used or disclosed alleged trade secrets, proprietary or confidential information of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.***

Some of our employees were previously employed at other medical device, pharmaceutical or tissue companies. We may also hire additional employees who are currently employed at other medical device, pharmaceutical or tissue companies, including our competitors. Additionally, consultants or other independent agents with which we may contract may be or have been in a contractual arrangement with one or more of our competitors. Although no claims are currently pending, we may be subject to claims that we, our employees, or our independent contractors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail to defend such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any future litigation or the threat thereof may adversely affect our ability to hire additional direct sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to market existing or new products, which could severely harm our business, financial condition and operating results.

#### **Risks Related to Our Past Audit Committee Investigation, Consolidated Financial Statements, Internal Controls and Related Matters**

***If we fail to maintain adequate internal control over financial reporting in the future, this could adversely affect our business, financial condition and operating results.***

We have in the past reported material weaknesses in our internal control over financial reporting which we have now remediated. If additional material weaknesses or deficiencies in our internal control over financial reporting are discovered or occur in the future, our consolidated financial statements might contain material misstatements and we could be required to restate our financial results. Moreover, because of the inherent limitations of any control system, material misstatements due to error or fraud may not be prevented or detected on a timely basis, or at all. If we are unable to provide reliable and timely financial reports in the future, our business and reputation may be further harmed. Failures in internal controls may also cause us to fail to meet reporting obligations, negatively affect investor confidence in our management and the accuracy of our financial statements and disclosures, or result in adverse publicity and concerns from investors, any of which could have a negative effect on the price of our Common Stock, subject us to regulatory investigations and penalties or shareholder litigation, and adversely impact our business, results of operations and financial condition.

***Negative publicity, including publicity relating to or arising from the Restatement, the Audit Committee Investigation, or related matters, has in the past had and could continue to have an adverse effect on our business, results of operations and financial condition.***

We have been and could continue to be the subject of negative publicity focusing on the Restatement, the results of the Audit Committee Investigation, and related matters. As a result, our customers and others with whom we do business have voiced concerns regarding our accounting and control environment and our ability to be a long-term provider to our customers. Further negative publicity could adversely affect our business, financial condition and results of operations.

We have incurred significant legal and accounting expenditures as a result of the Restatement and have become subject to a number of additional risks and uncertainties, including being a party to certain litigation relating to the Restatement. See Item 3, *Legal Proceedings* and Item 8, *Financial Statements and Supplementary Data*, Note 16, *Commitments and Contingencies* for additional information. As a result of the Restatement, we may continue to be at risk for further government investigations, shareholder litigation, and additional accounting and legal fees in connection therewith, as well as loss of investor confidence in us, and a negative impact on our stock price.

***We are currently, in the past have been, and in the future may be, subject to substantial litigation and ongoing investigations that could cause us to incur significant legal expenses, divert management's attention, and result in harm to our business.***

We are exposed to potential liabilities and reputational risk associated with litigation, regulatory proceedings and government enforcement actions. We were party to a securities class action lawsuit subject to appeal alleging, among other things, violations of Section 10(b) of the Securities Exchange Act of 1934. See Item 3, *Legal Proceedings* and Item 8, *Financial Statement and Supplementary Data*, Note 16, *Commitments and Contingencies* for information regarding proceedings that we believe may be significant to the Company as of the date of the filing of this Annual Report. We may be subject to additional lawsuits, including class action or securities derivative lawsuits, and further government investigations as well as incur additional legal fees and may face negative impacts to our stock price and reputation. In addition, we are obligated to indemnify and advance expenses to certain individuals involved in certain of these proceedings.

Any adverse judgment in or settlement of any pending or any future litigation could result in significant payments, fines and penalties that could have a material adverse effect on our business, results of operations, financial condition and reputation. Such payments, damages or settlement costs, if any, related to these matters could be in excess of our insurance coverage. The amount of time that is required to resolve these lawsuits is unpredictable and any litigation or claims against us, even those without merit, may cause us to incur substantial costs, divert management's attention from the day-to-day operation of our business, and materially harm our reputation.

## **Risks Related to the Securities Markets and Ownership of Our Common Stock**

### ***Our substantial indebtedness may adversely affect our financial health.***

As of December 31, 2022, the Company had an aggregate of \$50.0 million of borrowings outstanding under the Hayfin Loan Agreement. Our substantial outstanding debt may limit our ability to borrow additional funds or may adversely affect the terms on which such additional funds may be available. Additionally, a default under certain other indebtedness constitutes an event of default under the Hayfin Loan Agreement. Consequently, the effects of a default under other debt may be amplified by the lender exercising the remedies available to it in the Hayfin Loan Agreement for events of default, including foreclosure on the collateral securing our obligations and the declaration that all amounts outstanding under the Hayfin Loan Agreement are immediately due and payable. The limitations on our ability to access additional borrowing and the potential effects of a cross-default under the Hayfin Loan Agreement may limit our liquidity and have an adverse effect on our business, financial condition, and results of operations.

### ***The restrictive covenants in the Hayfin Loan Agreement, and the Company's obligation to make debt payments under the Hayfin Loan Agreement, limit our operating and financial flexibility and may adversely affect our business, results of operations and financial condition.***

The Hayfin Loan Agreement, as amended, imposes operating and financial restrictions and covenants. For example, the Hayfin Loan Agreement, as amended, contains (a) covenants that impose certain reporting and/or performance obligations on the Company and its subsidiaries, including (i) a Minimum Consolidated Total Net Sales (as defined in the Hayfin Loan Agreement) of varying amounts from now until maturity at June 30, 2025, in each case tested quarterly; and (ii) Minimum Liquidity (as defined in the Hayfin Loan Agreement) of \$20 million, an at-all-times covenant tested monthly and (b) certain negative covenants that generally limit, subject to various exceptions, the Company and its subsidiaries from taking certain actions, including, without limitation, incurring indebtedness, making investments, incurring liens, paying dividends and engaging in mergers and consolidations, sale and leaseback transactions and asset dispositions.

Our ability to comply with the financial covenants in the Hayfin Loan Agreement is in part dependent on our success in our overall strategies, including pursuing expansion beyond Advanced Wound Care into areas of Surgical Recovery, introducing new products and seeking international growth. A breach of a financial covenant in the Hayfin Loan Agreement could result in an event of default that would trigger the lenders' remedies, including the right to accelerate the entire principal balance of the loan under the Hayfin Loan Agreement. We currently have sufficient cash on hand to repay all amounts outstanding, however, there can be no assurances that we will be able to find alternative financing in case of such or other event of a default. Even if alternative financing were available, should an event of a default occur under the Hayfin Loan Agreement, it might be on unfavorable terms, and the interest rate charged on any new borrowings could be substantially higher than the interest rate under the Hayfin Loan Agreement, thus adversely affecting our cash flows, liquidity, and results of operations. Acceleration of the repayment of the loan pursuant to the terms of the Hayfin Loan Agreement, in combination with the Company's current commitments and contingent liabilities, could also cast doubt on the Company's ability to continue as a going concern.

### ***Our variable rate indebtedness under the Hayfin Loan Agreement subjects us to interest rate risk, which could result in higher expense in the event of increases in interest rates and adversely affect our business, financial condition, and results of operations.***

Borrowings under the Hayfin Loan Agreement, as amended, bear interest at a per annum rate equal to London Interbank Offered Rate ("**LIBOR**"), subject to a "floor" of 1.5%, plus a margin of 6.75%. As a result, we are exposed to interest rate risk, which we do not hedge. If LIBOR rises, the interest rate on outstanding borrowings under the Hayfin Loan Agreement will increase. Therefore, an increase in LIBOR will increase our interest payment obligations under the Hayfin Loan Agreement and have a negative effect on our cash flows and liquidity, and could have a negative effect on our ability to make payments due under the Hayfin Loan Agreement.

### ***EW Healthcare Partners and its interests may conflict with those of our other shareholders.***

As of December 31, 2022, EW Healthcare Partners and their affiliates own 90% of the outstanding shares of our Series B Preferred Stock which, upon conversion into shares of Common Stock, would result in an ownership interest of approximately 18.3% of our Common Stock (calculated on the basis described in Item 12, “*Security Ownership Of Certain Beneficial Owners And Management*” below). Also, for as long as EW Healthcare Partners and its affiliates collectively hold at least (i) 10% of the outstanding shares of our Common Stock (calculated on an as converted basis), EW Healthcare Partners has the right to designate two directors to our Board and (ii) 5% (but less than 10%) of the outstanding shares of our outstanding Common Stock (calculated on an as converted basis), EW Healthcare Partners has the right to designate one individual to serve on our Board. Such individuals will initially be preferred directors and therefore not subject to election by the holders of Common Stock. EW Healthcare Partners designated Martin P. Sutter and William A. Hawkins, III, who continue to serve on our board as preferred directors. The interests of EW Healthcare Partners may conflict with those of our other shareholders, and EW Healthcare Partners may seek to influence, and may be able to influence, us through its director designation rights and its share ownership.

***Holders of shares of our Series B Preferred Stock have rights, preferences and privileges that are not held by, and are preferential to, the rights of, our common shareholders.***

Holders of shares of our Series B Preferred Stock are currently entitled to cumulative dividends at a rate of 6.0% per annum, compounding quarterly in arrears. The dividends are payable quarterly in whole or in part, in cash. However, the Company may, at its option, elect not to pay any such dividend in cash and instead to accrue the amount of such dividend. The payment of regular dividends in cash to the holders of Series B Preferred Stock could impact our liquidity and reduce the amount of cash available for working capital, capital expenditures, growth opportunities, acquisitions, and other general corporate purposes. If we elect to accrue the dividends in lieu of paying them in cash, holders of Common Stock could effectively be diluted because such accrual of dividends will increase the number of shares of Common Stock into which the Series B Preferred Stock would then be convertible. Our obligations to the holders of Series B Preferred Stock could also limit our ability to obtain additional equity or debt financing or increase our borrowing costs, which could have an adverse effect on our financial condition.

The Series B Preferred Stock ranks senior to our Common Stock with respect to dividends and distributions on liquidation, winding-up, and dissolution. Upon a liquidation, dissolution, or winding-up of the Company, holders of Series B Preferred Stock will be entitled to receive \$1,000 per share of Series B Preferred Stock (subject to adjustment), plus any accrued and unpaid dividends. This amount will be payable prior to any distribution of our available assets to the holders of our Common Stock.

Holders of Series B Preferred Stock generally are entitled to vote together as a single class with the holders of the shares of Common Stock, on an as converted basis, on all matters submitted for a vote of holders of our Common Stock subject to certain limitations on their voting rights contained in the related Articles of Amendment to our Restated Articles of Incorporation. Additionally, certain matters will require the approval of the holders of a majority of the outstanding shares of Series B Preferred Stock, voting as a separate class, including the following actions:

- any changes to the rights, preferences, or privileges of the Series B Preferred Stock;
- amendments or restatements of any organizational document of the Company or its subsidiaries in a manner that materially, adversely, and disproportionately affects the rights, preferences, and privileges of the Series B Preferred Stock as compared to our Common Stock;
- the authorization or creation of any class or series of senior or parity equity securities; and
- the declaration of any dividends or any other distributions, or the repurchase or redemption, of any equity securities of the Company ranking junior to or on parity with the Series B Preferred Stock (subject to certain exceptions).

The interests of our holders of Series B Preferred Stock and our Common Stock may conflict in certain circumstances, and these provisions may constrain the Company from taking certain actions that may be in the best interest of the holders of its Common Stock. Additionally, as long as EW Healthcare Partners holds at least 10% of our outstanding Common Stock (calculated on an as converted basis), it has certain preemptive rights to participate in offerings of Common Stock to any person, subject to customary exceptions.

Furthermore, in the event that the Company undergoes a change of control (as defined), the holders of Series B Preferred Stock will have certain redemption rights, which, if exercised, could require us to repurchase all of the outstanding shares of Series B Preferred Stock for cash at the original purchase price of Series B Preferred Stock plus all accrued and unpaid dividends thereon. Any required repurchase of the outstanding Series B Preferred Stock could impact our liquidity and reduce

the amount of cash available for working capital, capital expenditures, growth opportunities, acquisitions, and other general corporate purposes.

The preferential rights of the Series B Preferred Stock could also result in divergent interests between the holders of Series B Preferred Stock and our common shareholders.

***Our Series B Preferred Stock is convertible into shares of our Common Stock, and any such conversion may dilute the value of our Common Stock.***

Holders of shares of Series B Preferred Stock have the right, at their option, to convert each share of Series B Preferred Stock into shares of our Common Stock, except that no holder may convert its shares of Series B Preferred Stock into shares of Common Stock if such conversion would result in such holder and its affiliates holding more than 19.9% of the aggregate voting power of our Common Stock or beneficially owning in excess of 19.9% of our then-outstanding shares of Common Stock. Additionally, each share of Series B Preferred Stock (including any accrued and unpaid dividends) will automatically convert into shares of our Common Stock at any time after July 2, 2023, provided that our Common Stock has traded at 200% or more of the then conversion price (i) for 20 out of 30 consecutive trading days preceding, and (ii) as of the close of trading on the date immediately prior to conversion. The conversion of Series B Preferred Stock may significantly dilute our common shareholders and adversely affect both our net income per share of Common Stock and the market price of our Common Stock.

***The price of our Common Stock has been, and will likely continue to be, volatile.***

The market price of our Common Stock, like that of the securities of many other healthcare companies that are engaged in research, development, and commercialization, has fluctuated over a wide range, and it is likely that the price of our Common Stock will fluctuate in the future. The market price of our Common Stock could be impacted by a variety of factors, including:

- Fluctuations in stock market prices and trading volumes of similar companies or of the markets generally;
- Our ability to successfully launch, market and earn significant revenue from our products;
- Our ability to obtain additional financing to support our continuing operations;
- Disclosure of the details and results of our clinical trials and our regulatory applications and proceedings;
- Developments in and disclosure or publicity regarding existing or new litigation or contingent liabilities;
- Changes in government regulations or our failure to comply with any such regulations;
- Additions or departures of key personnel;
- Our investments in research and development or other corporate resources;
- Announcements of technological innovations or new commercial products by us or our competitors;
- Developments in the patents or other proprietary rights owned or licensed by us or our competitors;
- The timing of new product introductions;
- Actual or anticipated fluctuations in our operating results, including as a result of seasonality in our business, as well as any restatements of previously reported results;
- Our ability to effectively and consistently process or manufacture our products and avoid costs associated with the recall of defective or potentially defective products;
- Our ability and the ability of our distribution partners to market and sell our products;
- Changes in reimbursement for our products or the price for our products to our customers;
- Removal of our products from the FSS, or changes in how government accounts purchase products such as ours or in the price for our products to government accounts;
- Activities of market participants and investors, including analysts and MIMEDX shareholders;
- Material amounts of short-selling of our Common Stock; and
- The other risks detailed in this Item 1A.

Any unanticipated shortfall in our revenue in any fiscal quarter could have an adverse effect on our results of operations in that quarter. The effect on our net income of such a shortfall could be exacerbated by the relatively fixed nature of most of our costs, which primarily include personnel costs as well as facilities costs. These fluctuations could cause the trading price of our stock to be negatively affected. Our quarterly operating results have varied substantially in the past and may vary substantially in the future, including as a result of seasonality in our business. Price volatility or a decrease in the market price of our Common Stock could have an adverse effect on our ability to raise capital, liquidity, business, financial condition and results of operations.

***Securities analysts may elect not to report on our common stock or may issue negative reports that adversely affect the stock price.***

We have conducted extensive investor relations outreach to the investment analysts community with the goal of attracting analyst coverage. However, at this time, only four securities analysts provide coverage on us, and we compensate one of those analyst's firms. There can be no assurance that any other analysts will cover our stock or, if they do, that they will continue to report on our common stock or that additional analysts will initiate reporting on our common stock.

If we fail to attract the coverage or securities analysts, or if securities analysts discontinue covering our common stock, the lack of research coverage may adversely affect the actual and potential market price of our common stock. The trading market for our common stock may be affected in part by the research and reports that industry participants, industry analysts or financial analysts publish about our business. If one or more analysts elect to cover us and then downgrade the stock, the stock price would likely decline rapidly. If one or more of these analysts cease coverage of us, we could lose visibility in the market, which in turn could cause our stock price to decline.

***Fluctuations in revenue or results of operations could cause additional volatility in our stock price.***

Any unanticipated shortfall in our revenue in any fiscal quarter could have an adverse effect on our results of operations in that quarter. The effect on our net income of such a shortfall could be exacerbated by the relatively fixed nature of most of our costs, which primarily include personnel costs as well as facilities costs. These fluctuations could cause the trading price of our stock to be negatively affected. Our quarterly operating results have varied substantially in the past and may vary substantially in the future.

***We do not intend to pay cash dividends on our Common Stock.***

Holders of our Series B Preferred Stock are entitled to contractually-determined dividends before holders of our Common Stock. See above “-  *Holders of shares of Series B Preferred Stock have rights, preferences and privileges that are not held by, and are preferential to, the rights of, our common shareholders.*”

We have never declared or paid cash dividends on our Common Stock. We currently expect to use available funds and any future earnings to pay dividends on the Series B Preferred Stock; in the development, operation and expansion of our business; to repay debt; and, to the extent authorized by our Board, repurchasing our Common Stock. We do not anticipate paying any cash dividends on our Common Stock in the foreseeable future. As a result, capital appreciation, if any, of our Common Stock will be an investor's only source of potential gain from our Common Stock for the foreseeable future.

***Certain provisions of Florida law and anti-takeover provisions in our organizational documents may discourage or prevent a change of control, even if an acquisition would be beneficial to shareholders, which could affect our share price adversely and prevent attempts by shareholders to remove current management.***

The Florida Business Corporation Act (the “**FBCA**”) includes several provisions applicable to the Company that may discourage potential acquirors. Such provisions include provisions that:

- allow directors to take other stakeholders into account in discharging their duties;
- a requirement that certain transactions with a shareholder of 10% or more ownership must be approved by the affirmative vote of two-thirds of the other shareholders unless approved by a majority of the disinterested directors or certain fair price requirements are met; and
- voting rights acquired by a shareholder at ownership levels at or above one-fifth, one-third and a majority of voting power are denied unless authorized by the Board prior to such acquisition or by a majority of the other shareholders (excluding interested shares (as defined in the FBCA)).

Additionally, our organizational documents contain provisions:

- authorizing the issuance of blank check preferred stock;
- restricting persons who may call shareholder meetings;
- permitting shareholders to remove directors only “for cause” and only by super-majority vote; and
- providing the Board with the exclusive right to fill vacancies and to fix the number of directors.

These provisions of Florida law and our articles of incorporation and bylaws could negatively affect our share price, prevent attempts by shareholders to remove current management, prohibit or delay mergers or other takeovers or changes of control of the Company and discourage attempts by other companies to acquire us, even if such a transaction would be beneficial to our shareholders.

### **Item 1B. Unresolved Staff Comments**

There are no unresolved SEC Staff comments with respect to our SEC filings.

### **Item 2. Properties**

Our corporate headquarters are located in Marietta, Georgia, where we lease office, laboratory, tissue processing and warehouse space. We lease a facility in Kennesaw, Georgia, which primarily consists of laboratory, tissue processing and warehouse space, and are currently subletting additional warehouse space in Marietta, Georgia through May 31, 2023. Our properties, excluding the sublet space, are used by our Wound & Surgical segment, which includes the design, manufacture and marketing of products and tissue processing services primarily for the wound care, burn, Surgical Recovery, and non-operative sports medicine sectors of healthcare, additionally, our Kennesaw facility is used for the Regenerative Medicine segment.

The Company's properties are suitable and adequate for current business operations. We are making investments to increase our manufacturing capacity, as well as enhancements to facilitate the processing of products required to be manufactured under CGMP.

### **Item 3. Legal Proceedings**

The description of our securities class action and the *Welker v. MiMedx, et. al.* case contained in [Note 16, Commitments and Contingencies](#) to our financial statements included in Item 8 is incorporated herein by reference.

### **Item 4. Mine Safety Disclosures**

Not applicable.

## **PART II**

### **Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

#### **Market for Common Stock**

Our Common Stock trades on The Nasdaq Stock Market under the trading symbol "MDXG".

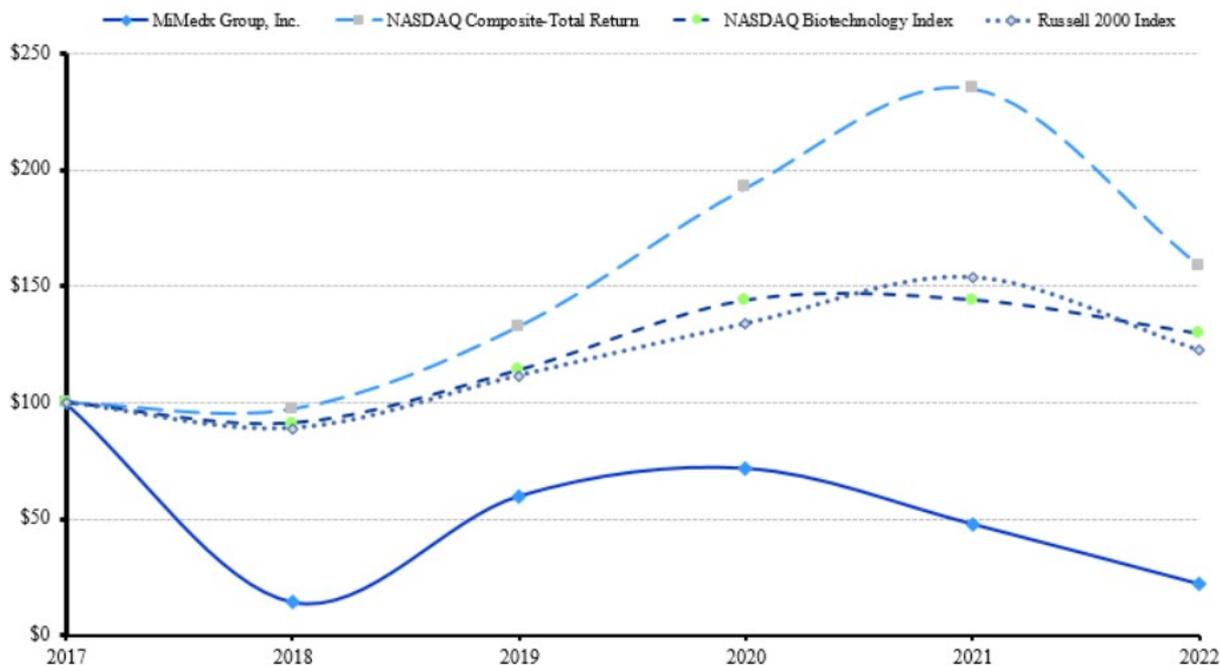
#### **Holders**

Based upon information supplied from our transfer agent, there were approximately 857 shareholders of record of our Common Stock as of February 21, 2023.

#### **Stock Performance Graph**

The following graph compares the cumulative total stockholder return on our Common Stock with the cumulative total stockholder return of the Nasdaq Composite Index, the Nasdaq Biotechnology Index and the Russell 2000 Index, assuming an investment of \$100.00 on December 31, 2017.

## COMPARISON OF CUMULATIVE TOTAL RETURN



ASSUMES \$100 INVESTED ON DEC. 31, 2017  
 ASSUMES DIVIDEND REINVESTMENT; NO DIVIDENDS ISSUED BY MIMEDX  
 FISCAL YEAR ENDED DEC. 31, 2022

### *Change in Comparison Index*

During 2022, we changed our Cumulative Total Return comparison from the Nasdaq Biotechnology Index to the Russell 2000 Index. The Russell 2000 Index, which includes the Company's common stock, is a stock index consisting of 2000 publicly-traded small-cap companies. We use the Russell 2000 for peer benchmarking in certain compensation arrangements with certain of our employees.

We believe the Russell 2000 provides more meaningful information than the Nasdaq Biotechnology Index because the breadth of the latter index contains significant diversity in market capitalization, stage of clinical development, total addressable markets, and other factors. The Company's common stock is not included on the Nasdaq Biotechnology Index.

### Securities Authorized for Issuance Under Equity Compensation Plans

Information about securities authorized for issuance under our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

### Recent Sales of Unregistered Securities

None.

### Purchases of Equity Securities by the Issuer and Affiliated Purchasers

The following table sets forth information regarding the purchases of the Company's equity securities made by or on behalf of the Company or any affiliated purchaser (as defined in Rule 10b-18 under the Exchange Act) during the three-month period ended December 31, 2022.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under Plans or Programs
October 1, 2022 - October 31, 2022	—	\$ —	—	\$ —
November 1, 2022 - November 30, 2022	—	\$ —	—	\$ —
December 1, 2022 - December 31, 2022	—	\$ —	—	\$ —
Total for the quarter	—	\$ —	—	\$ —

## Item 6. [Reserved]

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

### Overview

MIMEDX is a pioneer and leader in placental biologics focused on addressing the needs of patients with acute and chronic non-healing wounds. We are also advancing a promising late-stage biologics pipeline targeted at decreasing pain and improving function for patients with knee osteoarthritis ("KOA"). To accomplish these goals, we operate under two defined internal business units: Wound & Surgical and Regenerative Medicine. All of our products are regulated by the FDA.

We have two classes of products: (1) Advanced Wound Care products, or Section 361 products, consisting of our tissue and cord sheet allograft products, as well as certain particulate products regulated under Section 361, and (2) Section 351 products, consisting of our micronized and certain other particulate products, which, prior to May 31, 2021, the date the FDA's period of enforcement discretion ended (as described below), were used to treat a variety of clinical conditions, including both advanced wound care and musculoskeletal applications. Our Advanced Wound Care products include two product categories: Tissue/Other and Cord products. We apply Current Good Tissue Practices ("CGTP") and Current Good Manufacturing Practices ("CGMP") standards in addition to terminal sterilization to produce our allografts.

The Wound & Surgical business focuses on the Advanced Wound Care and Surgical Recovery markets through sales of our existing product portfolio (as described in detail in the *Our Products* section below) and product development to serve these primary end markets. This business unit is responsible for substantially all sales of our Advanced Wound Care products, as well as the sale of our Section 351 products internationally.

The Regenerative Medicine business focuses on progressing our placental biologics platform towards registration as an FDA-approved biological drug. Micronized dehydrated human amnion chorion membrane ("mDHACM") is an injectable placental biologic product candidate in our late-stage pipeline targeted at achieving FDA approval for an indication to help decrease pain and improve function in patients suffering from KOA. Prior to May 31, 2021, this business unit was responsible for domestic sales of our Section 351 products. Regenerative Medicine does not currently generate revenue.

### Our Products

Our primary platform technologies include tissue allografts derived from human placental membrane (EPIFIX, AMNIOFIX, and AMNIOEFFECT), tissue allografts derived from human umbilical cord (EPICORD and AMNIOCORD), and a particulate extracellular matrix derived from human placental disc (AXIOFILL).

EPIFIX and EPICORD products are marketed for external use, such as in Advanced Wound Care applications, while our AMNIOFIX, AMNIOEFFECT, AXIOFILL, and AMNIOCORD products are positioned for use in Surgical Recovery applications, including lower extremity repair, plastic surgery, vascular surgery and multiple orthopedic repairs and reconstructions.

In November 2017, the FDA published a series of guidance documents that established an updated framework for the regulation of cellular and tissue-based products. These guidance documents clarified the FDA's views about the criteria that differentiate those products subject to regulation under Section 361 of the Public Health Service Act from those considered to be drugs, devices, and/or biological products subject to licensure under Section 351 of the Public Health Service Act and related regulations. The FDA exercised enforcement discretion under limited conditions with respect to IND applications and pre-market approval requirements for Section 351 products. The FDA's period of enforcement discretion ended effective May 31, 2021. We are not currently marketing our micronized and certain particulate products affected by the guidance in the United States.

This discussion, which presents our results for the fiscal years ended December 31, 2022 and 2021, should be read in conjunction with our Consolidated Financial Statements and the accompanying notes. Also please refer to Part I, Item 1, *Business*, and Part I, Item 1A, *Risk Factors*, which include detailed discussions of various items impacting our business, results of operations and financial condition. We intend for this discussion to provide the reader with information that will assist in understanding our financial statements, the changes in certain key items in those financial statements from period to period and the primary factors that accounted for those changes. We also discuss certain performance metrics that management uses to assess the Company's performance.

Our Annual Report for the year ended December 31, 2021 includes a discussion and analysis of our total company financial condition and results of operations for 2021 compared to 2020 in Part II, Item 7, *Management's Discussion and Analysis of*

*Financial Condition and Results of Operations.* A discussion of the results of operations and financial condition for Wound & Surgical and Regenerative Medicine for 2021 compared to 2020 are presented herein.

### **Impact of COVID-19 Pandemic**

The COVID-19 pandemic is still ongoing, though the effects on our operations, such as access restrictions to hospitals and difficulties obtaining donor materials that we observed during the year ended December 31, 2020 and, to a lesser degree, during the year ended December 31, 2021, did not materially affect our operations during the year ended December 31, 2022. We are continuously monitoring developments with respect to novel variants of the virus and government and societal responses to mitigate the spread of COVID-19, which could impact our operations.

We continue to exercise an abundance of caution with respect to the health and well-being of our employees. Our offices are open and staffed, and we are operating under a hybrid work model for some personnel as well as encouraging all employees to get vaccinated if they have not already done so. None of these efforts have materially affected the Company's operations for the year ended December 31, 2022.

### **Components of and Key Factors Influencing Our Results of Operations**

In assessing the performance of our business, we consider a variety of performance and financial measures. We believe the items discussed below provide insight into the factors that affect these key measures.

#### *Net sales*

Net sales is recognized based on the consideration we expect to receive from the sale at the point in time when control of the goods is transferred to the customer, which generally occurs upon our delivery to a third-party carrier. This consists of the gross selling price of the product, less any discounts, rebates, fees paid to GPOs, and returns.

We derive the majority of our revenue from selling our tissue and cord products in the United States. We are actively working to broaden our product portfolio in a number of clinical applications, while also seeking regulatory approval with the appropriate regulators to expand our geographic footprint, beginning in Japan. In early 2023, we announced the execution of an exclusive distribution agreement with Gunze Medical Limited to sell EPIFIX in Japan.

#### *Cost of goods sold and gross profit*

Cost of goods sold includes product testing costs, quality assurance costs, personnel costs, manufacturing costs, raw materials and product costs, depreciation and facility costs associated with our manufacturing and warehouse facilities. Fluctuations in our cost of goods sold correspond with the fluctuations in these costs as well as sales volume.

Gross profit is calculated as net sales less cost of goods sold. Gross margin is calculated as gross profit divided by net sales. Our gross margin is affected by product and geographic sales mix, realized pricing of our products, the efficiency of our manufacturing operations and the costs of materials used to make our products. Regulatory actions, including with respect to reimbursement for our products, may require costly expenditures or result in pricing pressure, and may decrease our gross profit and gross margin.

#### *Selling, general and administrative expense*

Selling, general and administrative (“**SG&A**”) expense includes costs to execute our sales strategy. These include personnel costs pertaining to our sales force and sales support functions, including salaries, commissions and other incentive compensation, commissions to sales agents, customer support, travel expenses, and bad debt expense. We expect our SG&A expense to fluctuate based on revenue fluctuations, geographic changes, and any changes to the size of our headcount, particularly that of our sales and marketing forces. Certain of these costs scale with sales, but can fluctuate depending on sales mix. For example, we pay sales agents a greater commission than our internal sales force, meaning that we could incur greater commission expenses if a greater proportion of our sales are through sales agents.

SG&A expense also includes costs related to functions which support both of our business units, such as legal, finance, human resources, and other such functions. These costs include personnel costs associated with these units, as well as insurance, and certain professional fees. These costs tend to fluctuate based on headcount, which will vary depending on our projected business needs.

### Research and development expense

Research and development expense relates to our investments in clinical trials to expand our product pipeline and platforms, as well as expenditures in improvements to our manufacturing process and the enhancement of existing products. Our research and development costs also include expenses such as salaries and benefits related to our research department, consulting costs and advisory costs, and regulatory costs.

We expense research and development costs as incurred. Fluctuations in research and development expenses can be impacted by the timing and cadence of our clinical trials.

### Investigation, restatement and related expense

Investigation, restatement and related expense primarily relates to legal fees advanced to certain former officers and directors of the Company under certain indemnification agreements and our liability from legal proceedings taken against us which arose from the findings of the Audit Committee Investigation. The timing and extent of these expenses depend on the stage and status of legal proceedings. Other activity includes amounts received from certain director and officer insurance providers.

### Interest expense

We incur interest expense primarily through stated interest on our outstanding term loan. The interest on our term loan is tied to the three-month London Interbank Offered Rate (“**LIBOR**”), subject to a floor of 1.5%. Increases in LIBOR could cause our interest expense to increase. Other activity influencing interest expense relates to the amortization of deferred financing costs and original issue discount associated with credit facilities outstanding.

## Results of Operations for 2022 Compared to 2021

### Total Company

	Year Ended December 31,			
	(in thousands)			
	2022	2021	\$ Change	% Change
Net sales	\$ 267,841	\$ 258,615	\$ 9,226	3.6 %
Cost of sales	48,316	43,283	5,033	11.6 %
Gross profit	219,525	215,332	4,193	1.9 %
Selling, general and administrative	208,789	198,359	10,430	5.3 %
Research and development	22,829	17,344	5,485	31.6 %
Investigation, restatement and related	12,177	3,791	8,386	nm
Amortization of intangible assets	701	820	(119)	(14.5)%
Impairment of intangible assets	—	53	(53)	(100.0)%
Interest expense, net	(5,016)	(4,980)	(36)	0.7 %
Other expense, net	(4)	(23)	19	(82.6)%
Income tax provision expense	(206)	(247)	41	(16.6)%
Net loss	\$ (30,197)	\$ (10,285)	\$ (19,912)	nm

### Net Sales

We recorded net sales for the year ended December 31, 2022 of \$267.8 million, an increase of \$9.2 million or 3.6% over 2021 net sales of \$258.6 million.

Our sales by product were as follows (amounts in thousands):

	Year Ended December 31,		Change	
	2022	2021	\$	%
Advanced Wound Care				
Tissue/Other	\$ 241,992	\$ 216,418	\$ 25,574	11.8 %
Cord	23,211	23,599	(388)	(1.6)%
Total Advanced Wound Care	265,203	240,017	25,186	10.5 %
Section 351	2,379	17,610	(15,231)	(86.5)%
Other	259	988	(729)	(73.8)%
Total	\$ 267,841	\$ 258,615	\$ 9,226	3.6 %

The increase in net sales reflects sales growth in our Advanced Wound Care products of \$25.2 million or 10.5%, year-over-year. Our sales growth in this area was a result of our focus on the application of these products into areas of Surgical Recovery, including the introduction of AMNIOEFFECT and AXIOFILL to the market during 2022. We saw further gains as a result of our prior initiatives to expand, realign and train our sales team.

The increase was partially offset by our inability to sell our Section 351 products in the United States as a result of the end of the FDA's period of enforcement discretion on May 31, 2021. Sales of our Section 351 products were \$2.4 million for the year ended December 31, 2022 compared to \$17.6 million for the year ended December 31, 2021, a decrease of \$15.2 million. Sales of Section 351 products during the year ended December 31, 2022 were derived from outside the United States.

#### Gross Margin and Cost of Sales

Gross margin in 2022 was 82.0%, compared to 83.3% in 2021. Cost of sales and gross profit for 2021 included inventory write-downs of \$1.7 million related to our Section 351 products, resulting from the end of enforcement discretion and products which were discontinued. There were no significant unusual write-downs during 2022. Decreases in margins were driven by negative impacts from production variances, primarily due to lower product levels.

Cost of sales for the year ended December 31, 2022 was \$48.3 million, an increase of \$5.0 million, or 11.6%, compared to \$43.3 million for the year ended December 31, 2021. In addition to the factors affecting gross margin discussed above, overall increases in sales volume contributed to the increase in cost of sales.

#### Selling, General and Administrative Expense

SG&A expense increased \$10.4 million, or 5.3%, to \$208.8 million for 2022, compared to \$198.4 million for 2021. The increase in SG&A expense was driven by:

- an increase in travel expenses, reflecting the lifting of travel restrictions that were in place during the year ended December 31, 2021,
- increases in sales commissions, resulting from higher sales volumes through sales agents, who carry higher commission rates than our internal sales force.
- an increase in bad debt expense resulting from the deterioration of credit for certain specific customers, and
- an increase in severance costs incurred with the intention of reducing corporate costs. This effect was partially offset by a year-over-year decrease in share-based compensation expense, primarily driven by the reversal of previously recognized share-based compensation expense associated with forfeitures of awards from the separated individuals.

These amounts were offset, primarily, by year-over-year decreases in professional service expenses.

#### Research and Development Expense

Our research and development expense increased \$5.5 million, or 31.6%, to \$22.8 million for the year ended December 31, 2022, compared to \$17.3 million for the year ended December 31, 2021. The increase reflects higher personnel costs and clinical trial-related expenses to support clinical research efforts, primarily connected to our commercial and late-stage pipelines.

#### Investigation, Restatement and Related Expense

Investigation, restatement, and related expenses increased \$8.4 million to \$12.2 million for the year ended December 31, 2022, compared to \$3.8 million for the year ended December 31, 2021. In 2021, we received funds from insurance providers and reductions in legal expenses that were reflected as reductions to expense for the year ended December 31, 2021.

We remain subject to indemnification agreements with certain former officers and directors of the Company (other than Messrs. Petit and Taylor, our former Chief Executive Officer and Chief Operating Officer) for whom legal proceedings are still ongoing, in particular, our former Chief Financial Officer.

#### Amortization of Intangible Assets

Amortization expense related to intangible assets decreased \$0.1 million from \$0.8 million for the year ended December 31, 2021 to \$0.7 million for the year ended December 31, 2022. The decrease was the result of the avoidance of amortization expense from assets that had become fully-amortized during 2021.

#### Impairment of Intangible Assets

Impairment of intangible assets was \$0.1 million for the year ended December 31, 2021, reflecting the impairment of a supplier relationship asset. There were no impairments in 2022.

#### Interest Expense, Net

Interest expense was \$5.0 million for each of the years ended December 31, 2022 and 2021. The rise in LIBOR rates during 2022 caused an increase in interest expense on our outstanding term loan. In addition, we recognized interest income on our income tax receivable resulting from the Coronavirus Aid, Relief, and Economic Security Act. These effects were offset by the avoidance of interest expense associated with the delayed draw term loan facility option under the Hayfin Loan Agreement that terminated on June 30, 2021.

We expect interest expense to increase in future quarters as a result of rising interest rates.

#### Income Tax Provision Expense

The effective tax rate for 2022 and 2021 was (0.7)% and (2.5)%, respectively on pre-tax book losses of \$30.0 million and \$10.0 million, respectively. There were no discrete items which materially influenced the effective tax rate in either period, and net operating losses generated were offset by a valuation allowance.

### **Segment Results**

#### *Wound & Surgical*

Our Wound & Surgical business focuses on the Advanced Wound Care and Surgical Recovery markets through sales of our existing product portfolio and product development to serve these end markets. Its platform technologies include tissue allografts derived from human placental membrane (EPIFIX®, AMNIOFIX®, and AMNIOEFFECT™), tissue allografts derived from human umbilical cord (EPICORD® and AMNIOCORD®), and a particulate extracellular matrix derived from human placental disc (AXIOFILL™). This segment is also responsible for the international sales of our Section 351 products.

Several factors affect reported net sales for our Wound & Surgical business in any period, including product, payer and geographic sales mix, operational effectiveness, pricing realization, marketing and promotional efforts, timing of orders and shipments, regulatory actions including healthcare reimbursement scenarios, competition, and business acquisitions that involve our customers or competitors.

SG&A expense includes costs to execute our sales strategy. These include personnel costs pertaining to our sales force and sales support functions, including salaries, commissions and other incentive compensation, commissions to sales agents, customer support, travel expenses, and bad debt expense.

Research and development expenses for Wound & Surgical focus on the expansion of our product portfolio into similar areas of healthcare, specifically Advanced Wound Care and Surgical Recovery.

#### Wound & Surgical Results of Operations 2022 Compared to 2021

	Year Ended December 31,			
	(in thousands)			
	2022	2021	\$ Change	% Change
Net sales	\$ 264,906	\$ 238,940	\$ 25,966	10.9 %
Cost of sales	44,462	35,204	9,258	26.3 %
Selling, general and administrative expense	145,887	123,583	22,304	18.0 %
Research and development expense	7,836	5,864	1,972	33.6 %
Segment contribution	\$ 66,721	\$ 74,289	\$ (7,568)	(10.2)%

Our Wound & Surgical business recorded \$264.9 million of net sales for the year ended December 31, 2022, a \$26.0 million, or 10.9%, increase compared to the \$238.9 million we recorded for the year ended December 31, 2021. This increase was the result of our focus on the application of these products into areas of Surgical Recovery, including the introduction of AMNIOEFFECT and AXIOFILL to the market during 2022. We saw further gains as a result of our prior initiatives to expand, realign and train our sales team.

Cost of sales for the year ended December 31, 2022 was \$44.5 million, a \$9.3 million, or 26.3%, increase compared to the \$35.2 million recognized for the year ended December 31, 2021. Cost of sales increased due to negative impacts from production variances, primarily due to lower production levels, as well as increases in sales volume.

SG&A expense was \$145.9 million for the year ended December 31, 2022, a \$22.3 million, or 18.0%, increase over the year ended December 31, 2021, during which we incurred \$123.6 million of expenses. The increase was driven by travel expenses, sales commissions, and bad debt expense. Travel expenses increased due to the lifting of restrictions that were in place during the year ended December 31, 2021 due to the COVID-19 pandemic. Increases in sales commissions reflected our focus on sales of products into areas of Surgical Recovery, resulting in a proportional increase in sales through sales agents, who carry higher commission rates than our internal sales force. The increase in bad debt expense was primarily the result of the deterioration of credit for certain specific customers.

Research and development expense was \$7.8 million for the year ended December 31, 2022, compared to \$5.9 million for the year ended December 31, 2021, an increase of \$2.0 million, or 33.6%. The increase was primarily the result of expenses related to AMNIOEFFECT and AXIOFILL, both of which launched during the year ended December 31, 2022.

#### Wound & Surgical Results of Operations 2021 Compared to 2020

	Year Ended December 31,			
	(in thousands)			
	2021	2020	\$ Change	% Change
Net sales	\$ 238,940	\$ 213,489	\$ 25,451	11.9 %
Cost of sales	35,204	30,185	5,019	16.6 %
Selling, general and administrative expense	123,583	103,039	20,544	19.9 %
Research and development expense	5,864	3,979	1,885	47.4 %
Segment contribution	\$ 74,289	\$ 76,286	\$ (1,997)	(2.6)%

Our Wound & Surgical business recorded \$238.9 million of net sales for the year ended December 31, 2021, a \$25.5 million, or 11.9%, increase compared to the \$213.5 million we recorded for the year ended December 31, 2020. This increase was primarily the result of an increase in sales volume due to lessening of restrictions implemented at the onset of the COVID-19 pandemic, including access to hospitals and travel restrictions. The increase also reflected the initial results of our commercial focus on areas of Surgical Recovery. Finally, we saw growth in new products, such as EPICORD Expandable, which launched in September 2020.

Cost of sales for the year ended December 31, 2021 was \$35.2 million, a \$5.0 million, or 16.6%, increase compared to the \$30.2 million recognized for the year ended December 31, 2020. Cost of sales increased due to year-over-year increases in sales volumes as well as the unfavorable effects of production variances, year-over-year.

SG&A expense was \$123.6 million for the year ended December 31, 2021, a \$20.5 million, or 19.9%, increase over the year ended December 31, 2020, during which we incurred \$103.0 million of expenses. The increase was driven by salaries, travel expenses, and sales commissions. Salary expenses increased due to the restoration of full-salary levels, which were reduced for

a portion of 2020 as part of our response to the COVID-19 pandemic. Salary expenses also increased as a result of merit increases and costs associated with expansion of our sales force. Travel expenses increased due to the lifting of restrictions that were in place during the year ended December 31, 2020 due to the COVID-19 pandemic, as well as result of inflationary pressures experienced during the year ended December 31, 2021. Increases in sales commissions reflected higher sales volumes.

Research and development expense was \$5.9 million for the year ended December 31, 2021, compared to \$4.0 million for the year ended December 31, 2020, an increase of \$1.9 million, or 47.4%. The increase was driven by higher personnel costs due to headcount increases and the restoration of full salary levels and merit increases, which were restricted for a portion of 2020.

#### *Regenerative Medicine*

Our Regenerative Medicine business focuses solely on Regenerative Medicine technologies, specifically progressing our placental biologics platform towards registration as an FDA-approved biological drug. mDHACM is the lead product candidate in its late-stage pipeline targeted at achieving FDA approval for an indication to help decrease pain and improve function in patients suffering from KOA.

Prior to May 31, 2021, net sales for the Regenerative Medicine segment consisted of domestic sales of Section 351 products. Regenerative Medicine does not currently generate revenue, and will only produce revenue if and after such time that the FDA approves a BLA for mDHACM. After that point in time, we re-focused our sales and marketing efforts exclusively toward the advancement of our Wound & Surgical products in the United States. For this reason, our Regenerative Medicine segment does not generate meaningful SG&A expense.

Research and development expenditures for Regenerative Medicine are driven by clinical trial activities, primarily those undertaken by our clinical research organization, which we have engaged to provide full operational support related to our upcoming KOA clinical trial program.

#### Regenerative Medicine Results of Operations 2022 Compared to 2021

	Year Ended December 31,			
	(in thousands)			
	2022	2021	\$ Change	% Change
Net sales	\$ —	\$ 16,596	\$ (16,596)	(100.0)%
Cost of sales	—	3,655	(3,655)	(100.0)%
Selling, general and administrative expense	—	12,910	(12,910)	(100.0)%
Research and development expense	14,993	11,480	3,513	30.6 %
Segment contribution	\$ (14,993)	\$ (11,449)	\$ (3,544)	31.0 %

Research and development expense was \$15.0 million for the year ended December 31, 2022, compared to \$11.5 million for the year ended December 31, 2021, an increase of \$3.5 million, or 30.6%. The increase was primarily the result of increases in headcount and the incurrence of clinical trial expenses to support our clinical research efforts.

#### Regenerative Medicine Results of Operations 2021 Compared to 2020

	Year Ended December 31,			
	(in thousands)			
	2021	2020	\$ Change	% Change
Net sales	\$ 16,596	\$ 32,362	\$ (15,766)	(48.7)%
Cost of sales	3,655	5,856	(2,201)	(37.6)%
Selling, general and administrative expense	12,910	17,546	(4,636)	(26.4)%
Research and development expense	11,480	7,736	3,744	48.4 %
Segment contribution	\$ (11,449)	\$ 1,224	\$ (12,673)	nm

Our Regenerative Medicine business recorded \$16.6 million of net sales for the year ended December 31, 2021, a \$15.8 million, or 48.7%, decrease compared to the \$32.4 million we recorded for the year ended December 31, 2020. Likewise, cost of sales for the year ended December 31, 2021 was \$3.7 million, a \$2.2 million, or 37.6%, decrease compared to the year ended

December 31, 2020, where we recognized cost of sales of \$5.9 million. These decreases reflected our inability to sell our Section 351 products in the United States as a result of the end of the FDA's period of enforcement discretion on May 31, 2021.

SG&A expense for the year ended December 31, 2021 was \$12.9 million, a \$4.6 million, or 26.4%, decrease from the year ended December 31, 2020, where we recognized \$17.5 million. This decrease reflected the re-focusing of our sales and marketing efforts toward the advancement of our Wound & Surgical business.

Research and development expense was \$11.5 million for the year ended December 31, 2021, compared to \$7.7 million for the year ended December 31, 2020, an increase of \$3.7 million, or 48.4%. The increase was driven by higher personnel costs due to headcount increases to support investments in our clinical trials and the restoration of full salary levels and merit increases, which were restricted for a portion of 2020. We also incurred higher consulting fees in 2021, primarily to assist in the evaluation of the results of our clinical trials.

#### *Corporate*

Our Corporate function represents activities which support both of our business units, such as legal, finance, human resources, and other supporting functions. Corporate expenses include personnel costs associated with these units, as well as insurance, and certain professional fees.

SG&A expense for the Corporate function was \$62.9 million, or 23.5% of net sales, for the year ended December 31, 2022, compared to \$61.9 million, or 23.9% of consolidated net sales for the year ended December 31, 2021. The increase was primarily the result of an increase in severance costs associated with headcount reductions to lower ongoing costs. This effect was partially offset by a year-over-year decrease in share-based compensation expense, primarily driven by forfeitures of awards from the separated individuals.

SG&A expense for the Corporate function was \$61.9 million, or 23.9% of consolidated net sales, for the year ended December 31, 2021, compared to \$60.4 million, or 24.3% of consolidated net sales for the year ended December 31, 2020. The increase reflected greater personnel costs and professional services fees.

#### **Liquidity and Capital Resources**

We require capital for our operating activities, including costs associated with the sale of product through direct and indirect sales channels, the conduct of clinical trials and other research and development activities, compliance costs, costs to sell and market our products, regulatory fees, and legal and consulting fees in connection with ongoing litigation and other matters. We generally fund our operating capital requirements through our operating activities and cash reserves. We expect to use capital in the near and medium term to commence late-stage clinical trials for certain of our products, invest in the international expansion of our business and the broadening of our product portfolio, and invest in certain capital projects.

As of December 31, 2022, we had \$66.0 million of cash and cash equivalents.

Our net working capital at December 31, 2022 was \$90.6 million, a decrease of \$15.5 million from \$106.2 million at December 31, 2021. Our current ratio was 3.1 to 1 as of December 31, 2022 and 3.5 to 1 as of December 31, 2021.

The Company is currently paying its obligations in the ordinary course of business. We believe that our anticipated cash from operating activities and existing cash and cash equivalents will enable us to meet our operational liquidity needs for the twelve months following the filing date of this Annual Report.

#### *Contractual Obligations*

Contractual obligations associated with ongoing business activities are expected to result in cash payments in future periods. The table below summarizes the amounts and estimated timing of these future cash payments as of December 31, 2022 (in thousands):

Contractual Obligations	Total	Less than			
		1 year	1-3 years	3-5 years	Thereafter
Hayfin Term Loan Principal	\$ 50,000	\$ —	\$ 50,000	\$ —	\$ —
Hayfin Term Loan Interest <sup>(1)</sup>	14,558	5,836	8,722	—	—
Operating lease obligations	4,216	1,638	2,124	454	—
Severance obligations to former employees	3,677	2,513	1,164	—	—
Meeting space commitments	1,383	989	394	—	—
Finance lease obligations	115	55	60	—	—
<b>Total</b>	<b>\$ 73,949</b>	<b>\$ 11,031</b>	<b>\$ 62,464</b>	<b>\$ 454</b>	<b>\$ —</b>

(1) Reflects an interest rate of 11.5% through maturity.

#### *Nordic Agreement*

In June 2022, we entered into a collaboration agreement (the “**Nordic Agreement**”) with Nordic Bioscience Clinical Development A/S (“**NBCD**”) to provide full operational support for our upcoming KOA clinical trial program.

As part of the agreement, NBCD will perform site selection and monitoring, manage patient recruitment and enrollment, data management, statistical analysis and reporting activities for the duration of the trial. Under the terms of the Nordic Agreement, we are obligated to pay \$10.2 million upon the achievement of specified milestones over the course of the clinical trial. These amounts are not included in the table above because the timing of these payments is inherently uncertain.

The milestones are based upon various factors including, but not limited to, site selection and enrollment, patient enrollment, patient completion, and certain other activities related to clinical trial activities. The milestone payments are revised semi-annually based on fluctuations in the consumer price index. We have the ability to terminate the Nordic Agreement with 30 days written notice to NBCD. At such time, we would be required to pay for services performed through the date of termination and any non-cancelable obligations. In addition to the milestone payments, the Company will reimburse NBCD for actual expenses incurred related to third-party vendors to be contracted and managed by NBCD.

On January 24, 2023, we executed a change order to the Nordic Agreement (the “**Change Order**”), primarily to reflect additional elements required in conducting the trial. The Change Order modified the scope of NBCD’s responsibilities under the Nordic Agreement, shifting certain activities to other vendors to be administered by NBCD and certain other activities to MIMEDX. These responsibilities primarily related to areas of patient recruitment and screening and statistical analysis, among other areas of the trial. Pursuant to the Change Order, the total payments owed to NBCD relating to NBCD’s responsibilities decreased from \$13.3 million to \$10.2 million. While our total obligation to NBCD has decreased pursuant to the Change Order, we expect to pay these expenses to other vendors. We have paid \$2.0 million under the Nordic Agreement as of December 31, 2022 relating to milestones which have been achieved through that date.

#### *Turn Agreement*

As described above under Item 1. “*Business-Our Product Portfolio & Pipeline*”, we acquired intellectual property rights pursuant to the Turn Agreement. We paid an up-front cash payment of \$1.0 million upon the execution of the agreement, and are obligated to make additional payments upon the meeting of regulatory and product commercial milestones, including \$9.6 million if and when Turn receives 510(k) clearance from the FDA for FleX. In addition, we are obligated to pay royalties on the sales of FleX and any products derived from PermaFusion. These amounts are not included in the table above because the timing of these payments are inherently uncertain.

#### *Term Loan*

On June 30, 2020, we entered into a Loan Agreement with, among others, Hayfin Services, LLP, (“**Hayfin**”) an affiliate of Hayfin Capital Management, LLP (the “**Hayfin Loan Agreement**”), under which Hayfin provided us with a senior secured term loan of \$50 million (the “**Term Loan**”). The Term Loan matures on June 30, 2025 (the “**Maturity Date**”). On February 28, 2022, we executed an Amendment to the Hayfin Loan Agreement (as amended, the “**Amended Hayfin Loan Agreement**”).

No principal payments are due on the Term Loan until the Maturity Date. Interest is payable on the Term Loan for principal outstanding quarterly through the Maturity Date. Interest on any borrowings under the Term Loan is equal to LIBOR (subject to a floor of 1.5%) plus a margin of 6.75%. If LIBOR is unavailable, the loan will carry interest at the greatest of the Prime Rate, the Federal Funds Rate plus 0.5% per annum, and 2.5% plus the 6.75% margin. An additional 3.0% margin would be applied to the interest rate upon the occurrence of an Event of Default as defined in the Amended Hayfin Loan Agreement. As of December 31, 2022, the Term Loan carried an interest rate of 11.5%.

The Amended Hayfin Loan Agreement contains financial covenants requiring the Company, on a consolidated basis, to maintain the following:

- Minimum Consolidated Total Net Sales (as defined in the Amended Hayfin Loan Agreement) of varying amounts, required to be calculated on a quarterly basis, and
- Minimum Liquidity (as defined in the Amended Hayfin Loan Agreement) of \$20 million, an at-all-times financial covenant, tested monthly.

As of December 31, 2022, we are in compliance with all applicable financial covenants under the Amended Hayfin Loan Agreement.

The Amended Hayfin Loan Agreement also specifies that any prepayment of the Term Loan, voluntary or mandatory, as defined in the agreement, would subject us to a prepayment premium applicable as of the date of the prepayment, as follows:

- On or before July 2, 2023: 2% of the principal balance repaid.
- After July 2, 2023 but on or before July 2, 2024: 1% of the principal balance repaid.
- After July 2, 2024: no premium.

The Amended Hayfin Loan Agreement also includes certain negative covenants and events of default customary for facilities of this type, and upon the occurrence of such events of default, subject to customary cure rights, all outstanding loans under the Amended Hayfin Loan Agreement may be accelerated or the lenders' commitments terminated. Mandatory prepayments are also required in the event of a change in control, incurring other indebtedness, certain proceeds from disposal of assets and insured casualty event (as defined in the Amended Hayfin Loan Agreement). Annually, we are required to prepay the outstanding loans based on the percentage of our Excess Cash Flow (as defined in the Amended Hayfin Loan Agreement), if such is generated. To date, we have not been required to make any prepayments under this provision.

A breach of a financial covenant in the Amended Hayfin Loan Agreement, if uncured or unable to be cured, would likely result in an event of default that could trigger the lender's remedies, including acceleration of the entire principal balance of the loan as well as any applicable prepayment premiums. Future compliance with the financial covenants, as amended, requires continuing growth in net sales consistent with the Company's business strategy and plans. Our business is subject to inherent uncertainties that could impact the Company's net sales growth, including, but not limited to, the regulatory pathway of our cord-derived products.

While we currently have sufficient cash to repay all such amounts in an event of default, we may require alternative financing to cover other obligations. Even if alternative financing were available in an event of default under the Amended Hayfin Loan Agreement, it might be on unfavorable terms, and the interest rate charged on any new borrowings may be substantially higher than the interest rate under the Amended Hayfin Loan Agreement, thus adversely affecting our future cash flows, liquidity, and results of operations.

### *Series B Preferred Stock*

We have 100,000 shares of Series B Preferred Stock outstanding as of December 31, 2022.

The Series B Preferred Stock currently accumulates dividends at a rate of 6.0% per annum. Dividends are declared at the sole discretion of our board of directors. Dividends, if declared, are paid in cash at the end of each quarter based on dividend amounts that accumulate beginning on the last payment date through the day prior to the end of each quarter. In lieu of paying a dividend in cash, we may elect to accrue the dividend owed to shareholders. Dividend balances accumulate at the prevailing dividend rate for each dividend period for which they are outstanding.

Each share of Series B Preferred Stock, including any accrued and unpaid dividends, is convertible into our common stock at any time at the option of the holder at a conversion price of \$3.85 per common share, or 259.74 common shares for each Series B Preferred Share prior to any accrued and unpaid dividends. The Series B Preferred Stock, including any accrued and unpaid dividends, automatically converts into common stock at any time after July 2, 2023, provided that the common stock has traded at \$7.70 or higher (i) for 20 out of 30 consecutive trading days and (ii) on such date of conversion.

If we undergo a change of control, we will have the option to repurchase some or all of the then-outstanding shares of Series B Preferred Stock for cash in an amount equal to the liquidation preference and any accumulated and unpaid dividends, subject to the rights of the holders of the Series B Preferred Stock in connection with such change in control. If we do not exercise such repurchase right, holders of the Series B Preferred Stock will have the option to (1) require us to repurchase any or all of our then-outstanding shares of Series B Preferred Stock for cash in an amount equal to the liquidation preference or (2) convert the Series B Preferred Stock, including accrued and unpaid dividends into common stock and receive its pro rata consideration thereunder.

We have not declared or paid any cash dividends on our Series B Preferred Stock since their issuance. Dividends in arrears as of December 31, 2022 were \$13.8 million. Assuming we do not declare or pay a cash dividend, the holders do not exercise their option to convert, and the other conversion or redemption features are not triggered, we would accumulate and accrue \$7.0 million of dividends in 2023, \$15.3 million in aggregate in 1-3 years, and \$17.2 million in aggregate in 3-5 years.

As of December 31, 2022, the Series B Preferred Stock was convertible into 29,559,946 common shares.

Refer to Item 8, Note 11, *Equity*, for more detailed discussion regarding the rights and preferences of our Series B Preferred Stock.

### *Regulatory Items*

There is a possibility that the FDA may rule that our cord-derived products do not meet the requirements to be regulated solely under the authority of Section 361 of the Public Health Service Act. In such a case, in order to continue to market the products, we would be required to obtain the appropriate FDA clearance or approval. The loss of our ability to market and sell our umbilical cord-derived product would have an adverse effect on the Company's revenue, business, financial condition, and results of operations. Sales of our cord products were \$23.2 million and \$23.6 million in 2022 and 2021, respectively.

### *Reimbursement Developments*

Recently, several wide-ranging proposals have been published for public comment, including relating to payment methodology within the physician office, and are under consideration by the U.S. Centers for Medicare and Medicaid Services. In addition, three Medicare Administrative Contractors have recently published for public comment changes to their Local Coverage Determinations that they are considering. If adopted, these proposals would significantly change Medicare policies governing the reimbursement of skin substitute products principally when used for wound treatment in the private physician office setting. Refer to Item 1A, *Risk Factors — Our revenues depend on adequate reimbursement from public and private insurers and health systems and changes to the ways in which our products are reimbursed in various sites of service could adversely impact our financial results.*

### *Other Liquidity Considerations*

Further, our liquidity will be impacted by expected and unexpected costs, investments in clinical trials to support BLAs, and contingent liabilities:

- Advancement of our clinical trials will involve substantial cost. Products subject to the FDA's BLA requirements must comply with a range of pre- and post-market provisions. Pre-market compliance includes the conduct of clinical trials in support of BLA approval, the development and submission of a BLA, and the production of product for use in the

clinical trials that meets the FDA's quality expectations. See Item 1A - Risk Factors - "Obtaining and maintaining the necessary regulatory approvals for certain of our products will be expensive and time consuming and may impede our ability to fully exploit our technologies," and "If any of the BLAs are approved, the Company would be subject to additional regulation which will increase costs and could result in adverse sanctions for non-compliance."

- The continued expansion of our product lines and the development of new products will require continuous investment in intellectual property and research and development.
- International expansion of our business will require investment through the costs to achieve necessary regulatory approvals and reimbursement schemes, establishing a physical presence through office and warehouse space, identifying and hiring employees, and other costs to establish ongoing operations.
- We are exposed to potential liabilities and reputational risk associated with litigation, regulatory proceedings, and government enforcement actions. The amounts, if any, for which we may be liable resulting from such proceedings are highly uncertain. See Item 3, *Legal Proceedings* and Item 8, Note 16, *Commitments and Contingencies* and Item 1A, "Risk Factors" - "We are currently, and may in the future be, subject to substantial litigation and ongoing investigations that could cause us to incur significant legal expenses and result in harm to our business."
- The application of CGMP requires investment in our manufacturing establishments for production for our micronized products. The transition process includes development and enhancement of production processes, procedures, test and assays, and it requires extensive validation work. It can also involve the procurement and installation of new production or lab equipment. These efforts require human capital, expertise and resources. See Item 1A. - "Risk Factors" under the heading "Certain of our products no longer qualify for regulation as human cells, tissues and cellular and tissue-based products solely under Section 361 of the Public Health Service Act ("Section 361"), which has resulted in removal of the applicable products from the market, made the introduction of some new tissue products more expensive, significantly delayed the expansion of our tissue product offerings and subjected us to additional post-market regulatory requirements. Additional regulatory requirements may be imposed in the future."

## **Discussion of Cash Flows**

### *Operating Activities*

During the year ended December 31, 2022, net cash used in operating activities increased \$15.9 million to \$17.9 million compared to \$2.0 million for the year ended December 31, 2021. The increase in cash used was primarily the result of increases in selling, general, and administrative expenses and research and development expenses during the year ended December 31, 2022. In addition, cash used for the year ended December 31, 2021 was positively impacted by an income tax refund of \$9.2 million and insurance settlements of \$8.0 million.

### *Investing Activities*

During the year ended December 31, 2022, net cash used in investing activities was \$2.7 million, a decrease of \$0.7 million, compared to \$3.4 million for the year ended December 31, 2021. The primary reason for the decrease was a \$1.7 million decrease in capital expenditures, year-over-year, offset by \$1.0 million of payments made pursuant to the Turn Agreement.

### *Financing Activities*

During the year ended December 31, 2022, net cash used in financing activities was \$0.6 million, a decrease of \$2.8 million compared to cash used in financing activities of \$3.4 million for the year ended December 31, 2021. Activity in 2022 was driven by year-over-year decreases in the cash paid for shares repurchased for tax withholding (\$3.6 million), offset by decreases in proceeds from option exercises (\$0.8 million).

## Non-GAAP Financial Measures

In addition to our GAAP results, we provide the following Non-GAAP measures: Earnings Before Interest, Taxes, Depreciation and Amortization (“**EBITDA**”) and Adjusted EBITDA. We believe that the presentation of these measures provides important supplemental information to management and investors regarding our performance. These measurements are not, and should not be used as, a substitute for GAAP measures. Company management uses these Non-GAAP measures as aids in monitoring our on-going financial performance from quarter-to-quarter and year-to-year on a regular basis and for benchmarking against comparable companies.

We provide EBITDA and Adjusted EBITDA to facilitate comparisons to results of other companies. We use EBITDA as a measure of our operating performance, planning, and budgeting purposes as it eliminates the effects of financing and investing activities, as well as irregular and non-cash expenses. EBITDA is widely used by investors and analysts to measure operating performance and evaluate enterprise value.

EBITDA consists of GAAP net loss excluding: (i) depreciation, (ii) amortization of intangibles, (iii) interest expense, net, (iv) loss on extinguishment of debt, and (v) income tax provision.

Adjusted EBITDA is intended to provide an enduring, normalized view of EBITDA and our broader business operations that we expect to experience on an ongoing basis by removing from EBITDA certain items which may be irregular, non-recurring, or non-cash items not excluded when calculating EBITDA. This enables us to identify underlying trends in our business that could otherwise be masked by such items.

Adjusted EBITDA consists of GAAP net loss excluding: (i) depreciation, (ii) amortization of intangibles, (iii) interest expense, net, (iv) loss on extinguishment of debt, (v) income tax provision, (vi) costs incurred in connection with Audit Committee Investigation and Restatement, (vii) share-based compensation, and (viii) impairment of intangible assets.

A reconciliation of GAAP net loss to EBITDA and Adjusted EBITDA appears in the table below (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Net loss	\$ (30,197)	\$ (10,285)	\$ (49,284)
Non-GAAP Adjustments:			
Depreciation expense	3,345	4,363	5,782
Amortization of intangible assets	701	820	1,073
Interest expense, net	5,016	4,980	7,941
Loss on extinguishment of debt	—	—	8,201
Income tax provision expense (benefit)	206	247	(12,259)
EBITDA	\$ (20,929)	\$ 125	\$ (38,546)
Additional Non-GAAP Adjustments:			
Costs incurred in connection with Audit Committee Investigation and Restatement	12,177	3,791	59,465
Share-based compensation	12,666	14,757	15,357
Impairment of intangible assets	—	53	1,027
Adjusted EBITDA	\$ 3,914	\$ 18,726	\$ 37,303

## Critical Accounting Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations discusses our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The preparation of these financial statements requires that we make judgments and estimates which may affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. We derive these judgments and estimates on historical experience and other relevant factors which we believe to be reasonable. Actual results may differ from these estimates.

### *Net Sales*

#### Description

We record estimates for returns and allowances as a reduction to net sales based on our expectation for such returns.

#### Judgments and Uncertainties

We sell our products to individual customer and independent distributors (collectively referred to as "*customers*"). Customers obtain and use products either through ship and bill sales or consignment arrangements. We recognize revenue as performance obligations are fulfilled, which generally occurs upon the shipment of product to customers for ship and bill sales or upon implantation for consignment sales. We recognize revenue based on consideration we expect to receive from the sale. This consists of the gross selling price of the product, less any discounts, rebates, fees paid to GPOs, and an expectation for sales returns.

We maintain a return policy that allows our customers to return product for any reason within 30 days of sale, and to return product that is damaged or non-conforming, ordered in error, or due to recall at any time.

We derive an expectation for product returns based on historical return patterns and other factors, including shifts in our regulatory environment and product recalls. Determinations involving other factors are based on our estimates for product at customer sites that are eligible for return.

Additions or reversals to our return allowance, as determined necessary, are accounted for prospectively and recorded as a decrease or increase to net sales, respectively. Actual returns are recorded against the recorded accrual.

#### Sensitivity of Estimate to Change

We have accrued \$0.7 million for sales returns as of December 31, 2022. Changes in return patterns or unforeseen changes in regulations or identified product recalls could cause returns significantly in excess of this estimate.

### *Contingencies*

#### Description

We record contingent liabilities related to legal and other proceedings at such point in time when loss is probable and reasonably estimable.

#### Judgments and Uncertainties

We evaluate the probability of loss and the range of potential losses based on salient details about a case. These evaluations consider evidence derived from discussions with counsel and include the merits and jurisdiction of the proceeding, the nature and the number of other similar current and past proceedings, damages sought by the counterparty, settlement offers we have extended to the counterparty and other factors. From this information, we make a judgmental determination of whether loss from a case is probable and whether a reasonable estimate of loss can be derived. In situations where a reasonable estimate is a range of estimates, we record the most likely amount in the range or, if no single amount is more likely than any of the others, we record the minimum amount of the range.

### Sensitivity of Estimate to Change

As of December 31, 2022, we have reserved \$0.2 million for potential losses relating to legal proceedings discussed in Item 8, Note 16, *Commitments and Contingencies*. The outcome of court judgments could lead to a change in our evaluation of probability of loss or our estimate for such loss. In addition, court judgments may result from matters for which we had previously assessed loss as being not probable or which result in losses which materially depart from our estimate, either favorably or unfavorably.

We believe that our estimates applied are based on reasonable assumptions, but are inherently uncertain. Actual results may differ from the assumptions and judgments used to derive our accrual.

### *Income Taxes*

#### Description

We record a valuation allowance to offset our net deferred tax asset to the extent that realization is not likely.

#### Judgments and Uncertainties

Deferred income taxes arise from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements. Transactions which result in lower taxable income in the future give rise to deferred tax assets.

We evaluate our ability to recover deferred tax assets based on projected future taxable income, scheduled reversals of deferred tax liabilities, tax planning strategies, and our recent operating results. Judgment is required to determine whether the totality of this evidence suggests that we can recover our deferred tax assets in the future.

### Sensitivity of Estimate to Change

As of December 31, 2022, we had \$47.6 million of valuation allowances recorded, fully offsetting our net deferred tax asset. This determination may change due to changes in tax law, a revision to our expectation regarding taxable income in the future, taxable income generated in a period in which we had not previously anticipated taxable income, a change in scheduled reversals of deferred tax liabilities, and other changes.

Historically, exclusive of changes in tax law such as that enacted under the Coronavirus Aid, Relief and Economic Security Act, we have not reversed our valuation allowance.

If the weight of available evidence suggests that some or all of this amount is more likely than not to be realized, we will derecognize the valuation allowance as an income tax benefit to the extent that the underlying deferred tax asset is more likely than not to be realized.

### **Recently Adopted Accounting Pronouncements**

See Item 8, Note 2, *Significant Accounting Policies*, in the Consolidated Financial Statements for recently adopted accounting pronouncements.

### **Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to risks associated with changes in interest rates that could adversely affect our results of operations and financial condition. We do not hedge against interest rate risk.

The interest rate on our Term Loan is determined quarterly based on the 3-month U.S. dollar LIBOR rate, subject to a floor of 1.5%. As of December 31, 2022, the interest rate on our Term Loan was 11.5%. A 100 basis point change in LIBOR, to the extent that such change would not cause LIBOR to be below the 1.5% minimum, would change interest expense by \$0.5 million on an annualized basis.

During the year ended December 31, 2022, we incurred \$0.4 million in incremental interest expense as a result of increases in LIBOR during the year.

## Item 8. Financial Statements and Supplementary Data

### Index to Financial Statements

Report of Deloitte & Touche LLP, Independent Registered Public Accounting Firm (PCAOB ID: 34)	<a href="#">F- 2</a>
Report of BDO USA, LLP, Independent Registered Public Accounting Firm (PCAOB ID: 243)	<a href="#">F- 4</a>
Consolidated Balance Sheets – As of December 31, 2022 and 2021	<a href="#">F- 5</a>
Consolidated Statements of Operations – For the years ended December 31, 2022, 2021 and 2020	<a href="#">F- 6</a>
Consolidated Statements of Stockholders' (Deficit) Equity – For the years ended December 31, 2022, 2021 and 2020	<a href="#">F- 7</a>
Consolidated Statements of Cash Flows – For the years ended December 31, 2022, 2021 and 2020	<a href="#">F- 8</a>
Notes to Consolidated Financial Statements	<a href="#">F- 9</a>
Schedule II - Valuation and Qualifying Accounts	<a href="#">F- 44</a>

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of MiMedx Group, Inc.

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of MiMedx Group, Inc. and subsidiaries (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations, stockholders' (deficit) equity, and cash flows, for the years then ended, and the related notes and the schedule listed in the Index at Item 8 (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 28, 2023, expressed an unqualified opinion on the Company's internal control over financial reporting.

### Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

### Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

### Net Sales - Revenue Recognition — Refer to Note 2 to the Financial Statements

#### *Critical Audit Matter Description*

The Company sells its products primarily to individual customers and independent distributors (collectively referred to as "customers"). Customers obtain and use products either through ship and bill sales or consignment arrangements. Under ship and bill arrangements, the Company retains possession of the product until the customer submits an order and the product orders is shipped to the customer. Under consignment arrangements, the customer takes possession of the product, but the Company retains title until the implantation, or application of the Company's product to the end user. The Company recognizes revenue as performance obligations are fulfilled, which generally occurs upon the shipment of product to the customers for ship and bill orders or upon implantation for consignment sales.

We identified the timing of revenue recognition for ship and bill and consignment sales at or near year end as a critical audit matter because of the judgments involved in evaluating that the performance obligations are fulfilled. This required extensive audit effort due to the volume of transactions and a degree of auditor judgment when performing audit procedures and evaluating the results of those procedures.

*How the Critical Audit Matter Was Addressed in the Audit*

Our audit procedures related to the timing of revenue recognition transactions included the following, among others:

- We tested the effectiveness of controls over the recognition of ship and bill and consignment sales at or near year end.
- We created data visualizations using a detail of all revenue transactions and evaluated trends in the transactional revenue data with emphasis on activity at or near year end.
- We evaluated and tested corollary relationships between revenue and related accounts.
- We evaluated the appropriateness and consistency of the methods and assumptions utilized by management to estimate consignment revenue.
- We tested a sample of consignment revenue transactions manually accrued as of year end and evaluated whether the transactions were recorded in the correct period.
- We selected a sample of ship and bill revenue transactions close to year end by agreeing the amounts recognized to source documents and evaluating whether the transaction was recorded in the correct period.
- We tested a sample of credits issued after year end by agreeing to documents supporting the authorization for the issuance of the credit and to evaluate if the credit was issued in the correct period.

/s/ Deloitte & Touche LLP  
Atlanta, Georgia  
February 28, 2023

We have served as the Company's auditor since 2021.

## **Report of Independent Registered Public Accounting Firm**

Shareholders and Board of Directors  
MiMedx Group, Inc.  
Marietta, Georgia

### **Opinion on the Consolidated Financial Statements**

We have audited the accompanying consolidated statement of stockholders' equity (deficit), operations and cash flows for the year ended December 30, 2020 of MiMedx Group, Inc. (the "Company") and the related notes and schedule (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020, and the results of its operations and its cash flows for the year ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

### **Basis for Opinion**

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ BDO USA, LLP

We served as the Company's auditor from 2019 to 2020.  
Atlanta, Georgia

March 8, 2021, except for the change in reportable segments discussed in Notes 2 and 13, as to which the date is February 28, 2023

**MIMEDX GROUP, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
(in thousands, except share data)

	December 31,	
	2022	2021
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 65,950	\$ 87,083
Accounts receivable, net	43,084	40,353
Inventory	13,183	11,389
Prepaid expenses	8,646	6,146
Income tax receivable	704	743
Other current assets	2,631	2,809
<b>Total current assets</b>	<b>134,198</b>	<b>148,523</b>
Property and equipment, net	7,856	9,165
Right of use asset	3,400	4,696
Goodwill	19,976	19,976
Intangible assets, net	5,852	5,383
Other assets	148	186
<b>Total assets</b>	<b>\$ 171,430</b>	<b>\$ 187,929</b>
<b>LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' (DEFICIT) EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 8,847	\$ 7,385
Accrued compensation	21,852	23,595
Accrued expenses	11,024	9,812
Other current liabilities	1,834	1,565
<b>Total current liabilities</b>	<b>43,557</b>	<b>42,357</b>
Long term debt, net	48,594	48,127
Other liabilities	4,773	4,869
<b>Total liabilities</b>	<b>\$ 96,924</b>	<b>\$ 95,353</b>
Commitments and contingencies (Note 16)		
Convertible preferred stock Series B; \$.001 par value; 100,000 shares authorized, issued and outstanding at December 31, 2022 and December 31, 2021	\$ 92,494	\$ 92,494
Stockholders' (deficit) equity:		
Preferred stock Series A; \$.001 par value; 5,000,000 shares authorized; 0 issued and outstanding at December 31, 2022 and 0 issued and outstanding at December 31, 2021	\$ —	\$ —
Common stock; \$.001 par value; 187,500,000 shares authorized, 113,705,447 issued and outstanding at December 31, 2022 and 112,703,926 issued and 111,925,216 outstanding at December 31, 2021	114	113
Additional paid-in capital	173,804	165,695
Treasury stock at cost; 0 shares at December 31, 2022 and 778,710 shares at December 31, 2021	—	(4,017)
Accumulated deficit	(191,906)	(161,709)
<b>Total stockholders' (deficit) equity</b>	<b>(17,988)</b>	<b>82</b>
<b>Total liabilities, convertible preferred stock, and stockholders' (deficit) equity</b>	<b>\$ 171,430</b>	<b>\$ 187,929</b>

See notes to the consolidated financial statements.

**MIMEDX GROUP, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except share and per share data)

	Year Ended December 31,		
	2022	2021	2020
Net sales	\$ 267,841	\$ 258,615	\$ 248,234
Cost of sales	48,316	43,283	39,330
Gross profit	219,525	215,332	208,904
<b>Operating expenses:</b>			
Selling, general and administrative	208,789	198,359	181,022
Research and development	22,829	17,344	11,715
Investigation, restatement and related	12,177	3,791	59,465
Amortization of intangible assets	701	820	1,073
Impairment of intangible assets	—	53	1,027
Operating loss	(24,971)	(5,035)	(45,398)
<b>Other expense, net</b>			
Interest expense, net	(5,016)	(4,980)	(7,941)
Other expense, net	(4)	(23)	(3)
Loss on extinguishment of debt	—	—	(8,201)
Loss before income tax provision	(29,991)	(10,038)	(61,543)
Income tax provision (expense) benefit	(206)	(247)	12,259
Net loss	\$ (30,197)	\$ (10,285)	\$ (49,284)
Net loss available to common stockholders (Note 10)	\$ (36,777)	\$ (16,421)	\$ (83,328)
Net loss per common share - basic	\$ (0.33)	\$ (0.15)	\$ (0.77)
Net loss per common share - diluted	\$ (0.33)	\$ (0.15)	\$ (0.77)
Weighted average common shares outstanding - basic	112,909,266	110,353,406	108,257,112
Weighted average common shares outstanding - diluted	112,909,266	110,353,406	108,257,112

See notes to the consolidated financial statements.

**MIMEDX GROUP, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**  
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Treasury Stock		Accumulated Deficit	Total
	Shares	Amount		Shares	Amount		
Balance at December 31, 2019	112,703,926	\$ 113	\$ 147,231	1,885,277	\$ (10,806)	\$ (102,140)	\$ 34,398
Issuance of Series B Convertible Preferred Stock	—	—	32,954	—	—	—	32,954
Deemed dividends	—	—	(32,028)	—	—	—	(32,028)
Share-based compensation expense	—	—	15,733	—	—	—	15,733
Exercise of stock options	—	—	(3,180)	(359,328)	3,591	—	411
Issuance of restricted stock	—	—	(5,463)	(613,146)	5,463	—	—
Restricted stock shares canceled/forfeited	—	—	3,363	425,388	(3,363)	—	—
Shares repurchased for tax withholding	—	—	—	435,492	(2,334)	—	(2,334)
Net loss	—	—	—	—	—	(49,284)	(49,284)
Balance at December 31, 2020	<u>112,703,926</u>	<u>\$ 113</u>	<u>\$ 158,610</u>	<u>1,773,683</u>	<u>\$ (7,449)</u>	<u>\$ (151,424)</u>	<u>\$ (150)</u>
Deemed dividends	—	—	(926)	—	—	—	(926)
Shares repurchased for tax withholding	—	—	—	469,239	(4,751)	—	(4,751)
Share-based compensation expense	—	—	14,757	—	—	—	14,757
Exercise of stock options	—	—	(1,199)	(487,361)	2,636	—	1,437
Restricted stock shares canceled/forfeited	—	—	515	73,056	(515)	—	—
Issuance of restricted stock	—	—	(4,053)	(810,405)	4,053	—	—
Other	—	—	(2,009)	(239,502)	2,009	—	—
Net loss	—	—	—	—	—	(10,285)	(10,285)
Balance at December 31, 2021	<u>112,703,926</u>	<u>\$ 113</u>	<u>\$ 165,695</u>	<u>778,710</u>	<u>\$ (4,017)</u>	<u>\$ (161,709)</u>	<u>\$ 82</u>
Shares repurchased for tax withholding	—	—	—	249,442	(1,190)	—	(1,190)
Share-based compensation expense	—	—	12,666	—	—	—	12,666
Exercise of stock options	160,762	—	(618)	(151,239)	1,269	—	651
Issuance of restricted stock	840,759	1	(3,969)	(882,251)	3,968	—	—
Restricted stock shares canceled/forfeited	—	—	30	5,338	(30)	—	—
Net loss	—	—	—	—	—	(30,197)	(30,197)
Balance at December 31, 2022	<u>113,705,447</u>	<u>\$ 114</u>	<u>\$ 173,804</u>	<u>—</u>	<u>\$ —</u>	<u>\$ (191,906)</u>	<u>\$ (17,988)</u>

See notes to the consolidated financial statements.

**MIMEDX GROUP, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)

	Years Ended December 31,		
	2022	2021	2020
<b>Cash flows from operating activities:</b>			
Net loss	\$ (30,197)	\$ (10,285)	\$ (49,284)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Share-based compensation	12,666	14,757	15,357
Depreciation	3,345	4,363	5,782
Bad debt expense	2,820	—	—
Non cash lease expenses	1,259	989	983
Amortization of intangible assets	701	820	1,073
Amortization of deferred financing costs and debt discount	467	1,055	2,276
Accretion of asset retirement obligation	92	81	10
(Gain) loss on fixed asset disposal	(17)	262	1
Impairment of intangible assets	—	53	1,027
Loss on extinguishment of debt	—	—	8,201
<b>Increase (decrease) in cash resulting from changes in:</b>			
Accounts receivable	(5,550)	(4,930)	(3,096)
Inventory	(1,794)	(1,028)	(1,257)
Prepaid expenses	(2,500)	(542)	1,064
Other assets	(333)	675	(119)
Accounts payable	1,053	(326)	177
Accrued compensation	(1,744)	5,128	(2,459)
Accrued expenses	1,762	(21,197)	1,746
Income taxes	39	9,302	(10,027)
Other liabilities	38	(1,159)	(1,718)
<b>Net cash flows used in operating activities</b>	<b>(17,893)</b>	<b>(1,982)</b>	<b>(30,263)</b>
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(1,514)	(3,218)	(4,228)
Cash paid for licensing agreement	(1,000)	—	—
Patent application costs	(170)	(252)	(327)
Principal payments from note receivable	—	75	—
Proceeds from property and equipment sale	24	—	—
<b>Net cash flows used in investing activities</b>	<b>(2,660)</b>	<b>(3,395)</b>	<b>(4,555)</b>
<b>Cash flows from financing activities:</b>			
Stock repurchased for tax withholdings on vesting of restricted stock	(1,190)	(4,751)	(2,334)
Proceeds from exercise of stock options	651	1,437	411
Payments under finance lease obligations	(41)	(38)	—
Proceeds from sale of Series B convertible preferred stock	—	—	100,000
Stock issuance costs	—	—	(7,470)
Proceeds from term loans	—	—	59,500
Deferred financing costs	—	—	(3,235)
Repayment of term loans	—	—	(83,872)
Prepayment premium on early repayment of term loan	—	—	(1,439)
<b>Net cash flows (used in) provided by financing activities</b>	<b>(580)</b>	<b>(3,352)</b>	<b>61,561</b>
<b>Net change in cash</b>	<b>(21,133)</b>	<b>(8,729)</b>	<b>26,743</b>
Cash and cash equivalents, beginning of year	87,083	95,812	69,069
<b>Cash and cash equivalents, end of year</b>	<b>\$ 65,950</b>	<b>\$ 87,083</b>	<b>\$ 95,812</b>

See notes to the consolidated financial statements.

**MIMEDX GROUP, INC. AND SUBSIDIARIES**  
**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**1. Nature of Business**

MiMedx Group, Inc. (together with its subsidiaries, except where the context otherwise requires, “**MIMEDX**,” or the “**Company**”) is a pioneer and leader in placental biologics focused on addressing the needs of patients with acute and chronic non-healing wounds. The Company is also advancing a promising late-stage biologics pipeline targeted at decreasing pain and improving function for patients with knee osteoarthritis (“**KOA**”). To accomplish these goals, the Company operates as two defined, internal business units: Wound & Surgical and Regenerative Medicine. All of our products sold in the United States are regulated by the United States Food and Drug Administration (“**FDA**”).

The Wound & Surgical business focuses on the Advanced Wound Care and Surgical Recovery markets through sales of the Company’s existing product portfolio and product development to serve these end markets. This business unit is responsible for substantially all sales of the Company’s Advanced Wound Care products, as well as the sale of the Company’s micronized and certain particulate products (collectively, the “**Section 351 products**”) internationally.

The Regenerative Medicine business focuses on progressing the Company’s placental biologics platform towards registration as a FDA-approved biological drug. Micronized dehydrated human amnion chorion membrane (“**mDHACM**”) is an injectable placental biologic product candidate in its late-stage pipeline targeted at achieving FDA approval for an indication to help decrease pain and improve function in patients suffering from KOA. Prior to May 31, 2021, this business unit was responsible for domestic sales of the Company’s Section 351 products. Regenerative Medicine does not currently generate revenue.

Additional information regarding the principal operations and results of these business units can be found in Note 13, *Segment Information*.

The Company’s business is focused primarily on the United States of America but the Company is pursuing opportunities for international expansion, with specific focus on the sale of its placental tissue products in Japan.

**2. Significant Accounting Policies**

*Principles of Consolidation*

The consolidated financial statements include the accounts of MiMedx Group, Inc. and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated upon consolidation.

*Use of Estimates*

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“**GAAP**”). GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported consolidated statements of operations during the reporting period. Actual results could differ from those estimates. Significant estimates include estimated useful lives and potential impairment of property and equipment, goodwill and intangible assets, estimates of loss for contingent liabilities, estimate of allowance for doubtful accounts, management’s assessment of the Company’s ability to continue as a going concern, estimate of fair value of share-based payments, estimates of returns and allowances, and valuation of deferred tax assets.

*Segment Reporting*

The application of GAAP requires the use of the “management approach” model for segment reporting. The management approach model is based on the way a company’s chief operating decision maker (“**CODM**”) organizes segments within the Company for which separate financial information is available regarding resource allocation and assessing performance. The Company has concluded that its Chief Executive Officer (“**CEO**”) is its CODM. Prior to June 30, 2022, the Company assessed that it operated as one operating and reportable segment. The Company reassesses the existence of operating segments when facts and circumstances suggest that there may have been a change in the way that the Company is managed.

On September 30, 2022, the Company reassessed its operating segments, concluding that the CODM assesses performance and allocates resources between two, distinct reportable segments: Wound & Surgical and Regenerative Medicine. Information regarding the principal operations and results of these segments can be found in Note 13, *Segment Information*.

### *Cash and Cash Equivalents*

Cash and cash equivalents include cash held at various banks. The Company considers all highly-liquid investments purchased with an original maturity of three months or less at the date of purchase and money market mutual funds to be cash equivalents.

### *Market Concentrations and Credit Risk*

The Company places its cash and cash equivalents on deposit with U.S.-based financial institutions. The U.S. Federal Deposit Insurance Corporation (“**FDIC**”) provides insurance coverage for deposits up to \$250,000 for substantially all depository accounts. As of December 31, 2022 and 2021, the Company had cash and cash equivalents of approximately \$65.2 million and \$86.4 million, respectively, in excess of the insured amounts in four depository institutions.

### *Accounts Receivable*

Accounts receivable represent amounts due from customers for which revenue has been recognized. Generally, the Company does not require collateral or any other security to support its receivables.

Bad debt expense and the allowance for doubtful accounts are based on historical trends and current expectations for credit losses. The Company’s policy to reserve for potential bad debts is based on the aging of the individual receivables as well as customer-specific qualitative factors, such as bankruptcy proceedings. The Company manages credit risk by routinely performing credit checks on customers prior to sales. Individual receivables are written-off after all reasonable efforts to collect the funds have been made. Actual write-offs may differ from the amounts reserved.

### *Inventory*

Inventory is valued at the lower of cost or net realizable value. Costs of inventory sold are recognized using the first-in, first-out (“**FIFO**”) method. Inventory is tracked through raw material, work-in-process, and finished goods stages as the product progresses through various production steps and stocking locations. Labor and overhead costs are absorbed through the various production processes up to when the work order closes. Historical yields and normal capacities are utilized in the calculation of production overhead rates. Write-downs are utilized to account for slow-moving inventory as well as inventory no longer needed due to diminished demand or regulatory action.

### *Property and Equipment, Net*

Property and equipment are recorded at cost and depreciated on a straight-line method over their estimated useful lives, principally three to seven years. Leasehold improvements are depreciated on a straight-line method over the shorter of the estimated useful lives and the remaining lease term.

### *Asset Retirement Obligations*

The Company records obligations associated with the legal requirement to retire long-lived assets at the sooner of the imposition of the legal requirement and when an estimate for the cost of retirement can reasonably be made. The Company reviews legal obligations associated with the retirement of long-lived assets that result from contractual obligations or the acquisition, construction, development and/or normal use of the assets. If it is determined that a legal obligation exists, regardless of whether the obligation is conditional on a future event, the fair value of the liability for an asset retirement obligation is recognized in the period in which it is incurred, if a reasonable estimate of fair value can be made. The fair value is calculated as the estimate of the expected cash outflow to satisfy the legal obligation discounted to present value using the Company’s incremental borrowing rate. At such point in time, an asset and liability are recorded for the amount of the expected liability. The asset amount is depreciated, straight-line, over the life of the underlying asset, while the liability is accreted to the amount of the expected outflow through selling, general and administrative expense using the effective interest method. Subsequent revisions to estimates for future cash flows related to the asset retirement obligations are recorded as equal increases or decreases to the retirement asset and liability.

### *Impairment of Long-lived Assets*

The Company evaluates the recoverability of its long-lived assets (property, equipment, right of use, and intangible assets with finite lives) whenever adverse events or changes in business climate indicate that the expected undiscounted future cash flows from the related assets may be less than their carrying amounts. When a situation arises which results in a conclusion that it is more likely than not that an asset is not recoverable, the Company estimates cash flows expected to be derived from the continuing use and eventual disposition of the asset. If the sum of those cash flows, not discounted to present value, does not exceed the net book value of the asset, the Company estimates the fair value of the asset. Impairment loss is recorded to the extent that the net book value exceeds the fair value of the asset.

Impairment reviews are based on an estimated future cash flow approach that requires significant judgment with respect to future revenue and expense growth rates, selection of appropriate discount rate (as applicable), asset groupings, and other assumptions and estimates. The Company uses estimates that are consistent with its business plans and a market participant view of the assets being evaluated. Actual results may differ from these estimates.

The Company recorded impairment losses on amortizable intangible assets of \$0, \$0.1 million, and \$1.0 million in 2022, 2021, and 2020, respectively. The Company recorded no impairment losses with respect to any other classes of long-lived assets in those periods.

### *Goodwill and Indefinite-lived Intangible Assets*

The Company assesses goodwill for impairment at least annually on October 1 and more frequently whenever events or substantive changes in circumstances indicate that it is more likely than not that goodwill is impaired. In performing the goodwill impairment test, the Company first assesses qualitative factors to determine the existence of impairment. If the qualitative factors indicate that the carrying value of a reporting unit exceeds its fair value, the Company proceeds to a quantitative test to measure the existence and amount, if any, of goodwill impairment. The Company may also choose to bypass the qualitative assessment and proceed directly to the quantitative test.

In performing the quantitative test, impairment loss is recorded to the extent that the carrying value of the reporting unit exceeds its assessed fair value.

If the Company concludes that the way in which it is being managed has changed and results in a change to its concluded reporting units, the goodwill assigned to the original reporting unit is allocated to the new reporting units based on the relative fair value of the new reporting units.

The Company determines the fair value of reporting units using the income and market approaches, as applicable. Under the income approach, the fair value of a reporting unit is the present value of its future cash flows as viewed from the lens of a hypothetical market participant in an orderly transaction. These future cash flows are derived from expectations of revenue, expenses, tax deductions and credits, working capital flows, capital expenditures, and other projected sources and uses of cash, as applicable. Value indications are developed by discounting expected cash flows to their present value using a discount rate commensurate with the risks associated with the reporting unit subject to testing. Under the market approach, the Company uses market multiples derived from various comparable companies based on measures salient to investors in those companies.

As indicated above, on September 30, 2022, the Company changed its operating segments, determining that it operates as two reportable segments. In concert with this re-evaluation, the Company concluded that it has two reporting units for goodwill impairment testing purposes. Management performed a goodwill impairment test as of September 30, 2022 on its previous reporting unit, concluding that goodwill was not impaired as of that date. Management subsequently allocated the goodwill assigned to its previous reporting unit to its new reporting units. Refer to Note 7, *Goodwill and Intangible Assets, Net*, for information regarding the reallocation of goodwill to the reporting units.

As part of the goodwill impairment test performed on October 1, 2022, the Company performed a quantitative assessment, concluding that goodwill was not impaired for any of its reporting units.

There were no recorded impairment losses related to goodwill in 2022, 2021, or 2020. The Company recorded no impairment losses related to any of our other indefinite-lived intangible assets during 2022, 2021, or 2020.

### *Patent Costs*

The Company incurs certain legal and related costs in connection with patent applications. The Company capitalizes such costs to be amortized over the expected life of the patent to the extent that an economic benefit is anticipated from the resulting patent

or an alternative future use is available to the Company. The Company capitalized \$0.2 million, \$0.3 million, and \$0.3 million of patent costs for the years ended December 31, 2022, 2021, and 2020, respectively.

#### *Leases*

The Company determines if a contract is, or contains, a lease at inception. Leases provide the Company with the right to control an underlying asset for a contractual term, subject to certain renewal and other rights, in exchange for a series of stipulated cash flows. Right of use (“**ROU**”) assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease.

Lease assets and liabilities are recognized at the lease commencement date based on the estimated present value of lease payments over the lease term. The Company calculates the present value of lease payments by discounting the lease payments using the Company's incremental borrowing rate for a collateralized or secured borrowing over a term equivalent to that of the lease. Lease payments that vary according to an index or rate are measured using the index or rate at lease inception. The lease term and applicable payments include options to extend or terminate the lease when it is reasonably certain that the Company will exercise such options. Options to renew or terminate a lease are included in the lease term to the extent that such provisions are reasonably certain to be exercised. This determination is reassessed as new information arises and is accounted for prospectively. As an accounting policy election, the Company does not capitalize leases having initial terms of 12 months or fewer. The Company has made an accounting policy election not to separate lease components from non-lease components in the event that the agreement contains both.

Operating lease right of use assets and the related liabilities are included in right of use asset, other current liabilities, and other liabilities, respectively, in the consolidated balance sheets. Lease expense associated with operating leases is recognized, straight-line, over the lease term. The Company does not recognize interest expense as part of operating lease liabilities.

Finance lease right of use assets and the related liabilities are included in property and equipment, net, other current liabilities, and other liabilities, respectively, in the consolidated balance sheets. Finance lease right of use assets are amortized, straight-line, over the lease term as depreciation expense. Interest expense is recognized using the effective interest method on finance lease liabilities as part of interest expense, net.

#### *Treasury Stock*

Shares repurchased by the Company are recorded as treasury stock at the cost to acquire such shares. Subsequent issuances of shares held in treasury are assumed to be released on a FIFO basis.

#### *Contingencies*

The Company is or has been subject to various patent challenges, product liability claims, government investigations, former employee matters, and other legal proceedings, see Note 16, *Commitments and Contingencies*. Legal fees and other expenses related to litigation are expensed as incurred and included in selling, general and administrative expenses in the consolidated statements of operations. The Company records an accrual for resolution costs and other contingencies in the consolidated financial statements when the Company determines that a loss is both probable and reasonably estimable. Subsequent revisions to the Company's accrual are made as new information emerges and are accounted for prospectively. The Company discloses all ongoing legal matters for which a loss is reasonably possible, regardless of whether an estimate can be reasonably determined.

Due to the fact that legal proceedings and other contingencies are inherently unpredictable, the Company's estimates of the probability and amount of any such liabilities involve significant judgment regarding future events. The actual costs of resolving a claim may be substantially different from the amount of reserve the Company recorded. The Company records a receivable from its insurance carriers only when the resolution of any dispute has been reached and realization of the amounts equal to the potential claim for recovery is considered probable. Any recovery of an amount in excess of the related recorded contingent loss will be recognized only when all contingencies relating to recovery have been resolved.

#### *Revenue Recognition*

##### Current Policy

The Company sells its products primarily to individual customers and independent distributors (collectively referred to as “**customers**”). Customers obtain and use products either through ship and bill sales or consignment arrangements. Under ship and bill arrangements, the Company retains possession of the product until the customer submits an order. Upon approval of the sales order, the Company ships product to the customer and invoices them for the product sold. Under consignment

arrangements, the customer takes possession of the product, but the Company retains title until the implantation or application of the Company's product to the end user.

The Company recognizes revenue as performance obligations are fulfilled, which generally occurs upon the shipment of product to the customers for ship and bill orders or upon implantation for consignment sales.

Revenue is recognized based on the consideration the Company expects to receive from the sale. This consists of the gross selling price of the product, less any discounts, rebates or other amounts paid to customers, fees paid to Group Purchasing Organizations ("**GPOs**"), and returns (collectively, "**deductions**" or "**sales deductions**"). Gross selling price is a standard set by the Company for all customers unless a contract governing the sale provides for a specified price. Sales deductions are specified in individual contracts with customers. The Company estimates the total sales deductions which a specific customer will achieve over the relevant term and applies the reduction to sales as they are made throughout the period.

Sales deductions owed to customers and other parties are accrued and recorded in accrued expenses on the consolidated balance sheets.

The Company acts as the principal in all of its customer arrangements and records revenue on a gross basis. Shipping is considered immaterial in the context of the overall customer arrangement, and damages or loss of goods in transit are rare. Therefore, shipping is not deemed a separately recognized performance obligation and the Company has elected to treat shipping costs as activities to fulfill the promise to transfer the product. The Company maintains a returns policy that allows its customers to return product that is damaged or non-conforming, ordered in error, or due to a recall. The estimate of the provision for returns is based upon historical experience with actual returns. The Company's payment terms for customers are typically 30 to 60 days from receipt of title of the goods.

### Remaining Contracts

Prior to 2020, the Company's control environment was such that it created uncertainty surrounding all of its customer arrangements, which required consideration related to the proper revenue recognition under the applicable literature. The control environment allowed for the existence of extra-contractual or undocumented terms or arrangement initiated by or agreed to by the company and former members of Company management at the outset of the transactions (side agreements). Concessions were also agreed to subsequent to the initial sale (e.g. sales above established customer credit limits extended and unusually long payment terms, return or exchange rights, and contingent payment obligations) that precluded the Company from recognizing revenue at the time that product was shipped to a customer.

Because of the prevalence of these arrangements, the Company's sales arrangements did not qualify as contracts under Accounting Standards Codification ("**ASC**") Topic 606, *Revenue from Contracts with Customers*, until consideration was collected from customers. This determination precluded the recognition of revenue at the time of shipment. Instead, recognition of revenue was deferred until: (1) the customer returned the product prior to payment; or (2) the Company received payment from the customer. Cost of sales associated with product shipped was deferred until collection was received.

The Company implemented changes and remediated weaknesses, which gave rise to the above conclusion beginning in mid-2018. Management concluded that these efforts had been sufficiently implemented such that customers were aware of the Company's sales policies and procedures and that a contract existed prior to the transfer of title or the implantation of product for ship-and-bill and consignment sales, respectively, by the third quarter of 2019. Accordingly, the Company changed its pattern of revenue recognition effective October 1, 2019 to the policy described under the section titled "*Current Policy*" above.

The Company also reassessed whether the revenue recognition criteria had been met for all shipments of products where payment had not been received as of September 30, 2019. While the measures summarized above provided significant evidence necessary to understand the terms of the Company's contractual arrangements with its customers, certain of these customers continued to exhibit behaviors that resulted in extended periods until cash collection. Such delays in collection suggested that uncertainty regarding extra-contractual arrangements may continue, particularly as it relates to payment terms. As a result, the Company concluded the following for any existing arrangements, which remained unpaid at September 30, 2019:

- For customer arrangements where collection was considered probable within 90 days from the date of original shipment or implantation of the products, the Company concluded the revenue recognition criteria were met. The revenue associated with this event was recognized prior to 2020.
- For the remaining customer arrangements (the "**Remaining Contracts**"), the Company concluded that, due to the uncertainty that extra-contractual arrangements may continue, the revenue recognition criteria would not be satisfied until the Company received payment from the customer. At that point, the Company determined that an accounting

contract would exist and the performance obligations for the Company to deliver product and the customer to pay for the product would be satisfied. The Company continued to reassess the Remaining Contracts for settlement of the revenue recognition criteria prior to payment, concluding that the revenue recognition criteria continued to not be met due to the same circumstances described above.

The effect of the cash collections on the Remaining Contracts on net sales and cost of sales for each of the years ended December 31, 2022, 2021, and 2020 were as follows (amounts in thousands):

	Year Ended December 31,		
	2022	2021	2020
Net sales	\$ 259	\$ 1,038	\$ 7,767
Cost of sales	—	174	1,087
Gross profit	\$ 259	\$ 864	\$ 6,680

#### *Group Purchasing Organization Fees*

The Company sells to GPO members who transact directly with the Company at GPO-agreed pricing. Group Purchasing Organizations are funded by administrative fees that are paid by the Company. These fees are set as a percentage of the purchase volume, which is typically 3% of sales made to the GPO members. Fees paid to GPOs are presented as a reduction to net sales.

#### *Cost of Sales*

Cost of sales includes all costs directly related to bringing the Company's products to their final selling destination. Amounts include direct and indirect costs to manufacture products including raw materials, personnel costs and direct overhead expenses necessary to convert collected tissues into finished goods, product testing costs, quality assurance costs, facility costs associated with the Company's manufacturing and warehouse facilities, including depreciation, freight charges, costs to operate equipment and other shipping and handling costs for products shipped to customers.

The Company obtains raw material in the form of human placenta donations from participating mothers who give birth via scheduled Caesarean section.

#### *Research and Development Costs*

Research and development costs consist of direct and indirect costs associated with the development of the Company's technologies. These costs are expensed as incurred.

#### *Advertising expense*

Advertising expense consists primarily of print media promotional materials. Advertising costs are expensed as incurred. Advertising expense for the year ended December 31, 2022, 2021, and 2020 was \$0.2 million, \$0.1 million, and \$0.1 million respectively.

#### *Income Taxes*

Income tax provision (expense) benefit, deferred tax assets and liabilities, and liabilities for unrecognized tax benefits reflect management's best assessment of estimated current and future taxes to be paid. The Company is subject to income taxes in the United States and numerous states.

Deferred income taxes arise from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements, which will result in taxable or deductible amounts in the future. The Company recognizes deferred tax assets to the extent that it believes these assets are more likely than not to be realized. If the Company determines that it would be able to realize its deferred tax assets in the future in excess of their net recorded amount, the Company would make an adjustment to the deferred tax asset valuation allowance.

In evaluating the Company's ability to recover its deferred tax assets within the jurisdiction from which they arise, management considers all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax-planning strategies, results of recent operations, and changes in tax laws. In projecting future taxable income, the Company begins with historical results and incorporates assumptions about the amount of future state and federal

pretax operating income adjusted for items that do not have tax consequences. The assumptions about future taxable income require significant judgment and are consistent with the plans and estimates the Company uses to manage the underlying businesses. In evaluating the objective evidence that historical results provide, management considers three years of cumulative income (loss). The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined on the basis of the differences between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in the tax provision (benefit) in the period that includes the enactment date.

The calculation of income tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations both for U.S. federal income tax purposes and across numerous state jurisdictions. ASC Topic 740, *Income Taxes*, states that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, on the basis of the technical merits. The Company (1) records unrecognized tax benefits as liabilities in accordance with ASC Topic 740 included within other liabilities on the consolidated balance sheets, and (2) adjusts these liabilities when management's judgment changes as a result of the evaluation of new information not previously available. Because of the complexity of some of these uncertainties, the ultimate resolution may result in a payment that is materially different from management's current estimate of the unrecognized tax benefit liabilities. These differences will be reflected as increases or decreases to the deferred tax asset or income tax expense in the period in which new information is available.

The Company records uncertain tax positions in accordance with ASC Topic 740 on the basis of a two-step process whereby (1) it determines whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position, and (2) for those tax positions that meet the more-likely-than-not recognition threshold, it recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority.

The Company recognizes interest and penalties related to unrecognized tax benefits within the income tax expense line in the consolidated statements of operations. Accrued interest and penalties, if any, are included within the related deferred tax liability line in the consolidated balance sheets and recorded as a component of income tax expense.

#### *Share-based Compensation*

The Company grants share-based awards to employees and members of the Company's Board of Directors (the "**Board**"). Awards to employees and the Board are generally made annually. Grants are issued outside of the annual cadence for certain new hires, promotions, and other events.

The amount of expense to be recognized is determined by the fair value of the award using inputs available as of the grant date. The fair value of equity incentive awards that are not subject to a market condition is the value of common stock on the grant date. For equity incentive awards that are subject to a market condition, the fair value of common stock on the grant date is adjusted to reflect the value of the market condition, generally using a path-dependent pricing model, such as a Monte Carlo simulation.

For awards with service-based vesting conditions only, the Company recognizes share-based compensation expense on a straight-line basis through the vesting date of the last tranche of the award. For awards with service- and performance-based vesting conditions, the Company recognizes stock-based compensation expense using the graded-vesting method, treating each tranche as if it were a separately-granted award and recognizing expense through the vesting date of each individual tranche. In each scenario, the Company recognizes share-based compensation expense based upon the probability that the award will ultimately vest. The Company recognizes the cumulative effect of changes in the probability outcomes in the period in which the changes occur.

For awards subject to a market condition, the resolution of the market condition is not subsequently considered in expense recognition. Consequently, the Company could recognize expense for awards that do not ultimately vest.

#### *Basic and Diluted Net Loss per Common Share*

Basic net loss per common share is calculated as net loss available to common stockholders divided by weighted average common shares outstanding for the applicable period. Net loss available to common stockholders is calculated by adjusting net loss for periodic preferred accrued or deemed dividends. These amounts include (i) dividends accumulated on the Company's Series B Convertible Preferred Stock ("**Series B Preferred Stock**") during the period, (ii) periodic amortization of the beneficial conversion feature, and (iii) periodic accretion of the increasing-rate dividend feature.

This amount is divided by the weighted average common shares outstanding during the period. Weighted average common shares outstanding is calculated as shares of the Company outstanding adjusted for the portion of the period for which they are outstanding. Unvested restricted stock awards are excluded from the calculation of weighted average common shares outstanding until they have vested.

Diluted net loss per common share adjusts basic net loss per common share for convertible securities, options, equity incentive awards, and other share-based payment awards which have yet to vest, to the extent such adjustments reduce basic net loss per common share.

The Company uses the if-converted method to calculate the dilutive effect of the Series B Preferred Stock and other convertible securities to the extent they are outstanding. The if-converted method assumes that convertible securities are converted at the later of the issuance date or the beginning of the period. If the hypothetical conversion of convertible securities, and the consequential avoidance of any deemed or accumulated preferred dividends, would decrease basic net loss per common share, these effects are incorporated in the calculation of diluted net loss per common share, adjusted for the proportion of the period the securities were outstanding.

The Company uses the treasury stock method to calculate the dilutive effect of outstanding options, restricted stock awards, and other share-based payments. The treasury stock method assumes that the proceeds from exercise are used to repurchase common shares at the weighted average market price during the period, increasing the denominator for the net effect of shares issued upon exercise less hypothetical shares repurchased.

If the dilutive effects noted above would cause diluted net loss per common share to exceed basic net loss per common share, such effects are not incorporated into the calculation, as they are deemed antidilutive. For all periods with a net loss available to common stockholders, any adjustment for potential common shares would be naturally anti-dilutive. Therefore, the weighted average shares outstanding used to calculate both basic and diluted net loss per common share are the same for periods with a net loss.

#### *Fair Value of Financial Instruments and Fair Value Measurements*

The respective carrying value of certain on-balance sheet financial instruments approximated their fair values due to the short-term nature and type of these instruments. These financial instruments include cash and cash equivalents, accounts receivable, notes receivable, and certain other financial assets and liabilities.

The Company measures certain non-financial assets at fair value on a non-recurring basis. These non-recurring valuations include evaluating assets such as long-lived assets, and non-amortizing intangible assets for impairment, allocating value to assets in an acquired asset group, and accounting for business combinations. The Company uses the fair value measurement framework to value these assets and reports these fair values in the periods in which they are recorded or written down.

Fair value financial instruments are recorded in accordance with the fair value measurement framework. The fair value measurement framework includes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair values in their broad levels. These levels from highest to lowest priority are as follows:

- Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities;
- Level 2: Quoted prices in active markets for similar assets or liabilities or observable prices that are based on inputs not quoted on active markets, but corroborated by market data.
- Level 3: Unobservable inputs or valuation techniques that are used when little or no market data is available.

The determination of fair value and the assessment of a measurement's placement within the hierarchy require judgment. Level 3 valuations often involve a higher degree of judgment and complexity. Level 3 valuations may require the use of various valuation methodologies which incorporate unobservable inputs, management estimates, and assumptions. Management's assumptions could vary depending on the asset or liability valued and the valuation method used. Such assumptions could include: estimates of prices, earnings, costs, actions of market participants, market factors, or the weighting of various valuation methods. The Company may also engage external advisors to assist it in determining fair value, as appropriate.

Although the Company believes that the recorded fair value of its financial instruments is appropriate, these fair values may not be indicative of net realizable value or reflective of future fair values.

#### *Government Assistance*

The Company receives benefits from various government entities for various purposes from time to time. With respect to any benefits that are not dependent on income (which are subject to the policy described under *Income Taxes*, above), the Company recognizes such benefits at the point in time in which all barriers to receive the assistance have been overcome in an amount equal to the expected benefit. Benefits are reflected in the consolidated statements of operations in the line item to which the associated benefit relates.

#### *Recently Adopted Accounting Pronouncements*

In November 2021, the Financial Accounting Standards Board (“**FASB**”) issued Accounting Standards Update (“**ASU**”) 2021-10, “*Government Assistance (Topic 832)*”, which provides disclosure requirements regarding government grants and contributions. The ASU requires disclosure of the nature of transactions and related accounting policies used to account for transactions, the effect, including amounts, of government assistance on individual line items on the financial statements, and significant terms and conditions of the transactions, including commitments and contingencies. This ASU is effective for fiscal years beginning after December 15, 2021. The Company adopted the provisions of this ASU effective January 1, 2022. There was no impact upon adoption. Refer to Note 20, *Government Assistance*, for the disclosures required by this ASU.

#### *Recently Issued Accounting Pronouncements Not Yet Adopted*

In March 2020, the FASB issued ASU 2020-04, “*Reference Rate Reform (Topic 848)*”, which provides temporary, optional expedients and exceptions to accounting guidance for certain contract modifications and hedging arrangements to ease financial reporting burdens as a result of market transitions from the London Interbank Offered Rate (“**LIBOR**”) to alternative reference rates. The guidance is available for prospective application and can generally be applied to contract modifications and hedging relationships entered into beginning March 12, 2020 through December 31, 2022. In December 2022, following the issuance of ASU 2022-06, “*Reference Rate Reform (Topic 848) — Deferral of the Sunset Date of Topic 848*”, the end date was extended to December 31, 2024.

As of December 31, 2022, the Company has long-term debt outstanding which carries an interest rate tied to LIBOR, the agreement for which contemplates an interest rate alternative in the event that LIBOR is unavailable. The LIBOR tenor which underlies the Company’s term loan is expected to sunset effective June 30, 2023.

The Company is evaluating the possibility of adoption and the related impact on its financial statements. If adopted, the Company does not expect the provisions of this ASU to have a material impact on its consolidated financial statements.

All other ASUs issued and not yet effective as of December 31, 2022, and through the date of this report, were assessed and determined to be either not applicable or are expected to have minimal impact on the Company’s current or future financial position or results of operations.

### **3. Accounts Receivable, Net**

Accounts receivable, net, consists of the following (in thousands):

	December 31,	
	2022	2021
Accounts receivable, gross	\$ 46,867	\$ 41,540
Allowance for doubtful accounts	(3,783)	(1,187)
Accounts receivable, net	<u>\$ 43,084</u>	<u>\$ 40,353</u>

Activity related to the Company’s allowance for doubtful accounts during the year ended December 31, 2022 was as follows (in thousands):

	Allowance for Doubtful Accounts	
Balance at December 31, 2021	\$	1,187
Bad debt expense		2,820
Write-offs		(224)
Balance at December 31, 2022	<u>\$</u>	<u>3,783</u>

Bad debt expense and write-offs were not material for the year ended December 31, 2021.

#### 4. Inventory

Inventory consists of the following (in thousands):

	December 31,	
	2022	2021
Raw materials	\$ 810	\$ 364
Work in process	6,855	6,112
Finished goods	5,518	4,913
Inventory	<u>\$ 13,183</u>	<u>\$ 11,389</u>

As a result of the conclusion of the FDA's period of enforcement discretion on May 31, 2021, the Company wrote down \$1.0 million of its Section 351 product inventory and \$0.7 million related to discontinued product during the year ended December 31, 2021. There were no significant, unusual write-downs of inventory during the year ended December 31, 2022.

Consignment inventory, included as a component of finished goods in the table above, was \$3.4 million and \$2.6 million as of December 31, 2022 and 2021, respectively.

#### 5. Property and Equipment, Net

Property and equipment, net, consists of the following (in thousands):

	December 31,	
	2022	2021
Lab and clean room equipment	\$ 16,422	\$ 16,567
Furniture and office equipment	15,016	14,975
Leasehold improvements	9,190	9,052
Construction in progress	1,983	397
Asset retirement cost	983	863
Finance lease assets	189	189
Property and equipment, gross	43,783	42,043
Less: accumulated depreciation and amortization	(35,927)	(32,878)
Property and equipment, net of accumulated depreciation and amortization	<u>\$ 7,856</u>	<u>\$ 9,165</u>

Depreciation expense for each of the years ended December 31, 2022, 2021, and 2020 was recorded in certain captions of the consolidated statements of operations for those periods in the amounts shown in the table below (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Cost of sales	\$ 1,816	\$ 1,787	\$ 2,022
Selling, general, and administrative expense	1,243	2,278	3,416
Research and development expense	286	298	344
Total	<u>\$ 3,345</u>	<u>\$ 4,363</u>	<u>\$ 5,782</u>

## 6. Leases

The Company has leases for corporate offices, manufacturing facilities, vehicles, and certain equipment. Such leases do not require any contingent rental payments, impose any financial restrictions, or contain any residual value guarantees.

Supplemental balance sheet information related to the Company's leases, including the financial statement caption in which the amounts are presented, is as follows (amounts in thousands, except lease term and discount rate):

	Operating Leases		Finance Leases	
	December 31,		December 31,	
	2022	2021	2022	2021
<b>Assets</b>				
Right of use asset	\$ 3,400	\$ 4,696	\$ —	\$ —
Property and equipment, net	—	—	98	145
<b>Total assets</b>	<b>\$ 3,400</b>	<b>\$ 4,696</b>	<b>\$ 98</b>	<b>\$ 145</b>
<b>Liabilities</b>				
Other current liabilities	\$ 1,391	\$ 1,203	\$ 49	\$ 45
Other liabilities	2,381	3,812	57	106
<b>Total liabilities</b>	<b>\$ 3,772</b>	<b>\$ 5,015</b>	<b>\$ 106</b>	<b>\$ 151</b>
Weighted-average remaining lease term (years)	2.8	4.0	2.1	3.1
Weighted-average discount rate	8.3 %	8.4 %	8.3 %	8.3 %

Information related to lease costs are as follows (amounts in thousands):

	Year Ended December 31,		
	2022	2021	2020
Operating lease cost	\$ 1,620	\$ 1,327	\$ 1,392
Amortization of finance lease ROU assets	47	43	—
Interest expense on finance lease liabilities	10	13	—

Maturities of lease liabilities are as follows (amounts in thousands):

Year Ending December 31,	Operating Leases	Finance Leases	Total
2023	\$ 1,638	\$ 55	\$ 1,693
2024	1,618	55	1,673
2025	506	5	511
2026	419	—	419
2027	35	—	35
Thereafter	—	—	—
<b>Total lease payments</b>	<b>4,216</b>	<b>115</b>	<b>4,331</b>
Less: imputed interest	(444)	(9)	(453)
<b>Lease liability</b>	<b>\$ 3,772</b>	<b>\$ 106</b>	<b>\$ 3,878</b>

### Asset Retirement Obligations

Certain lease agreements require the Company to return designated areas of leased space to its original condition upon termination of the lease agreement, for which the Company records an asset retirement obligation and a corresponding capital asset in an amount equal to the estimated fair value of the obligation. In subsequent periods, the asset retirement obligation is accreted for the change in its present value and the capitalized asset is depreciated, both over the term of the associated lease

agreement. Asset retirement obligations of \$1.2 million and \$1.0 million are included in other liabilities in the consolidated balance sheets as of December 31, 2022 and 2021, respectively.

#### *Sublease*

The Company subleases one of its leased industrial warehouse spaces. The sublease income from the facility offsets the lease expense associated with the facility. Sublease income for the facility was \$0.1 million for each of the years ended December 31, 2022, 2021, and 2020, respectively, and is presented as a reduction to selling, general, and administrative expense on the consolidated statements of operations in those periods.

### **7. Goodwill and Intangible Assets, Net**

#### *Goodwill*

Historically, the Company had concluded that it operated as a single operating segment and single reporting unit. For the year ended December 31, 2022, as a result of changes in the management of the Company's business, management concluded that the Company operates as three operating segments, including two distinct reportable segments: Wound & Surgical and Regenerative Medicine. See Note 13, *Segment Information*, for a description of the Company's operating segments. Management further concluded that these two reportable segments reflected its reporting units for goodwill impairment testing purposes.

The Company allocated \$20.0 million of consolidated goodwill, which was entirely allocated to its previous reporting unit, to each of its Wound & Surgical and Regenerative Medicine segments based on their relative fair values from a market participant standpoint. The result was \$19.4 million and \$0.5 million allocated to Wound & Surgical and Regenerative Medicine, respectively. A third reporting unit associated with the Company's third operating segment was deemed immaterial and no goodwill was assigned to it.

The Company performed goodwill impairment tests using the Company's single reporting unit and the new reporting units on September 30, 2022. In all cases, the Company concluded that the estimated fair values of each reporting unit exceeded its respective carrying values. Therefore, the Company did not record impairment for goodwill on September 30, 2022.

For the annual impairment test performed October 1, 2022, the Company performed a quantitative assessment to determine the existence of impairment. The quantitative assessment concluded that it was more likely than not that goodwill was not impaired. No impairment was recorded for the year ended December 31, 2022.

For the annual impairment test performed on October 1, 2021, the Company performed a qualitative assessment to determine the existence of impairment. The qualitative assessment concluded that it was more likely than not that goodwill was not impaired. The Company did not proceed to the quantitative assessment, and no impairment was recorded for the year ended December 31, 2021.

The following table indicates the changes in the carrying amount of goodwill for 2022 and 2021 (in thousands):

	Previous Reporting Unit	Wound & Surgical	Regenerative Medicine	Total Company
Balance as of January 1, 2021	\$ 19,976	\$ —	\$ —	\$ 19,976
Activity	—	—	—	—
Balance as of December 31, 2021	\$ 19,976	\$ —	\$ —	\$ 19,976
Reallocation	(19,976)	19,441	535	—
Balance as of December 31, 2022	\$ —	\$ 19,441	\$ 535	\$ 19,976

*Intangible Assets, Net*

Intangible assets, net, are summarized as follows (in thousands):

	December 31, 2022			December 31, 2021		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
<b>Amortized intangible assets</b>						
Patents and know-how	\$ 9,923	\$ (7,106)	\$ 2,817	\$ 9,578	\$ (6,408)	\$ 3,170
Licenses	1,000	(4)	996	—	—	—
<b>Total amortized intangible assets</b>	<b>\$ 10,923</b>	<b>\$ (7,110)</b>	<b>\$ 3,813</b>	<b>\$ 9,578</b>	<b>\$ (6,408)</b>	<b>\$ 3,170</b>
<b>Unamortized intangible assets</b>						
Tradenames and trademarks	\$ 1,008		\$ 1,008	\$ 1,008		\$ 1,008
Patents in process	1,031		1,031	1,205		1,205
<b>Total intangible assets</b>	<b>\$ 12,962</b>		<b>\$ 5,852</b>	<b>\$ 11,791</b>		<b>\$ 5,383</b>

Amortization expense and impairment expense for the years ended December 31, 2022, 2021, and 2020, is summarized in the table below (amounts in thousands):

	Year ended December 31,		
	2022	2021	2020
Amortization of intangible assets	\$ 701	\$ 820	\$ 1,073
Impairment of intangible assets	—	53	1,027

Impairment of intangible assets in 2021 related to supplier relationship assets that were determined to be unrecoverable due to attrition. Impairment of intangible assets in 2020 related to customer relationship assets that were determined to be unrecoverable due to lower than expected margins.

Expected future amortization of intangible assets as of December 31, 2022, is as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2023	\$ 756
2024	756
2025	361
2026	207
2027	206
Thereafter	1,527
<b>Total amortization expense</b>	<b>\$ 3,813</b>

## 8. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31,	
	2022	2021
Legal costs	\$ 4,447	\$ 2,806
External commissions	2,941	2,630
Accrued rebates	707	1,343
Estimated returns	659	788
Accrued GPO Fees	638	559
Accrued travel	566	385
Accrued clinical trials	90	694
Other	976	607
Total	\$ 11,024	\$ 9,812

## 9. Long Term Debt

### *Hayfin Loan Agreement*

On June 30, 2020, the Company entered into a Loan Agreement with, among others, Hayfin Services, LLP, (“**Hayfin**”) an affiliate of Hayfin Capital Management LLP (the “**Hayfin Loan Agreement**”), which was funded on July 2, 2020 and provided the Company with a senior secured term loan in an aggregate amount of \$50.0 million (the “**Term Loan**”). The Term Loan matures on June 30, 2025 (the “**Maturity Date**”). Interest is payable quarterly on the Term Loan for the principal balance outstanding through the Maturity Date. No principal payments are due and payable until the Maturity Date.

The Hayfin Loan Agreement also provided the Company with an option to draw on an additional delayed draw term loan (the “**DD TL**”, collectively with the Term Loan, the “**Credit Facilities**”) in the form of a committed but undrawn \$25.0 million facility until June 30, 2021. The Company did not exercise the option.

On February 28, 2022, the Company executed an Amendment to the Hayfin Loan Agreement (as amended, the “**Amended Hayfin Loan Agreement**”). The amendment was accounted for as a modification. No gain or loss was recognized nor was there a change to the carrying amount of the debt as a result of the amendment.

Interest on any borrowings under the Amended Hayfin Loan Agreement is equal to the London Interbank Offered Rate (“**LIBOR**”) (subject to a floor of 1.5%) plus a margin of 6.75% per annum. If LIBOR is unavailable, the Term Loan will carry interest at the 6.75% margin plus the greatest of the Prime Rate, the Federal Funds Rate plus 0.5% per annum, and 2.5%.

An additional 3.0% margin is applied to the interest rate in the event of default as defined by the Amended Hayfin Loan Agreement. The Term Loan carried an interest rate of 8.3% at issuance and 11.5% as of December 31, 2022.

The Amended Hayfin Loan Agreement contains financial covenants requiring the Company, on a consolidated basis, to maintain the following:

- Minimum Consolidated Total Net Sales (as defined in the Amended Hayfin Loan Agreement) of varying amounts, required to be calculated on a quarterly basis, and
- Minimum Liquidity (as defined in the Amended Hayfin Loan Agreement) of \$20 million, an at-all-times financial covenant tested monthly.

As of December 31, 2022, the Company is in compliance with all applicable financial covenants under the Amended Hayfin Loan Agreement.

The Amended Hayfin Loan Agreement also includes certain negative covenants and events of default customary for facilities of this type, and upon the occurrence of such events of default, subject to customary cure rights, the Term Loan may be accelerated or the lenders' commitments terminated. Mandatory prepayments are also required in the event of a change in control, incurring other indebtedness, certain proceeds from disposal of assets and insured casualty event (as defined in the Amended Hayfin Loan Agreement). Annually, beginning with the fiscal year ended December 31, 2021, the Company is required to prepay the outstanding loans based on a percentage of Excess Cash Flow (as defined in the Amended Hayfin Loan Agreement), if such is generated. No such prepayments have been required as of December 31, 2022.

The Amended Hayfin Loan Agreement, as amended, also specifies that any prepayment of the loan, voluntary or mandatory, will subject the Company to a prepayment premium applicable as of the date of the prepayment:

- On or before July 2, 2023: 2% of the principal balance repaid.
- After July 2, 2023, but on or before July 2, 2024: 1% of the principal balance repaid.
- After July 2, 2024: no premium.

Hayfin maintains a first-priority security interest in substantially all of the Company's assets.

A breach of a financial covenant in the Amended Hayfin Loan Agreement, if uncured or unable to be cured, would likely result in an event of default that could trigger the lender's remedies, including acceleration of the entire principal balance of the loan as well as any applicable prepayment premiums. Future compliance with the financial covenants, as amended, requires continuing growth in net sales consistent with the Company's business strategy and plans. The Company is subject to inherent uncertainties that could impact the Company's net sales growth, including, but not limited to, the regulatory pathway of the Company's EPICORD® and AMNIOCARD®. If the FDA were to determine that these products do not meet the requirements for regulation solely under Section 361, the Company would be required to obtain the appropriate FDA clearance or approval to continue marketing these products. The loss of the Company's ability to market and sell its umbilical cord-derived products would have an adverse effect on the Company's revenue, business, financial condition, and results of operations, including its ability to comply with the financial covenants set forth pursuant to the Amended Hayfin Loan Agreement. Refer to Note 12, *Revenue*, for net sales derived from the Company's cord products.

Original issue discount and deferred financing costs were allocated between the sale of the Series B Preferred Stock (which occurred simultaneously with the funding of the Hayfin Loan Agreement, collectively the "*Financing Transactions*") and the Term Loan on the basis of the relative fair values of the transactions. The costs allocated to the Hayfin Loan Agreement were further allocated between the Term Loan and the DD TL on the basis of the maximum potential principal outstanding between the Credit Facilities. The allocation of the deferred financing costs and original issue discount between Term Loan and the DD TL on July 2, 2020 was as follows (amounts in thousands):

	July 2, 2020		
	Term Loan	DD TL	Total
Original issue discount	\$ 333	\$ 167	\$ 500
Deferred financing costs	2,169	1,084	3,253

Deferred financing costs and original issue discount allocated to the Term Loan are amortized using the effective interest method through the Maturity Date. The amortization of such amounts is presented as part of interest expense, net on the consolidated statement of operations for the years ended December 31, 2022, 2021, and 2020.

Deferred financing costs and original issue discount associated with the DD TL were amortized using the straight-line method through the expiration of the DD TL commitment term on June 30, 2021. Amortization of these amounts are presented as part of interest expense, net on the consolidated statements of operations for the years ended December 31, 2021 and 2020.

The balances of the Term Loan as of December 31, 2022 and 2021 were as follows (amounts in thousands):

	December 31,	
	2022	2021
Outstanding principal	\$ 50,000	\$ 50,000
Deferred financing costs	(1,219)	(1,624)
Original issue discount	(187)	(249)
Long term debt, net	<u>\$ 48,594</u>	<u>\$ 48,127</u>

Interest expense related to the Term Loan, included in interest expense, net in the consolidated statements of operations, was as follows (amounts in thousands):

	Year Ended December 31,		
	2022	2021	2020
Stated interest	\$ 4,559	\$ 4,182	\$ 2,085
Amortization of deferred financing costs	405	372	173
Accretion of original issue discount	62	58	26
Interest expense	<u>\$ 5,026</u>	<u>\$ 4,612</u>	<u>\$ 2,284</u>

Interest expense related to the DD TL, included in interest expense, net in the consolidated statements of operations, was as follows (amounts in thousands):

	Year Ended December 31,		
	2022	2021	2020
Commitment fee	\$ —	\$ 126	\$ 128
Amortization of deferred financing costs	—	542	542
Accretion of original issue discount	—	83	83
Interest expense	<u>\$ —</u>	<u>\$ 751</u>	<u>\$ 753</u>

Scheduled principal payments on the Term Loan as of December 31, 2022 are as follows:

Year ending December 31,	Principal
2023	\$ —
2024	—
2025	50,000
2026	—
2027	—
Thereafter	—
Outstanding principal	<u>\$ 50,000</u>

As of December 31, 2022, the fair value of the Term Loan was \$46.7 million. This valuation was calculated based on a series of Level 2 and Level 3 inputs, including a discount rate based on the credit risk spread of debt instruments of similar risk character in reference to U.S. Treasury instruments with similar maturities, with an incremental risk premium for risk factors specific to the Company. The remaining cash flows associated with the Term Loan were discounted to December 31, 2022 using this discount rate to derive the fair value.

*BT Term Loan*

On June 10, 2019, the Company entered into a loan agreement (the “**BT Loan Agreement**”) with Blue Torch Finance LLC (“**Blue Torch**”), as administrative agent and collateral agent, to borrow funds with a face value of \$75.0 million (the “**BT Term Loan**”), of which the full amount was borrowed and funded. The proceeds from the BT Term Loan were used (i) for working capital and general corporate purposes and (ii) to pay transaction fees, costs and expenses incurred in connection with the BT Term Loan and the related transactions. The BT Term Loan would have matured on June 20, 2022 and was repayable in quarterly installments of \$0.9 million, with the balance due on June 20, 2022. Blue Torch maintained a first-priority security interest in substantially all the Company’s assets. The BT Term Loan was issued net of the original issue discount of \$2.3 million. The Company incurred \$6.7 million of deferred financing costs.

On April 22, 2020, the Company amended the BT Loan Agreement with Blue Torch. The amendment provided for an increase in the maximum Total Leverage Ratio, which was a quarterly test, for the remainder of 2020, and also provided for a reduction in the minimum Liquidity requirement from April 2020 through November 2020. In connection with the amendment, the Company agreed to pay a one-time fee of approximately \$0.7 million, added to the principal balance, and a 1 percentage point increase in the interest rate to LIBOR plus 9%.

On July 2, 2020, a portion of the proceeds from the Financing Transactions was used to repay the outstanding balance of principal, accrued but unpaid interest, and prepayment premium under the BT Loan Agreement. In connection with the repayment of the BT Term Loan, the Company terminated the BT Loan Agreement. The Company has no continuing obligations related to the BT Term Loan as of December 31, 2021.

The Company recorded a loss on extinguishment of debt of \$8.2 million during the year ended December 31, 2020. The composition of the loss on extinguishment of debt was as follows (amounts in thousands):

	July 2, 2020	
Unamortized deferred financing costs	\$	4,528
Unamortized original issue discount		1,538
Unamortized amendment fee		671
Prepayment premium		1,439
Other fees		25
Loss on extinguishment of debt	\$	<u>8,201</u>

Interest expense related to the BT Term Loan, included in interest expense, net in the consolidated statements of operations was as follows (amounts in thousands):

	Year ended December 31, 2020	
Interest on principal balance	\$	3,773
Accretion of original issue discount		354
Accretion of amendment fee		53
Amortization of deferred financing costs		1,051
Total BT Term Loan interest expense	\$	<u>5,231</u>

#### *Paycheck Protection Program Loan*

The Company applied for and, on April 24, 2020, received proceeds of \$10.0 million in the form of a loan under the Paycheck Protection Program (the “**PPP Loan**”). On May 11, 2020, the Company repaid the PPP Loan in full. There are no continuing obligations under the PPP Loan as of December 31, 2022.

#### **10. Basic and Diluted Net Loss Per Common Share**

Net loss per common share is calculated using two methods: basic and diluted.

##### *Basic Net Loss Per Common Share*

The following table provides a reconciliation of net loss to net loss available to common shareholders and calculation of basic net loss per common share for each of the years ended December 31, 2022, 2021, and 2020 (amounts in thousands, except share and per-share amounts):

	Year ended December 31,		
	2022	2021	2020
Net loss	\$ (30,197)	\$ (10,285)	\$ (49,284)
Adjustments to reconcile to net loss available to common stockholders:			
Accumulated dividend on Series B Preferred Stock	6,580	5,210	2,016
Amortization of beneficial conversion feature	—	—	31,110
Accretion of increasing-rate dividend feature	—	926	918
Total adjustments	6,580	6,136	34,044
Net loss available to common stockholders	\$ (36,777)	\$ (16,421)	\$ (83,328)
Weighted average common shares outstanding	112,909,266	110,353,406	108,257,112
Basic net loss per common share	\$ (0.33)	\$ (0.15)	\$ (0.77)

#### *Diluted Net Loss Per Common Share*

The following table sets forth the computation of diluted net loss per common share (in thousands, except share and per-share amounts):

	Year ended December 31,		
	2022	2021	2020
Net loss available to common stockholders	\$ (36,777)	\$ (16,421)	\$ (83,328)
Adjustments:			
Dividends on Series B Preferred Stock	6,580	6,136	34,044
Less: antidilutive adjustments	(6,580)	(6,136)	(34,044)
Total adjustments	—	—	—
Numerator	\$ (36,777)	\$ (16,421)	\$ (83,328)
Weighted average common shares outstanding	112,909,266	110,353,406	108,257,112
Adjustments:			
Potential common shares	28,705,593	29,801,836	15,687,044
Less: antidilutive potential common shares (a)	(28,705,593)	(29,801,836)	(15,687,044)
Total adjustments	—	—	—
Weighted average common shares outstanding adjusted for potential common shares	112,909,266	110,353,406	108,257,112
Diluted net loss per common share	\$ (0.33)	\$ (0.15)	\$ (0.77)

(a) Weighted average common shares outstanding for the calculation of diluted net loss per common share does not include the following adjustments for potential common shares below because their effects were determined to be anti-dilutive for the periods presented:

	Year ended December 31,		
	2022	2021	2020
Series B Preferred Stock	27,850,916	26,497,570	12,987,013
Restricted stock unit awards	546,883	1,393,910	616,141
Restricted stock awards	217,971	1,121,019	1,299,770
Outstanding stock options	65,720	771,409	752,499
Performance stock unit awards	5,251	17,928	31,621
Employee stock purchase plan	18,852	—	—
Potential common shares	28,705,593	29,801,836	15,687,044

## 11. Equity

### *Series B Convertible Preferred Stock*

The Series B Preferred Stock are convertible, cumulative securities which rank senior to the Company's Series A Junior Participating Preferred Stock and the Company's common stock. The Series B Preferred Stock accumulated dividends at a rate of 4.0% per annum through June 30, 2021, and 6.0% per annum thereafter. Dividends are declared at the sole discretion of the Board. Dividends are paid at the end of each quarter based on the dividend amounts that accumulate beginning of the last payment date through the day prior to the end of each quarter. In lieu of paying a dividend, the Company may elect to accrue the dividend owed to the holders of the Series B Preferred Stock. Accrued dividend balances accumulate dividends at the prevailing dividend rate for each dividend period for which they are outstanding.

Each share of Series B Preferred Stock is convertible into Company's common stock at any time at the option of the Holder. Shares are converted based on the liquidation preference of \$1,000 per share (the "**Liquidation Preference**") plus any accrued or accumulated dividends through the date of the conversion at a conversion price of \$3.85 per common share. The Series B Preferred Stock, including any accumulated and unpaid dividends, automatically converts into common stock at any time after July 2, 2023, provided that the common stock has traded at \$7.70 per common share or more (i) for 20 out of 30 consecutive trading days and (ii) on such date of conversion.

The holders of the Series B Preferred Stock, voting as a class, are entitled to appoint two members to the board of directors. The holders of the Series B Preferred Stock are entitled to vote on all matters to be voted on by the Company's shareholders on an as-converted basis as a single class with the common stock; provided that the votes represented by a single holder of Series B Preferred Stock cannot exceed 19.9% of the total voting stock of the Company and no share of Series B Preferred Stock held can entitle the holder to a number of votes that exceeds the quotient of the Liquidation Preference divided by \$5.25 per share.

Holders of the Series B Preferred Stock are also entitled to the Liquidation Preference and all accumulated and unpaid dividends in the event of a liquidation, dissolution, or winding-up of the Company.

If the Company undergoes a change of control (as defined), the Company will have the option to repurchase some or all of the then-outstanding shares of Series B Preferred Stock for cash in an amount equal to the Liquidation Preference plus any accumulated and unpaid dividends, subject to the rights of the holders of the Series B Preferred Stock in connection with such change in control. If the Company does not exercise such repurchase right, holders of the Series B Preferred Stock will have the option to (1) require the Company to repurchase any or all of their then-outstanding shares of Series B Preferred Stock for cash in an amount equal to the Liquidation Preference plus accumulated and unpaid dividends or (2) convert the Series B Preferred Stock into common stock and receive their pro rata consideration thereunder. Since the contingent redemption of the Series B Preferred Stock by the holders in the event of a change in control is outside the Company's control, the Series B Preferred Stock is classified as temporary equity.

At the time of the issuance of the Series B Preferred Stock, the Company's common stock, into which the Company's Series B Preferred Stock is convertible, had an estimated fair value exceeding the effective conversion price of the Series B Preferred Stock, giving rise to a beneficial conversion feature in the amount of \$31.1 million. This amount was immediately recognized as a deemed dividend on the commitment date since there is no stated redemption date and the Series B Preferred Stock is immediately convertible.

The Series B Preferred Stock instrument contains an increasing-rate cumulative dividend feature. The Company determined the present value of the difference between the (1) dividends that will be payable in the period preceding commencement of the perpetual dividend and (2) the perpetual dividend amount for a corresponding number of periods in order to ascribe a fair value to this feature. These amounts were discounted to present value using a market rate for dividend yield as of the date on which the Series B Preferred Stock was issued. The Company calculated the amount of the increasing-rate dividend feature as \$1.8 million. This amount was amortized as a deemed dividend to preferred shareholders using the effective interest method through June 30, 2021. During each of the years ended December 31, 2021 and 2020, the Company recognized \$0.9 million of deemed dividends related to the amortization of the increasing-rate dividend feature.

The below table illustrates changes in the Company's balance of the Series B Preferred Stock for the years ended December 31, 2022, 2021, and 2020 (in thousands, except per share amounts):

	Series B Preferred Stock	
	Shares	Amount
Balance at December 31, 2019	—	\$ —
Issuance of Series B Preferred Stock	100,000	59,540
Deemed dividends	—	32,028
Balance at December 31, 2020	100,000	\$ 91,568
Deemed dividends	—	926
Balance at December 31, 2021	100,000	\$ 92,494
Activity	—	—
Balance at December 31, 2022	100,000	\$ 92,494

The Company has not declared or paid any dividends on the Series B Preferred Stock since issuance. Dividends in arrears as of December 31, 2022 were \$13.8 million. As this amount has not been declared, the Company has not recorded this amount on its consolidated balance sheet as of December 31, 2022.

As of December 31, 2022, based on accumulated dividends as of that date, the Series B Preferred Stock was convertible into an aggregate of 29,559,946 shares of the Company's common stock.

#### Stock Incentive Plans

The Company has two share-based compensation plans which provide for the granting of equity awards, including qualified incentive and non-qualified stock options and restricted stock awards: the MiMedx Group, Inc. 2016 Equity and Cash Incentive Plan Amended and Restated through October 2, 2020 (the "**2016 Plan**"), which was approved by shareholders on May 18, 2016, and the MiMedx Group, Inc. Assumed 2006 Stock Incentive Plan (the "**Prior Incentive Plan**"). During the years ended December 31, 2022, 2021, and 2020 the Company used only the 2016 Plan to make grants.

The 2016 Plan permits the grant of equity awards to the Company's employees, directors, consultants and advisors for up to 8,400,000 shares of the Company's common stock plus (i) the number of shares of the Company's common stock that remain available for issuance under the Prior Incentive Plan, and (ii) the number of shares that are represented by outstanding awards that later become available because of the expiration or forfeiture of the award without the issuance of the underlying shares. Awards granted under the 2016 Plan are subject to a vesting schedule as set forth in each individual agreement.

#### Stock Options

A summary of stock option activity for the year ended December 31, 2022 is presented below:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2022	1,444,845	\$ 5.18		
Granted	—	—		
Exercised	(312,001)	2.09		
Unvested options forfeited	—	—		
Vested options expired	(198,950)	4.02		
Outstanding at December 31, 2022	933,894	6.46	0.87	—
Exercisable at December 31, 2022	933,894	\$ 6.46	0.87	\$ —

The intrinsic values of the options exercised during the years ended December 31, 2022, 2021 and 2020 were \$0.6 million, \$3.3 million, and \$1.9 million, respectively. Cash received from option exercise under all share-based payment arrangements for the years ended December 31, 2022, 2021 and 2020 was \$0.7 million, \$1.4 million, and \$0.4 million, respectively. The actual tax

benefit for the tax deductions from option exercise of the share-based payment arrangements totaled \$0.2 million, \$2.0 million, and \$1.6 million, respectively, for the years ended December 31, 2022, 2021 and 2020. The Company has a policy of using its available repurchased treasury stock to satisfy option exercises prior to the issuance of new shares of common stock.

No options vested during the years ended December 31, 2022, 2021 and 2020. There was no unrecognized compensation expense at December 31, 2022.

During 2021 and 2020, certain stock option holders elected to return restricted shares to the Company as consideration to exercise stock options. In total, 41,810 and 148,972 shares were returned to the Company during the year ended December 31, 2021 and 2020, respectively, for an aggregate fair value of \$0.4 million and \$0.9 million, respectively. There were no similar transactions for the year ended December 31, 2022.

#### Equity Incentive Awards

The Company has issued several classes of stock awards to employees: restricted stock (“*RSAs*”), restricted stock unit awards (“*RSUs*”), and performance stock unit awards (“*PSUs*”, collectively the “*Equity Incentive Awards*”). The following is summary information for such awards for the year ended December 31, 2022.

Restricted stock and RSUs generally vest over a one- to three-year period in equal annual increments and require the recipient to provide continuous service through each vesting date. PSUs vest based on the achievement of specific performance targets subject to agreements with employees and also require the recipient to provide continuous service through a specified date or event.

As of December 31, 2022, there was \$19.8 million of total unrecognized stock-based compensation related to unvested Equity Incentive Awards. That expense is expected to be recognized over a weighted-average period of 1.72 years, which approximates the remaining vesting period of these grants. RSAs are considered common shares issued and outstanding upon grant, while shares underlying the RSUs and PSUs are considered issued and outstanding only upon vesting. Therefore, all RSAs noted below as unvested are considered issued and outstanding as of December 31, 2022, while unvested RSUs and PSUs are not considered issued and outstanding as of December 31, 2022. RSAs, RSUs, and PSUs are not reflected in weighted average common shares outstanding for purposes of calculated basic net loss per common share.

A summary of Equity Incentive Award activity, by class of award, for the year ended December 31, 2022 is presented below:

	RSA		RSU		PSU	
	Number of Shares	Weighted-Average Grant Date Fair Value	Number of Shares	Weighted-Average Grant Date Fair Value	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested at January 1, 2022	877,197	\$ 4.26	4,228,919	\$ 8.64	—	\$ —
Granted	—	—	4,232,390	4.80	441,965	4.62
Vested	(749,104)	3.95	(1,724,530)	8.33	—	—
Forfeited	(5,338)	5.11	(1,961,808)	6.37	(200,893)	4.62
Unvested at December 31, 2022	<u>122,755</u>	<u>\$ 6.13</u>	<u>4,774,971</u>	<u>\$ 6.28</u>	<u>241,072</u>	<u>\$ 4.62</u>

The total fair value of equity incentive awards vested during the years ended December 31, 2022, 2021 and 2020, was \$10.9 million, \$20.1 million, and \$10.1 million, respectively.

For the years ended December 31, 2022, 2021, and 2020 the Company recognized share-based compensation as follows (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Cost of sales	\$ 1,213	\$ 813	\$ 520
Selling, general and administrative expenses	9,578	13,108	14,549
Research and development expense	1,875	836	288
Total share-based compensation	12,666	14,757	15,357
Income tax benefit, before consideration of valuation allowance	(3,132)	(3,649)	(3,792)
Total share-based compensation, net of tax benefit	\$ 9,533	\$ 11,108	\$ 11,565

#### Performance Stock Units

The Company granted 441,965 PSUs to certain executive officers during the year ended December 31, 2022. These PSUs vest based on and to the extent that stipulated cumulative net sales targets are achieved. Of the granted PSUs:

- 25% can vest based on net sales achieved for the year ended December 31, 2022,
- 25% can vest based on net sales achieved for the two-year period ending December 31, 2023, and
- the remaining award can vest based on net sales achieved for the three-year period ending December 31, 2024.

Achievement of the performance targets allow for vesting of 50% to 150% of the PSUs granted. If performance is below 50%, the PSUs do not vest. To the extent that the vesting percentage in a subsequent period exceeds the vesting percentage achieved in a previous period, a recipient is eligible to receive the amount of shares from the previous period based on the vesting percentage in the subsequent period. If total shareholder return (“*TSR*”), as defined below, is negative, vesting is limited to 100% of the award for all periods, regardless of actual achievement against the stipulated net sales targets.

All of the PSUs require recipients to continue employment with the Company through the vesting date, which will occur upon approval of the results with respect to the established targets by the Compensation Committee of the Board of Directors after December 31, 2024, but no later than March 15, 2025.

The *TSR* is calculated as the average trading price of the Company’s common stock during the final 30 trading days of 2024, adjusted for dividends paid on the Company’s common stock, less the average trading price during the final 30 trading days of 2021. Since *TSR* is based on the Company’s share price, it represents a market condition, which is incorporated in the grant date fair value of the shares in excess of 100% vesting. These awards are not reflected in the table above.

The fair value of these awards on the date of grant was estimated using a Monte Carlo simulation, the inputs for which were informed by a Black-Scholes option pricing model. The assumptions used in determining the fair value of these PSUs were as follows:

	Assumption	
Risk-free interest rate		2.68 %
Expected term (years)		2.74
Expected volatility (annualized)		63.7 %
Dividend yield		— %
Closing stock price on grant date	\$	4.62
Grant date fair value	\$	2.78

The expected term was derived from the date of the grant through the latest date of the resolution of the market condition. The risk-free interest rate was derived based on the U.S. Treasury Yield curve in effect at the date of grant for maturities of similar periods to the concluded term. The expected volatility was based on the Company’s historical daily stock price movements for a term similar in length to the expected term. The dividend yield was based on the Company’s history of dividends on its common stock.

Expense related to PSUs is recognized, straight-line, based on the grant date fair value of the relevant shares, over the requisite service period related to each individual tranche, limited to the extent that the achievement of the associated performance condition associated with that tranche is probable. These expectations are derived from the Company's actual results, latest budget, and forecasts for net sales in the associated periods. Subsequent adjustments to the expectation for vesting are reflected as a cumulative adjustment to expense. The fair value of the portion of the award subject to a market condition and expense recognized on such awards are not subsequently reconsidered based on the probability of or actual achievement of the market condition. Accordingly, the Company may recognize share-based compensation expense for awards that do not ultimately vest.

#### Employee Stock Purchase Plan

On June 7, 2022, the Company adopted the Employee Stock Purchase Plan of MiMedx Group, Inc. (the "**ESPP**"). The ESPP is intended to qualify as an "employee stock purchase plan" under Section 423 of the Internal Revenue Code. All regular full-time employees of the Company (including officers) and all other employees who meet the eligibility requirements of the plan may participate in the ESPP. The ESPP provides eligible employees an opportunity to acquire the Company's common stock on a semi-annual basis at a purchase price of 85% of the lower of the closing price per share of the Company's common stock on the first day and the last day of each six-month purchase period (the "**Purchase Period**"). The aggregate number of shares which may be issued and sold under the ESPP is 3 million shares of common stock. The first Purchase Period under the ESPP commenced on August 1, 2022 and resulted in a purchase of shares on January 31, 2023.

For the year ended December 31, 2022, the Company recorded \$0.2 million in stock-based compensation related to the ESPP. As of December 31, 2022, the Company had cumulative payroll deferrals under the ESPP for future share purchases of \$0.6 million. This amount is included in accrued compensation in the consolidated balance sheet. No shares have been issued under the plan to date.

Unrecognized stock compensation for the period is less than \$0.1 million to be recognized over a weighted average period of 0.08 years.

#### 2020 RSU Modification

During the year ended December 31, 2019, the Company granted a fixed-dollar value RSU award to the members of its Board in the amount of \$1.6 million. The RSU awards vested at the date of the 2019 Annual Meeting and were settled in common stock with the number of shares of common stock based on the closing price of the Company's share price on August 5, 2020, a date thirty days after the Company became current on its SEC filings. Upon this event, these awards were modified from a fixed dollar-amount of awards to be settled in a variable number of shares to a fixed number of shares based on the closing price of the Company's common stock on August 5, 2020. This event constituted a modification of the awards from liability-based awards to equity-based awards. This event did not change the total amount of expense recognized. Prior to August 5, 2020, the Company recorded \$1.3 million of expense, of which \$0.9 million was recognized during the year ended December 31, 2020. The Company reclassified \$1.3 million of recorded liability to additional paid-in capital to reflect this modification on August 5, 2020. Subsequent to the modification, \$0.3 million of expense was recognized as additional paid-in capital during the year ended December 31, 2020.

#### *Treasury Stock*

Repurchases of shares of Common Stock in connection with the satisfaction of employee tax withholding obligations upon vesting of restricted stock and exercise of stock options for the years ended December 31, 2022, 2021, and 2020 were 249,442, 469,239, and 435,492, respectively, for an aggregate purchase price of \$1.2 million, \$4.8 million, and \$2.3 million, respectively.

## **12. Revenue**

#### *Net Sales by Product*

MIMEDX has two classes of products: (1) Advanced Wound Care, or Section 361, products, consisting of its tissue and cord sheet allograft products as well as certain particulate products regulated under Section 361, and (2) Section 351 products, consisting of the Company's micronized and certain other particulate products. Advanced Wound Care is further disaggregated between the Company's Tissue/Other and Cord products.

Information regarding the business units responsible for the sale of each of these classes of product can be found in Note 13, *Segment Information*.

Below is a summary of net sales by each class of product (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Advanced Wound Care			
Tissue/Other	\$ 241,992	\$ 216,418	\$ 192,566
Cord	23,211	23,599	16,073
Advanced Wound Care	265,203	240,017	208,639
Section 351	2,379	17,610	31,828
Other <sup>(1)</sup>	259	988	7,767
Total	\$ 267,841	\$ 258,615	\$ 248,234

(1) "Other" includes the Remaining Contracts and other revenue transactions in the indicated period relating to performance obligations settled prior to October 1, 2019, the date at which the Company changed its pattern of revenue recognition. For all practical purposes, the Company is not able to allocate these revenue transactions to different product groups. This revenue is reflected as part of the Wound & Surgical segment.

#### *Net Sales by Site of Service*

MIMEDX has three sites of service for its products (1) Hospital settings and wound care clinics, which are stable reimbursement settings in which products are used for surgical applications, (2) Private offices, which generally represents doctors and practitioners with independent operations, and (3) Other, which includes federal facilities, international sales, and other sites of service.

Below is a summary of net sales by site of service (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Hospital	\$ 163,206	\$ 154,580	\$ 144,285
Private Office	77,158	75,816	75,638
Other	27,477	28,219	28,311
Total	\$ 267,841	\$ 258,615	\$ 248,234

#### *Disaggregation of Revenue by Customer*

Prior to May 31, 2021, the conclusion of the FDA's enforcement discretion period, the Company evaluated its revenue on the basis of its two primary distribution channels: (1) direct to customers (healthcare professionals and/or facilities) ("**Direct Customers**"); and (2) sales through distributors ("**Distributors**").

Below is a summary of net sales by each customer type (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Direct Customers	\$ 261,508	\$ 250,009	\$ 240,690
Distributors	6,333	8,606	7,544
Total	\$ 267,841	\$ 258,615	\$ 248,234

The Company did not have significant foreign operations or a single external customer from which 10% or more of revenues were derived during the years ended December 31, 2022, 2021, or 2020.

### **13. Segment Information**

The Company has two reportable segments: Wound & Surgical and Regenerative Medicine.

- **Wound & Surgical** focuses on the Advanced Wound Care and Surgical Recovery markets through the sale of the Company's existing product portfolio and product development to serve these primary end markets. Its platform technologies include tissue allografts derived from human placental membrane (EPIFIX®, AMNIOFIX®, and AMNIOEFFECT®), tissue allografts derived from human umbilical cord (EPICORD® and AMNIOCORD®), and a particulate extracellular matrix derived from human placental disc (AXIOFILL®™). This segment is also responsible for the international sales of the Company's Section 351 products.
- The **Regenerative Medicine** business focuses solely on Regenerative Medicine technologies, specifically progressing the Company's placental biologics platform towards registration as an FDA-approved biological drug. mDHACM is the lead product candidate in its late-stage pipeline targeted at achieving FDA approval for an indication to help decrease pain and improve function in patients suffering from KOA.

The Company's Corporate function includes expenses incurred by executive, finance, human resource, information systems, legal, other functions which are generally shared and whose activities are not specifically identifiable solely to either of the other segments. It also includes amortization of intangible assets. The Company has another operating segment related to an expiring dental sales contract, reflecting all sales of the Company's dental product. All net sales and cost of sales presented in the Corporate & Other columns below relate to this operating segment.

Wound & Surgical net sales reflects sales of the Company's Advanced Wound Care products (as discussed in Note 12, *Revenue*), except for sales of the Company's dental product. In addition, Wound & Surgical reflects international sales of the Company's Section 351 products, which represent all Section 351 sales not reflected in Regenerative Medicine.

The Company evaluates the performance of its segments and allocates resources based on segment contribution, defined as net sales less (i) cost of sales, (ii) selling, general and administrative expense, (iii) research and development expense, and (iv) amortization of intangible assets. Prior period results were recast on the basis of new operating segments. The only components which comprise loss before income tax provision that are not included in operating loss are interest expense, net and other expense, net.

Net sales and segment contribution for each reportable segment for the year ended December 31, 2022 were as follows (in thousands):

	Wound & Surgical	Regenerative Medicine	Corporate & Other	Consolidated
Net sales	\$ 264,906	\$ —	\$ 2,935	\$ 267,841
Cost of sales	44,462	—	3,854	48,316
Selling, general and administrative expense	145,887	—	62,902	208,789
Research and development expense	7,836	14,993	—	22,829
Amortization of intangible assets	—	—	701	701
Segment contribution	<u>\$ 66,721</u>	<u>\$ (14,993)</u>		
Investigation, restatement and related expense				12,177
Operating loss				\$ (24,971)
<i>Supplemental information</i>				
Depreciation expense	\$ 1,791	\$ 165	\$ 1,389	\$ 3,345
Share-based compensation	\$ 6,513	\$ 1,158	\$ 4,995	\$ 12,666

Net sales and segment contribution for each reportable segment for the year ended December 31, 2021 were as follows (in thousands):

	Wound & Surgical	Regenerative Medicine	Corporate & Other	Consolidated
Net sales	\$ 238,940	\$ 16,596	\$ 3,079	\$ 258,615
Cost of sales	35,204	3,655	4,424	43,283
Selling, general and administrative expense	123,583	12,910	61,866	198,359
Research and development expense	5,864	11,480	—	17,344
Amortization of intangible assets	—	—	820	820
Segment contribution	<u>\$ 74,289</u>	<u>\$ (11,449)</u>		
Investigation, restatement and related expense				3,791
Impairment of intangible assets				53
Operating loss				<u>\$ (5,035)</u>
<i>Supplemental information</i>				
Depreciation expense	\$ 1,644	\$ 246	\$ 2,473	\$ 4,363
Share-based compensation	\$ 5,158	\$ 1,461	\$ 8,138	\$ 14,757

Net sales and segment contribution for each reportable segment for the year ended December 31, 2020 were as follows (in thousands):

	Wound & Surgical	Regenerative Medicine	Corporate & Other	Consolidated
Net sales	\$ 213,489	\$ 32,362	\$ 2,383	\$ 248,234
Cost of sales	30,185	5,856	3,289	39,330
Selling, general and administrative expense	103,039	17,546	60,437	181,022
Research and development expense	3,979	7,736	—	11,715
Amortization of intangible assets	—	—	1,073	1,073
Segment contribution	<u>\$ 76,286</u>	<u>\$ 1,224</u>		
Investigation, restatement and related expense				59,465
Impairment of intangibles				1,027
Operating loss				<u>\$ (45,398)</u>
<i>Supplemental information</i>				
Depreciation expense	\$ 1,755	\$ 451	\$ 3,576	\$ 5,782
Share-based compensation	\$ 4,373	\$ 1,256	\$ 9,728	\$ 15,357

The Company does not allocate any assets to the reportable segments. No asset information is reported or disclosed to the CODM in the financial information for each segment.

#### 14. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

Significant components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2022	2021
<b>Deferred Tax Assets:</b>		
Net operating loss	\$ 23,719	\$ 23,333
Research and development and other tax credits	8,384	6,297
Interest limitation carry forward	4,898	3,970
Accrued expenses	3,501	3,385
Capitalized research and development expenditures	3,586	—
Share-based compensation	3,145	4,220
Allowance for doubtful accounts	1,033	601
Lease liabilities	962	1,277
Sales return and allowances	163	195
Accrued settlement costs	50	235
Other	885	1,115
<b>Deferred Tax Liabilities:</b>		
Prepaid expenses	(1,400)	(1,337)
Right of use asset	(867)	(1,197)
Intangible assets	(351)	(263)
Property and equipment	(77)	(705)
Net Deferred Tax Assets	47,631	41,126
Less: Valuation allowance	(47,631)	(41,126)
Net Deferred Tax Assets after Valuation Allowance	\$ —	\$ —

The reconciliation of the federal statutory income tax rate of 21% to the effective rate is as follows:

	Year ended December 31,		
	2022	2021	2020
Federal statutory rate	21.00 %	21.00 %	21.00 %
Tax credits	5.85 %	2.01 %	0.32 %
Employee retention credit	— %	3.37 %	— %
NOL carryback rate differential	— %	— %	10.99 %
Meals and entertainment	(0.10)%	(1.13)%	(0.50)%
State taxes, net of federal benefit	(0.55)%	4.53 %	(0.20)%
Uncertain tax positions	(0.58)%	0.02 %	0.24 %
Nondeductible compensation	(2.22)%	(13.77)%	(0.89)%
Deferred tax adjustments	(2.89)%	14.63 %	— %
Share-based compensation	(4.03)%	23.31 %	(1.24)%
Valuation allowance	(17.59)%	(52.70)%	(8.14)%
Other	0.42 %	(3.73)%	(1.66)%
Effective tax rate	(0.69)%	(2.46)%	19.92 %

Current and deferred income tax (benefit) expense is as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
<b>Current:</b>			
Federal	\$ —	\$ 91	\$ (12,418)
State	206	156	159
<b>Total current</b>	<b>206</b>	<b>247</b>	<b>(12,259)</b>
<b>Deferred:</b>			
Federal	—	—	—
State	—	—	—
<b>Total deferred</b>	<b>—</b>	<b>—</b>	<b>—</b>
<b>Total expense (benefit)</b>	<b>\$ 206</b>	<b>\$ 247</b>	<b>\$ (12,259)</b>

Certain items of income and expense are not reported in tax returns and financial statements in the same year. The tax effects of such temporary differences are reported as deferred income tax assets and liabilities. The measurement of deferred tax assets is reduced, if necessary, by the amount of any tax benefit that, based on available evidence, is not expected to be realized. The Company establishes a valuation allowance for deferred tax assets for which realization is not more likely than not. As of each reporting date, management considers new evidence, both positive and negative, that could affect its view of the future realization of deferred tax assets.

A valuation allowance of \$47.6 million and \$41.1 million was recorded against the deferred tax asset balance as of December 31, 2022 and 2021, respectively. The Company maintains a full valuation allowance because it is not more likely than not the deferred tax assets will be utilized based on all available positive and negative evidence. In the event that the weight of the evidence changes in the future, any reduction in the valuation allowance would result in an income tax benefit.

At December 31, 2022 and 2021, the Company had income tax net operating loss (“*NOL*”) carryforwards for federal and state purposes of \$84.9 million and \$109.8 million and \$84.2 million and \$104.2 million, respectively. A portion of the Company’s NOLs and tax credits are subject to annual limitations due to ownership change limitations provided by Internal Revenue Code Section 382. All of the Company’s federal NOL carryforwards have been generated since 2018 and will carry forward indefinitely. The majority of the Company’s state NOL carryforwards will expire between 2027 and 2042; the remainder of the Company’s state NOLs will carryforward indefinitely. As of December 31, 2022, the Company has recorded a deferred tax asset for both federal and state NOL carryforwards of approximately \$17.8 million and \$5.9 million, respectively. As of December 31, 2021, the Company has recorded a deferred tax asset for federal and state NOL carryforwards of \$17.7 million and approximately \$5.6 million, respectively.

#### *Unrecognized Tax Benefits*

The following is a tabular reconciliation of the total amounts of unrecognized tax benefits (in thousands) included in other liabilities in the consolidated balance sheets:

	2022	2021	2020
Unrecognized tax benefits - January 1	\$ 469	\$ 477	\$ 627
Increases - tax positions in current period	98	20	—
Increases - tax positions in prior period	78	—	—
Decreases in prior year positions	—	(28)	(150)
<b>Unrecognized tax benefits - December 31</b>	<b>\$ 645</b>	<b>\$ 469</b>	<b>\$ 477</b>

Included in the balance of unrecognized tax benefits are tax benefits of \$0.6 million and \$0.5 million for the years ended December 31, 2022 and 2021, respectively, that, if recognized, would affect the effective tax rate.

The Company recognizes accrued interest related to unrecognized tax benefits and penalties as income tax expense. Related to the unrecognized tax benefits noted above, the Company accrued \$0.0 million of interest during the years ended December 31, 2022 and 2021. The Company accrued and recognized \$0.1 million of interest during 2020.

The Company is subject to taxation in the U.S. and various state jurisdictions. As of December 31, 2022, the Company's tax returns for 2019 through 2022 generally remain open for exam by taxing jurisdictions. Additional prior years may be open to the extent attributes are being carried forward to an open tax year.

#### *CARES Act*

On March 27, 2020, the U.S. government enacted the Coronavirus Aid, Relief, and Economic Security Act (the "**CARES Act**") which, among other changes, eliminated the taxable income limit for certain net operating losses ("**NOL**"), allowed businesses to carry back NOLs arising in 2018, 2019, and 2020 to the five prior years, and provided a payment delay of employer payroll taxes during 2020 after the date of enactment. These provisions allowed the Company to carry back federal tax losses related to 2018 and 2019. The Company recorded net tax receivable totaling \$11.3 million in 2020 related to these provisions, of which \$1.2 million had been collected as of December 31, 2020, and another \$9.2 million was collected during the year ended December 31, 2021. The remaining \$0.9 million is reflected in income tax receivable on the consolidated balance sheets as of December 31, 2022 and 2021.

The Company had a deferred payment of \$2.2 million in employer taxes that was included as part of accrued compensation on the consolidated balance sheet as of December 31, 2021. \$1.1 million was paid in January 2022 and the remaining balance paid in December 2022.

### **15. Supplemental Disclosure of Cash Flow and Non-Cash Investing and Financing Activities**

Selected cash payments, receipts, and non-cash activities are as follows (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Cash paid for interest	\$ 4,569	\$ 4,327	\$ 7,456
Income taxes paid	181	169	208
Cash paid for operating leases	1,567	1,522	1,569
Non-cash activities:			
Purchases of equipment included in accounts payable	417	8	1,062
Lease right of use asset and liability	(37)	2,251	1,169
Deemed dividends of Series B Preferred Stock	—	926	32,028
Fair value of non-cash consideration received for option exercise	—	380	922
Note receivable for sale of property and equipment	—	75	—
Amendment fee on previous term loan	—	—	722
Deferred financing costs	—	—	53

### **16. Commitments and Contingencies**

#### *Contractual Commitments*

The Company has commitments for meeting spaces, generally for hotel and conference spaces for company functions. These commitments generally contain renewal options.

The estimated meeting space commitments are as follows (in thousands):

Year ending December 31,	Meeting Space Commitments
2023	\$ 989
2024	394
<b>Total</b>	<b>\$ 1,383</b>

### *Separation Agreement with Timothy R. Wright*

On September 15, 2022, the Company entered into a Separation Agreement and General Release with Timothy R. Wright, the former Chief Executive Officer of the Company (the “**Separation Agreement**”). Pursuant to the terms of the Separation Agreement and Mr. Wright’s general release of all claims against the Company, the Company will pay Mr. Wright a total of \$3.1 million in cash in a series of installments through September 2024. The terms of the severance benefits provided in the Separation Agreement were the same as those provided for in the original employment Letter Agreement between Mr. Wright and the Company dated April 8, 2019. The \$3.1 million was recorded as part of selling, general and administrative expense on the consolidated statement of operations for the year ended December 31, 2022.

Of the \$3.1 million, \$1.9 million is reflected in accrued compensation and \$1.2 million is reflected in other liabilities in the consolidated balance sheet as of December 31, 2022. No payments were required to be made to Mr. Wright under the terms of the Separation Agreement during the year ended December 31, 2022.

### *Nordic Agreement*

In June 2022, the Company entered into a collaboration agreement (the “**Nordic Agreement**”) with Nordic Bioscience Clinical Development A/S (“**NBCD**”) to provide full operational support for the Company’s upcoming Knee Osteoarthritis (“**KOA**”) clinical trial program. As part of the agreement, NBCD will perform site selection and monitoring, manage patient recruitment and enrollment, data management, statistical analysis and reporting activities for the duration of the trial. Under the terms of the Nordic Agreement, as of December 31, 2022, the Company was obligated to pay \$13.3 million upon the achievement of specified milestones over the course of the clinical trial. The milestones are based upon various factors including, but not limited to, site selection and enrollment, patient enrollment, patient completion, and certain other activities related to clinical trial operations. These milestone payments are revised semi-annually based on fluctuations in the consumer price index. The Company has the ability to terminate the Nordic Agreement with 30 days written notice to NBCD. At such time, the Company would be required to pay for services performed through the date of termination and any non-cancelable obligations.

In addition to the \$13.3 million, the Company will reimburse NBCD for actual expenses incurred related to third-party vendors to be contracted and managed by NBCD.

As of December 31, 2022, the Company has paid \$2.0 million under the Nordic Agreement, relating to milestones which have been achieved from inception through that date. During the year ended December 31, 2022, the Company recognized \$1.0 million of expense related to the Nordic Agreement. This amount is included as part of research and development expense in the consolidated statement of operations. The remaining \$1.0 million is reflected in prepaid expenses on the consolidated balance sheet as of December 31, 2022.

In January 2023, the Company executed a change order to the Nordic Agreement. Refer to Note 21, *Subsequent Events*, for more details.

### *Turn Agreement*

On December 7, 2022, the Company acquired intellectual property rights pursuant to a Platform Intellectual Property License (the “**Turn Agreement**”) with Global Health Solutions, Inc. (d.b.a. Turn Therapeutics or “**Turn**”). The Turn Agreement provided MIMEDX with an exclusive, worldwide, sub-licensable license to use Turn’s proprietary antimicrobial technology platform (PermaFusion®) to develop antimicrobial line extensions and new products. In addition, the Turn Agreement granted the Company the commercial rights to Turn’s placental collagen matrix product, FleX™ AM (“**FleX**”), contingent upon Turn’s receipt of FDA 510(k) clearance and other conditions.

During the year ended December 31, 2022, the Company paid \$1.0 million upon the execution of the Turn Agreement to acquire the license. This amount was capitalized and is included as part of intangible assets, net, on the consolidated balance sheet as of December 31, 2022. The Company is obligated to make additional payments upon the meeting of regulatory and product commercial milestones, including \$9.6 million if and when Turn receives 510(k) clearance from the FDA for FleX. This amount is not reflected in the consolidated balance sheet as of December 31, 2022.

### *Litigation and Regulatory Matters*

In the ordinary course of business, the Company and its subsidiaries may be a party to pending and threatened legal, regulatory, and governmental actions and proceedings (including those described below). In view of the inherent difficulty of predicting the outcome of such matters, particularly where the plaintiffs or claimants seek very large or indeterminate damages or where the matters present novel legal theories or involve a large number of parties, the Company generally cannot predict what the

eventual outcome of the pending matters will be, what the timing of the ultimate resolution of these matters will be, or what the eventual recovery, loss, fines or penalties related to each pending matter may be.

In accordance with applicable accounting guidance, the Company accrues a liability when those matters present loss contingencies that are both probable and estimable. The Company's financial statements at December 31, 2022 reflect the Company's current best estimate of probable losses associated with these matters, including costs to comply with various settlement agreements, where applicable. As of December 31, 2022, the Company had reserved \$0.2 million related to expected settlement costs related to legal matters.

The Company paid \$0.7 million toward the resolution of legal matters involving the Company during the year ended December 31, 2022. In addition, insurance providers paid \$0.6 million on the Company's behalf to settle legal matters.

The Company paid \$6.7 million to settle legal proceedings during 2021. In addition, \$1.1 million was paid on the Company's behalf through an insurance provider during 2021 relating directly to settlement matters. In addition, during 2021, the Company received funds from certain director and officer insurance policies for previously-incurred legal expenses under the Company's indemnification agreements. These funds were recognized as a reduction to investigation, restatement and related expense on the consolidated statement of operations.

The Company paid \$7.4 million to settle legal proceedings during 2020. In addition, \$3.5 million was paid on the Company's behalf through an insurance provider during 2020.

The actual costs of resolving these matters may be in excess of the amounts reserved.

#### *Securities Class Action*

On January 16, 2019, the United States District Court for the Northern District of Georgia entered an order consolidating two purported securities class actions (*MacPhee v. MiMedx Group, Inc.*, et al. filed February 23, 2018 and *Kline v. MiMedx Group, Inc.*, et al. filed February 26, 2018). The order also appointed Carpenters Pension Fund of Illinois ("**CPFI**") as lead plaintiff. On May 1, 2019, CPFI filed a consolidated amended complaint, naming as defendants the Company, Michael J. Senken, Parker H. "Pete" Petit, William C. Taylor, Christopher M. Cashman and Cherry Bekaert & Holland LLP. The amended complaint alleged violations of Section 10(b) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), Rule 10b-5 promulgated thereunder, and Section 20(a) of the Exchange Act. It asserted a class period of March 7, 2013 through June 29, 2018. Following the filing of motions to dismiss by the various defendants, CPFI was granted leave to file an amended complaint. CPFI filed its amended complaint against the Company, Michael J. Senken, Parker H. Petit, William C. Taylor, and Cherry Bekaert & Holland (Christopher Cashman was dropped as a defendant) on March 30, 2020; defendants filed motions to dismiss on May 29, 2020. On March 25, 2021, the Court granted defendants' respective motions to dismiss, finding that CPFI lacked standing to bring the underlying claims and also could not establish loss causation because it sold all of its shares in MIMEDX prior to any corrective disclosures, and dismissed the case. On April 22, 2021, CPFI filed a motion for reconsideration of the dismissal and for leave to amend to add a new plaintiff to attempt to cure the standing and loss causation issues. The Company opposed CPFI's motions and the hearing on the same was held on September 24, 2021.

On January 28, 2022, the Court denied CPFI's motion to reconsider and motion to substitute class representative. On February 25, 2022, CPFI filed a Notice of Appeal in the 11th Circuit Court of Appeals. Oral arguments were held on January 24, 2023.

#### *Welker v. MiMedx, et. al.*

On November 4, 2022, Troy Welker and Min Turner, former optionholders of the Company, brought a lawsuit in Fulton County State Court against the Company, former directors Terry Dewberry and Charles Evans, and former officers Parker H. "Pete" Petit, William C. Taylor, and Michael Senken alleging violations of the Georgia Racketeer Influenced and Corrupt Organizations ("**RICO**") Act against all defendants and conspiracy to violate the Georgia RICO Act and breach of fiduciary duty against the individual defendants.

The Company is defending against the allegations and removed the case to the United States District Court for the Northern District of Georgia. Plaintiffs have filed a motion to remand back to state court, which is currently pending.

### *Investigations*

On February 8, 2021, the Company received a subpoena issued by the Department of Defense Office of Inspector General seeking records regarding the sales of the Company's micronized and other products to federal medical facilities and federal contracting offices, including those operated by the Department of Veterans Affairs or the Department of Defense. The subpoena also seeks information regarding the Company's communications with the FDA regarding its products. The Company understands that the Office of the United States Attorney for the Western District of Washington Civil Division is overseeing the investigation, which is being conducted principally by agents employed by the Department of the Army Criminal Investigation Command. The Company is cooperating with the government's investigation and at this time the Company is unable to predict the outcome of the investigation, including whether the investigation will result in any action or proceeding against the Company.

### *Former Employee Litigation and Related Matters*

On January 12, 2021, the Company filed suit in the Circuit Court of the Eleventh Judicial District in and for Miami-Dade County, Florida (*MiMedx Group, Inc. v. Petit, et. al.*) against its former CEO, Parker H. "Pete" Petit, and its former COO, William C. Taylor, seeking a determination of its rights and obligations under indemnification agreements with Petit and Taylor following a federal jury's guilty verdict against Petit for securities fraud and Taylor for conspiracy to commit securities fraud. The Company is seeking a declaratory judgment that it is not obligated to indemnify or advance expenses to Petit and Taylor in connection with certain cases to which Petit and Taylor are parties and also seeking to recoup amounts previously paid on behalf of Petit and Taylor in connection with such cases. On April 22, 2021, Petit and Taylor filed an answer and asserted counterclaims against the Company alleging breach of their indemnification agreements, breach of the covenant of good faith and fair dealing with respect to their indemnification agreements, and seeking a declaration that the Company remains obligated to indemnify and advance fees in connection with certain cases. Petit and Taylor simultaneously filed a motion seeking to compel the Company to advance and reinstate its payments of Petit and Taylor's legal expenses. The Company opposed Petit and Taylor's motion and a hearing was set for June 23, 2021. At the joint request of the parties, the hearing was cancelled to allow the parties to attend a mediation to attempt a resolution of this matter; such mediation was held on August 11, 2021.

Following the mediation, the Company and Taylor reached an agreement to settle the matter between them. Negotiations with Petit are ongoing.

### *Other Matters*

Under the Florida Business Corporation Act and agreements with its current and former officers and directors, the Company is obligated to indemnify its current and former officers and directors who are made party to a proceeding, including a proceeding brought by or in the right of the corporation, with certain exceptions, and to advance expenses to defend such matters. The Company has already borne substantial costs to satisfy these indemnification and expense advance obligations and may continue to do so in the future.

In addition to the matters described above, the Company is a party to a variety of other legal matters that arise in the ordinary course of the Company's business, none of which is deemed to be individually material at this time.

### **Previously-Settled Matters**

The matters discussed below have been settled with the counterparty and their resolution has been disclosed in previously-issued financial statements. There are no contingent or continuing obligations associated with these matters.

### *Shareholder Derivative Suits*

On December 6, 2018, the United States District Court for the Northern District of Georgia entered an order consolidating three shareholder derivative actions (*Evans v. Petit, et al.* filed September 25, 2018, *Georgalas v. Petit, et al.* filed September 27, 2018, and *Roloson v. Petit, et al.* filed October 22, 2018) that had been filed in the Northern District of Georgia. On January 22, 2019, plaintiffs filed a verified consolidated shareholder derivative complaint. The consolidated action sets forth claims of breach of fiduciary duty, corporate waste and unjust enrichment against certain former officers, and certain current and former directors, of the Company: Parker H. Petit, William C. Taylor, Michael J. Senken, John E. Cranston, Alexandra O. Haden, Joseph G. Bleser, J. Terry Dewberry, Charles R. Evans, Larry W. Papasan, Luis A. Aguilar, Bruce L. Hack, Charles E. Koob, Neil S. Yeston and Christopher M. Cashman. The allegations generally involve claims that the defendants breached their fiduciary duties by causing or allowing the Company to misrepresent its financial statements as a result of improper revenue recognition. The Company filed a motion to stay on February 18, 2019, pending the completion of the investigation by the Company's Special Litigation Committee. The Special Litigation Committee completed its investigation relating to this action and filed an executive summary of its findings with the Court on July 1, 2019. The parties (together with parties from the

Hialeah derivative lawsuit, the Nix and Demaio derivative lawsuit, and the Murphy derivative lawsuit, each described below) held a mediation on February 11, 2020. Following continued discussions, on May 1, 2020, the parties notified the Court that plaintiffs and the Company had reached an agreement in principle to settle this consolidated derivative action, which settlement also encompasses all claims asserted in the Hialeah derivative lawsuit, the Nix and Demaio derivative lawsuit, and the Murphy derivative lawsuit. The hearing on final approval was held on December 21, 2020 and the Court entered an Order granting final approval of the settlement the same day.

On October 29, 2018, the City of Hialeah Employees Retirement System (“*Hialeah*”) filed a shareholder derivative complaint in the Circuit Court for the Second Judicial Circuit in and for Leon County, Florida (the “*Florida Court*”). The complaint alleges claims for breaches of fiduciary duty and unjust enrichment against certain former officers, and certain current and former directors, of the Company: Parker H. Petit, William C. Taylor, Michael J. Senken, John E. Cranston, Alexandra O. Haden, Joseph G. Bleser, J. Terry Dewberry, Charles R. Evans, Bruce L. Hack, Charles E. Koob, Larry W. Papasan, and Neil S. Yeston. The allegations generally involve claims that the defendants breached their fiduciary duties by causing or allowing the Company to misrepresent its financial statements as a result of improper revenue recognition. The Company moved to stay the action on February 7, 2019, to allow the prior-filed consolidated derivative action in the Northern District of Georgia to be resolved first and to allow the Company’s Special Litigation Committee time to complete its investigation. The Company also filed a motion to dismiss on April 8, 2019. As discussed above, the plaintiff participated in the mediation that took place in connection with the prior-filed consolidated derivative action in the Northern District of Georgia and is a party to the agreement settling that consolidated derivative action. In accordance with the terms of the settlement, Hialeah filed a motion for leave to dismiss its derivative action with prejudice on January 4, 2021.

On May 15, 2019, two individuals purporting to be shareholders of the Company filed a shareholder derivative complaint in the Superior Court for Cobb County, Georgia. (*Nix and Demaio v. Evans, et al.*) The complaint alleges claims for breaches of fiduciary duty, corporate waste and unjust enrichment against certain current and former directors and officers of the Company: Parker H. Petit, William C. Taylor, Michael J. Senken, John E. Cranston, Alexandra O. Haden, Chris Cashman, Lou Roselli, Mark Diaz, Charles R. Evans, Luis A. Aguilar, Joseph G. Bleser, J. Terry Dewberry, Bruce L. Hack, Charles E. Koob, Larry W. Papasan and Neil S. Yeston. The allegations generally involved claims that the defendants breached their fiduciary duties by causing or allowing the Company to misrepresent its financial statements as a result of improper revenue recognition. The Court ordered this matter stayed pending the resolution of the consolidated derivative suit pending in the Northern District of Georgia. As discussed above, the plaintiffs participated in the mediation that took place in connection with the prior-filed consolidated derivative action in the Northern District of Georgia and are a party to the agreement settling that consolidated derivative action. In accordance with the terms of the settlement, plaintiffs filed a notice of settlement and voluntary dismissal with prejudice on January 13, 2021.

On August 12, 2019, John Murphy filed a shareholder derivative complaint in the United States District Court for the Southern District of Florida (*Murphy v. Petit, et al.*). The complaint alleged claims for breaches of fiduciary duty and unjust enrichment against certain former officers, and certain current and former directors, of the Company: Parker H. Petit, William C. Taylor, Michael J. Senken, John E. Cranston, Alexandra O. Haden, Charles R. Evans, Luis A. Aguilar, Joseph G. Bleser, J. Terry Dewberry, Bruce L. Hack, Charles E. Koob, Larry W. Papasan and Neil S. Yeston. The allegations generally involve claims that the defendants breached their fiduciary duties by causing or allowing the Company to misrepresent its financial statements as a result of improper revenue recognition. The Company filed a motion to transfer this action to the Northern District of Georgia. Prior to resolution of that motion, the plaintiff voluntarily dismissed this action without prejudice. As discussed above, the plaintiff participated in the mediation that took place in connection with the prior-filed consolidated derivative action in the Northern District of Georgia and is a party to the agreement settling that consolidated derivative action. Pursuant to the terms of the settlement, this action is deemed dismissed with prejudice.

#### *Qui Tam Matters*

On January 19, 2017, a former employee of the Company filed a *qui tam* False Claims Act complaint in the United States District Court for the District of South Carolina (*United States of America, ex rel. Jon Vitale v. MiMedx Group, Inc.*) alleging that the Company’s donations to the patient assistance program, Patient Access Network Foundation, violated the Anti-Kickback Statute and resulted in submission of false claims to the government. The government declined to intervene and the complaint was unsealed on August 10, 2018. The Company filed a motion to dismiss on October 1, 2018. The Company’s motion to dismiss was granted in part and denied in part on May 15, 2019. The parties have reached an agreement to resolve this matter.

On January 20, 2017, two former employees of the Company, filed a *qui tam* False Claims Act complaint in the United States District Court for the District of Minnesota (*Kruchoski et. al. v. MiMedx Group, Inc.*). An amended complaint was filed on January 27, 2017. The operative complaint alleges that the Company failed to provide truthful, complete and accurate information about the pricing offered to commercial customers in connection with the Company’s Federal Supply Schedule contract. On May 7, 2019, the Department of Justice (“*DOJ*”) declined to intervene, and the case was unsealed. In April 2020,

without admitting the allegations, the Company agreed to pay \$6.5 million to the DOJ to resolve this matter. This amount was paid during the year ended December 31, 2020.

#### *Former Employee Matters*

In December 2019, MiMedx received notice of a complaint filed in July 2018 with the Occupational Safety and Health Administration (“OSHA”) section of the Department of Labor (“DOL”) by Thomas Tierney, a former Regional Sales Director, against MiMedx and the referenced individuals, *Tierney v. MiMedx Group, Inc., Parker Petit, William Taylor, Christopher Cashman, Thornton Kuntz, Jr. and Alexandra Haden*, DOL No. 4-5070-18-243. Mr. Tierney alleged that he was terminated from MiMedx in retaliation for reporting concerns about revenue recognition practices, compliance issues, and the corporate culture, in violation of the anti-retaliation provisions of the Sarbanes-Oxley Act. The parties settled this matter and OSHA dismissed the complaint on May 20, 2020.

#### *Intellectual Property Litigation*

##### The NuTech Action

On March 2, 2015, the Company filed a patent infringement lawsuit against NuTech Medical, Inc. (“**NuTech**”) and DCI Donor Services, Inc. (“**DCI**”) in the United States District Court for the Northern District of Alabama (*MiMedx Group, Inc. v. NuTech Medical, Inc. et. al.*). The Company has alleged that NuTech and DCI infringed and continue to infringe on the Company’s patents through the manufacture, use, sale and/or offering of their tissue graft product. The Company also asserted that NuTech knowingly and willfully made false and misleading representations about its products to customers and prospective customers. The Company is seeking permanent injunctive relief and unspecified damages. The case was stayed pending the restatement of the Company’s financial statements. Since the Company has completed its restatement, the case resumed. The parties reached a settlement in the matter and the case was dismissed with prejudice.

##### The Osiris Action

On February 20, 2019, Osiris Therapeutics, Inc. (“**Osiris**”) refiled its trade secret and breach of contract action against the Company (which had been dismissed in a different forum) in the United States District Court for the Northern District of Georgia (*Osiris Therapeutics, Inc. v. MiMedx Group, Inc.*). The parties reached a settlement in the matter and the case was dismissed with prejudice on October 26, 2020.

#### **17. 401(k) Plan**

The Company has a 401(k) plan (the “**401(k) Plan**”) covering all employees who have completed one month of service. Under the 401(k) Plan, participants could defer up to 90% of their eligible wages to a maximum of \$20,500 per year (annual limit for 2022). Employees age 50 or over in 2022 could make additional pre-tax contributions up to \$6,500. In 2022 and 2021, the Company matched 50% of employee contributions up to 8% of the employee’s eligible compensation. In 2020, the Company matched 50% of employee contributions up to 5% of the employee’s eligible compensation. The matching contribution for the years ended December 31, 2022, 2021, and 2020 was \$3.3 million, \$2.7 million, and \$1.5 million, respectively.

#### **18. Related Party Transactions**

The Company has employed Thomas Koob as its Chief Scientific Officer (a non-executive officer) since 2006. Thomas Koob is the brother of a former director, Charles Koob. Subsequent to the Company’s employment of Thomas Koob, Charles Koob was appointed as a director of the Company in March 2008. Charles Koob’s term as a Director expired at the 2020 Annual Meeting held on November 20, 2020. In 2020, the Company paid Thomas Koob an annual salary of \$0.2 million and provided equity, incentive compensation and other compensation of \$0.3 million.

The Company had no related party transactions for the years ended December 31, 2022 or 2021.

#### **19. Restructuring**

##### *2018 Restructuring*

Set forth below are disclosures relating to restructuring initiatives that resulted in material cash expenditures during the year ended December 31, 2020. Employee retention and certain other employee benefit-related costs related to the Company’s restructuring were expensed ratably over an agreed-upon service period. One-time employee separation and related employee benefit costs were generally expensed as incurred.

In December 2018, the Company announced a reduction of the Company’s workforce by approximately 240 full-time employees, or 24% of its total workforce, of which approximately half were sales personnel as part of the plans to implement a broad-based organizational realignment, cost reduction and efficiency program to better ensure the Company’s cost structure was appropriate given its revenue expectations.

The Company’s restructuring program concluded in 2020. All obligations related to the Company’s restructuring program were settled as of December 31, 2020.

Changes to this liability during the year ended December 31, 2020 was as follows (in thousands):

Liability balance as of December 31, 2019	3,561
Expenses	—
Cash distributions	(3,561)
Liability balance as of December 31, 2020	\$ —

### 2022 Reorganization

On September 2, 2022, the Company separated from its Chief Executive Officer. Subsequent to this event, the Company realigned the organization to improve profitability. As part of these efforts, the Company incurred \$2.0 million of one-time employee separation costs. Of this amount, \$0.6 million was outstanding as of December 31, 2022. The remaining amount is reflected as part of accrued compensation on the consolidated balance sheet as of that date.

## 20. Government Assistance

### Employee Retention Credit

The CARES Act provided an employee retention credit (“**ERC**”), which was a refundable tax credit against certain payroll taxes. Upon determination that the Company overcame the barriers required to receive the credit, the Company qualified and filed to claim the ERC. The Company reflected the ERC as a reduction to the respective captions on the consolidated statements of operations associated with the employees to which the payroll tax benefit related. For the year ended December 31, 2021, the Company recorded \$1.6 million as a reduction to selling, general and administrative expense. Of this amount, \$1.4 million and \$1.6 million were reflected as part of other current assets in the consolidated balance sheets as December 31, 2022 and 2021, respectively. During year ended December 31, 2022, the Company received \$0.2 million relating to the ERC.

## 21. Subsequent Events

### Nordic Agreement Change Order

On January 24, 2023, the Company executed a change order to the Nordic Agreement (the “**Change Order**”), primarily to reflect additional elements required in conducting the trial. The Change Order modified the scope of NBCD’s responsibilities under the Nordic Agreement, shifting certain activities to other vendors to be administered by NBCD and certain other activities to MIMEDX. These responsibilities primarily related to areas of patient recruitment and screening and statistical analysis, among other areas of the trial. Pursuant to the Change Order, the total payments owed to NBCD relating to NBCD’s responsibilities decreased from \$13.3 million to \$10.2 million.

### Hiring of Chief Executive Officer

On January 27, 2023, the Board of Directors appointed Joseph H. Capper to serve as Chief Executive Officer. The Company entered into a Letter Agreement with Mr. Capper that included, among other things, a grant of 3,300,000 PSUs and a grant of a non-qualified stock option (the “**Option**”) for 3,600,000 shares of the Company’s common stock.

The PSUs vest over a four-year performance period ending December 31, 2026 based upon the achievement of specified performance conditions, up to a maximum of 200% of the granted PSUs, and subject to Mr. Capper’s continued employment. The Option vests over a four-year period ending January 31, 2027 contingent upon the achievement of share price performance goals and subject to Mr. Capper’s continued employment. Mr. Capper will be eligible to vest in 25% of the Option on or after each of the first four anniversary dates subsequent to the date of grant, provided certain share price performance targets are achieved at any point during the four-year vesting period.

In concert with the hiring of Mr. Capper's, K. Todd Newton stepped down and ceased to serve as Interim Chief Executive Officer. Upon Mr. Capper's hiring, 200,000 RSUs granted to Mr. Newton pursuant to the Interim Executive Employment Agreement between him and the Company vested immediately. Mr. Newton remains on the Board of Directors.

**Schedule II Valuation and Qualifying Accounts**

**MIMEDX GROUP, INC. AND SUBSIDIARIES**  
**SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS**

Years ended December 31, 2022, 2021 and 2020 (in thousands)

	Balance at Beginning of Year	Additions charged to Expense or Revenue	Deductions and write-offs	Balance at End of Year
<b>For the year ended December 31, 2022</b>				
Allowance for product returns	\$ 2,549	\$ 2,449	\$ (2,304)	\$ 2,694
<b>For the year ended December 31, 2021</b>				
Allowance for product returns	\$ 2,321	\$ 2,508	\$ (2,280)	\$ 2,549
<b>For the year ended December 31, 2020</b>				
Allowance for product returns	\$ 4,115	\$ 705	\$ (2,499)	\$ 2,321

## **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

### **Item 9A. Controls and Procedures**

#### **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Stockholders and the Board of Directors of MiMedx Group, Inc.

#### **Opinion on Internal Control over Financial Reporting**

We have audited the internal control over financial reporting of MiMedx Group, Inc. and subsidiaries (the “Company”) as of December 31, 2022, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control — Integrated Framework (2013) issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2022, of the Company and our report dated February 28, 2023, expressed an unqualified opinion on those financial statements.

#### **Basis for Opinion**

The Company’s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A Managements Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company’s internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

#### **Definition and Limitations of Internal Control over Financial Reporting**

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Deloitte & Touche LLP  
Atlanta, Georgia  
February 28, 2023

## **Evaluation of Disclosure Controls and Procedures**

Management maintains a set of disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”), designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to management, including our CEO and CFO, to allow for timely decisions regarding required disclosure.

An evaluation of the effectiveness of the design and operation of our disclosure controls and procedures was performed under the supervision and with the participation of our management, including our CEO and CFO. As a result of this evaluation, our CEO and CFO concluded that our disclosure controls and procedures were effective as of December 31, 2022.

## **Management's Report on Internal Control Over Financial Reporting**

Management, including our CEO and CFO, is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act and based upon the criteria established in Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the “*COSO framework*”). The Company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with United States Generally Accepted Accounting Principles (“*GAAP*”).

An effective internal control system, no matter how well designed, has inherent limitations, including the possibility of human error or overriding of controls, and therefore can provide only reasonable assurance with respect to reliable financial reporting. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may demonstrate.

Under the supervision and with the participation of our management, including our CEO and CFO, we have conducted an evaluation of the effectiveness of our internal control over financial reporting based on the COSO framework. Based on evaluation under these criteria, management determined that we did maintain effective internal control over financial reporting as of December 31, 2022.

Our independent registered public accounting firm, Deloitte & Touche LLP, has audited the effectiveness of our internal control over financial reporting as of December 31, 2022, as stated in their report which appears on page 79 of this Form 10-K.

## **Changes in Internal Control Over Financial Reporting**

There were no changes during the quarter ended December 31, 2022 in our internal control over financial reporting (as such term is defined in the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **Item 9B. Other Information**

None.

## **Item 9C. Disclosures Regarding Foreign Jurisdictions that Prevent Inspections**

Not applicable.

## **PART III**

## **Item 10. Directors, Executive Officers and Corporate Governance**

Information required by this Item will be contained in our definitive proxy statement relating to our 2023 Annual Meeting of Shareholders under the captions “Executive Officers,” “Election of Directors” and similar captions which are incorporated herein by reference.

**Item 11. Executive Compensation**

Information required by this Item will be contained in our definitive proxy statement relating to our 2023 Annual Meeting of Shareholders under the caption "Executive Compensation Discussion and Analysis," "Summary Compensation Table (2022, 2021 and 2020)," "Grants of Plan Based Awards for 2022," "Outstanding Equity Awards on December 31, 2022," "2022 Options Exercised and Stock Vested Table," "2022 Potential Payments Upon Termination or Change in Control," "2022 Director Compensation," "Compensation Committee Report" and "Compensation Committee Interlocks and Insider Participation" or similar captions which are incorporated herein by reference.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

Information required by this Item will be contained in our definitive proxy statement relating to our 2023 Annual Meeting of Shareholders under the captions "Security Ownership of Certain Beneficial Owners and Management," and "Equity Compensation Plan Information," or similar captions which are incorporated herein by reference.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

Information required by this Item will be contained in our definitive proxy statement relating to our 2023 Annual Meeting of Shareholders under the captions "Policies and Procedures for Approval of Related Party Transactions," "Related Party Transactions," and "Director Independence" or similar captions which are incorporated herein by reference.

**Item 14. Principal Accounting Fees and Services**

Information required by this Item will be contained in our definitive proxy statement relating to our 2023 Annual Meeting of Shareholders under the captions "Audit Matters," or a similar caption which is incorporated herein by reference.

## PART IV

### Item 15. Exhibits, Financial Statement Schedules

(a) Documents filed as part of this report:

- (i) Financial Statements
- (ii) Financial Statement Schedule:

The following Financial Statement Schedule is filed as part of this Report:

Schedule II Valuation and Qualifying Accounts for the years ended December 31, 2022, 2021 and 2020

- (iii) Exhibits

See Item 15(b) below. Each management contract or compensation plan has been identified with an asterisk.

(b) Exhibits

#### Notes

- \* Indicates a management contract or compensatory plan or arrangement
- # Filed herewith
- ## Certain exhibits and schedules have been omitted pursuant to Item 601(b)(10) of Regulation S-K, but a copy will be furnished supplementally to the Securities and Exchange Commission upon request.

Exhibit Number	Description
3.1	Restated Articles of Incorporation, adopted March 4, 2021, effective March 5, 2021 ( <a href="#">incorporated by reference to Exhibit 3.1 to the Registrant's Annual Report on Form 10-K filed on March 8, 2021</a> ).
3.2	Articles of Amendment to Restated Articles of Incorporation, effective June 3, 2021 ( <a href="#">incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on June 10, 2021</a> ).
3.3	Articles of Amendment to Restated Articles of Incorporation, effective June 3, 2021 ( <a href="#">incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed on June 10, 2021</a> ).
3.4	Amended and Restated Bylaws of MiMedx Group, Inc., as amended and restated as of February 16, 2023 ( <a href="#">incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on February 23, 2023</a> ).
4.1	The description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 ( <a href="#">incorporated by reference to the Registrant's Registration Statement on Form 8-A filed on November 2, 2020</a> ).
10.1##	Loan Agreement dated as of June 30, 2020 by and among MiMedx Group, Inc., certain subsidiaries of MiMedx Group, Inc. parties thereto, the Lenders from time to time party hereto, Hayfin Services LLP, as administrative agent for the Lenders and as collateral agent for the Secured Parties ( <a href="#">incorporated by reference to Exhibit 10.36 to Registrant's Annual Report on Form 10-K filed on July 6, 2020</a> ).
10.2##	Securities Purchase Agreement, dated as of June 30, 2020, by and between MiMedx Group, Inc., Falcon Fund 2 Holding Company, L.P. and certain other investors ( <a href="#">incorporated by reference to Exhibit 10.38 to the Registrant's Annual Report on Form 10-K filed July 6, 2020</a> ).
10.3	Registration Rights Agreement dated as of July 2, 2020, by and between MiMedx Group, Inc. and Falcon Fund 2 Holding Company, L.P. ( <a href="#">incorporated by reference to Exhibit 10.39 to the Registrant's Annual Report on Form 10-K filed on July 6, 2020</a> ).
10.4	Lease effective May 1, 2013 between Hub Properties of GA, LLC and MiMedx Group, Inc. ( <a href="#">incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on May 10, 2013</a> ).
10.5	First Amendment to Lease dated March 7, 2017 between CPVF II West Oak LLC (as successor in interest to HUB Properties of GA, LLC) and MiMedx Group, Inc. ( <a href="#">incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on March 13, 2017</a> ).

<b>Exhibit Number</b>	<b>Description</b>
10.6	Third Amendment to Lease made as of November 30, 2021 for real property and improvements located at 1775 West Oak Commons Court, Marietta, Georgia between RE Fields, LLC, successor in interest to HUB Properties GA, LLC, and CPVF II West Oak LLC, and MiMedx Group, Inc., dated January 25, 2013, as amended March 7, 2017 ( <a href="#">incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K filed on February 28, 2022</a> ).
10.7*	MiMedx Group, Inc. Assumed 2006 Stock Incentive Plan, as amended and restated effective February 25, 2014 ( <a href="#">incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on March 3, 2014</a> ).
10.8*	Form of Incentive Stock Option Agreement under the MiMedx Group, Inc. Assumed 2006 Stock Incentive Plan ( <a href="#">incorporated by reference to Exhibit 10.4 to the Registrant's Annual Report on Form 10-K filed on March 4, 2014</a> ).
10.9*	Form of Nonqualified Stock Option Agreement under the MiMedx Group, Inc. Assumed 2006 Stock Incentive Plan ( <a href="#">incorporated by reference to Exhibit 10.5 to the Registrant's Annual Report on Form 10-K filed on March 4, 2014</a> ).
10.10*	Form of Restricted Stock Agreement for Non-Employee Directors under the MiMedx Group, Inc. 2006 Assumed Stock Incentive Plan ( <a href="#">incorporated by reference to Exhibit 10.66 to the Registrant's Quarterly Report on Form 10-Q filed on August 8, 2013</a> ).
10.11*	Form of Restricted Stock Agreement under the MiMedx Group, Inc. 2006 Assumed Stock Incentive Plan ( <a href="#">incorporated by reference to Exhibit 10.3 to the Registrant's Annual Report on Form 10-K filed on March 4, 2014</a> ).
10.12*	2016 Equity and Cash Incentive Plan, as amended and restated through October 2, 2020 ( <a href="#">incorporated by reference to Exhibit 4.6 to the Registrant's Registration Statement on Form S-8 filed on December 17, 2020</a> ).
10.13*	Form of Incentive Stock Option Agreement under the MiMedx Group, Inc. 2016 Equity and Cash Incentive Plan ( <a href="#">incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on August 2, 2016</a> ).
10.14*	Form of Restricted Stock Agreement under the MiMedx Group, Inc. 2016 Equity and Cash Incentive Plan (for shares not registered under the Securities Act of 1933) ( <a href="#">incorporated by reference to Exhibit 10.9 to the Registrant's Current Report on Form 8-K filed on May 30, 2019</a> ).
10.15*	Form of Restricted Stock Agreement under the MiMedx Group, Inc. 2016 Equity and Cash Incentive Plan ( <a href="#">incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed on August 2, 2016</a> ).
10.16*	Form of Restricted Stock Agreement for Non-Employee Directors under the MiMedx Group, Inc. 2016 Equity and Cash Incentive Plan ( <a href="#">incorporated by reference to Exhibit 10.11 to the Registrant's Current Report on Form 8-K filed on May 30, 2019</a> ).
10.17*	Form of Nonqualified Stock Option Agreement under the MiMedx Group, Inc. 2016 Equity and Cash Incentive Plan ( <a href="#">incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed on August 2, 2016</a> ).
10.18*	Form of Director Restricted Stock Unit Award Agreement ( <a href="#">incorporated by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K filed on March 17, 2020</a> ).
10.19*	Form of Employee (Time-Vested) Restricted Stock Unit Award Agreement ( <a href="#">incorporated by reference to Exhibit 10.33 to the Registrant's Annual Report on Form 10-K filed on July 6, 2020</a> ).
10.20*	Form of Employee (Performance-Vested, uncertain number of shares) Restricted Stock Unit Award Agreement ( <a href="#">incorporated by reference to Exhibit 10.34 to the Registrant's Annual Report on Form 10-K filed on July 6, 2020</a> ).
10.21*	Form of Employee (Performance-Vested, certain number of shares) Restricted Stock Unit Award Agreement ( <a href="#">incorporated by reference to Exhibit 10.35 to the Registrant's Annual Report on Form 10-K filed on July 6, 2020</a> ).
10.22*	Form of Non-Employee Restricted Stock Award Agreement (vest into retirement) ( <a href="#">incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed on August 4, 2020</a> ).
10.23*	Form of Employee (Time-Vested) Restricted Stock Unit Award Agreement ( <a href="#">incorporated by reference to Exhibit 10.25 to the Registrant's Annual Report on Form 10-K filed on March 8, 2021</a> ).
10.24*	Letter Agreement dated April 10, 2019 between MiMedx Group, Inc. and Timothy R. Wright ( <a href="#">incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 9, 2019</a> ).
10.25*	Employment Offer Letter between MiMedx Group, Inc. and Peter M. Carlson, as amended and restated on June 30, 2021 ( <a href="#">incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q filed on August 3, 2021</a> ).
10.26*	Employment Offer Letter between MiMedx Group, Inc. and William F. Hulse IV dated November 4, 2019, ( <a href="#">incorporated by reference to Exhibit 10.30 to the Registrant's Annual Report on Form 10-K filed on July 6, 2020</a> ).

<b>Exhibit Number</b>	<b>Description</b>
10.27*	Employment Offer Letter between MiMedx Group, Inc. and Rohit Kashyap dated as of July 23, 2020 ( <a href="#">incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on November 20, 2020</a> ).
10.28*	Employment Offer Letter between MiMedx Group, Inc. and Robert B. Stein effective August 1, 2020 ( <a href="#">incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed on November 20, 2020</a> ).
10.29*	Form of Key Employee Retention and Restrictive Covenant Agreement ( <a href="#">incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on December 21, 2020</a> ).
10.30*	Form of Indemnification Agreement ( <a href="#">incorporated by reference to Exhibit 10.65 to the Registrant's Current Report on Form 8-K filed on July 15, 2008</a> ).
10.31*	Form of Director Restricted Stock Unit Award Agreement (Type I - Initial Grant, Full Amount) ( <a href="#">incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on August 3, 2021</a> ).
10.32*	Form of Director Restricted Stock Unit Award Agreement (Type II - Initial Grant, Pro Rata Amount) ( <a href="#">incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q filed on August 3, 2021</a> ).
10.33*	Form of Director Restricted Stock Unit Award Agreement (Type III - Annual Grant) ( <a href="#">incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q filed on August 3, 2021</a> ).
10.34	Technology License Agreement dated January 29, 2007 between MiMedx, Inc., Shriners' Hospitals for Children and University of South Florida Research Foundation ( <a href="#">incorporated by reference to Exhibit 10.32 to the Registrant's Current Report on Form 8-K filed on February 8, 2008</a> ).
10.35	Cooperation Agreement dated as of May 29, 2019 among MiMedx Group, Inc., M. Kathleen Behrens Wilsey, K. Todd Newton, Richard J. Barry, Prescience Partners, LP, Prescience Point Special Opportunity LP, Prescience Capital LLC, Prescience Investment Group, LLC d/b/a Prescience Point Capital Management LLC and Eiad Asbahi ( <a href="#">incorporated by reference to Exhibit 10.32 to the Registrant's Current Report on Form 8-K filed on May 30, 2019</a> ).
10.36##	Amendment No. 1 to Loan Agreement dated as of February 28, 2022, which amends that certain Loan Agreement dated as of June 30, 2020 by and among MiMedx Group, Inc., certain subsidiaries of MiMedx Group, Inc. parties thereto, the Lenders from time to time party hereto, Hayfin Services LLP, as administrative agent for the Lenders and as collateral agent for the Secured Parties ( <a href="#">incorporated by reference to Exhibit 10.38 to the Registrant's Annual Report on Form 10-K filed on February 28, 2022</a> ).
10.37*	Separation Agreement and General Release between MiMedx Group, Inc. and Timothy R. Wright dated September 15, 2022 ( <a href="#">incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on September 14, 2022</a> ).
10.38*	Interim Executive Employment Agreement between MiMedx Group, Inc. and K. Todd Newton dated September 14, 2022 ( <a href="#">incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on September 14, 2022</a> ).
10.39*	Restricted Stock Unit Agreement between MiMedx Group, Inc. and K. Todd Newton dated September 15, 2022 ( <a href="#">incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on September 14, 2022</a> ).
10.40*	Employment Offer Letter between MiMedx Group, Inc. and Ricci S. Whitlow dated December 27, 2022 ( <a href="#">incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on January 3, 2023</a> ).
10.41*	Letter Agreement between MiMedx Group, Inc. and Joseph H. Capper dated January 27, 2023 ( <a href="#">incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on January 27, 2023</a> ).
10.42*	Performance Stock Unit Agreement between MiMedx Group, Inc. and Joseph H. Capper dated January 27, 2023 ( <a href="#">incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on January 27, 2023</a> ).
10.43*	Nonqualified Stock Option Agreement between MiMedx Group, Inc. and Joseph H. Capper dated January 27, 2023 ( <a href="#">incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed on January 27, 2023</a> ).
10.44# ##	<a href="#">Platform Intellectual Property License Agreement by and between MiMedx Group, Inc. and Global Health Solutions, Inc. (d.b.a. Turn Therapeutics)</a> , dated as of December 7, 2022.
16.1	Letter from BDO USA, LLP dated March 30, 2021 ( <a href="#">incorporated by reference to Exhibit 16.1 to the Registrant's Current Report on Form 8-K filed on March 30, 2021</a> ).
21.1#	<a href="#">Subsidiaries of MiMedx Group, Inc.</a>
23.1#	<a href="#">Consent of Deloitte &amp; Touche LLP, Independent Registered Public Accounting Firm.</a>
23.2#	<a href="#">Consent of BDO USA, LLP, Independent Registered Public Accounting Firm.</a>
24.1#	Power of Attorney (included on the signature page to this Report).
31.1#	<a href="#">Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>

<b>Exhibit Number</b>	<b>Description</b>
31.2#	<a href="#">Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>
32.1#	<a href="#">Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>
32.2#	<a href="#">Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>
101.INS#	XBRL Instance Document
101.SCH#	XBRL Taxonomy Extension Schema Document
101.CAL#	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF#	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB#	XBRL Taxonomy Extension Label Linkbase Document
101.PRE#	XBRL Taxonomy Extension Presentation Linkbase Document

**Item 16. Form 10-K Summary**

Not applicable.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MIMEDX GROUP, INC.

February 28, 2023

By: /s/ Peter M. Carlson

Peter M. Carlson

Chief Financial Officer and Principal Financial Officer

## POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints William F. Hulse IV and Sajid N. Ajmeri and each of them acting individually, as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for him or her in any and all capacities, to sign any and all amendments to this Annual Report for the year ended December 31, 2022, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming our signatures as they may be signed by our said attorney to any and all amendments to said Annual Report.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<b>Signature / Name</b>	<b>Title</b>	<b>Date</b>
<u>/s/ Joseph H. Capper</u> Joseph H. Capper	Chief Executive Officer and Director (Principal Executive Officer)	February 28, 2023
<u>/s/ Peter M. Carlson</u> Peter M. Carlson	Chief Financial Officer (Principal Financial Officer)	February 28, 2023
<u>/s/ William L. Phelan</u> William L. Phelan	Senior Vice President and Chief Accounting Officer (Principal Accounting Officer)	February 28, 2023
<u>/s/ M. Kathleen Behrens</u> M. Kathleen Behrens	Chair of the Board (Director)	February 28, 2023
<u>/s/ James L. Bierman</u> James L. Bierman	Director	February 28, 2023
<u>/s/ Michael J. Giuliani</u> Michael J. Giuliani	Director	February 28, 2023
<u>/s/ William A. Hawkins III</u> William A. Hawkins III	Director	February 28, 2023
<u>/s/ Cato T. Laurencin</u> Cato T. Laurencin	Director	February 28, 2023
<u>/s/ K. Todd Newton</u> K. Todd Newton	Director	February 28, 2023
<u>/s/ Martin P. Sutter</u> Martin P. Sutter	Director	February 28, 2023
<u>/s/ Phyllis I. Gardner</u> Phyllis I. Gardner	Director	February 28, 2023

[\*\*\*] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and is the type that the registrant treats as private or confidential.

## PLATFORM INTELLECTUAL PROPERTY LICENSE AGREEMENT

THIS PLATFORM INTELLECTUAL PROPERTY LICENSE (the “**Agreement**”), effective as of the 30th day of November 2022 (the “**Effective Date**”), is made by and between Global Health Solutions, Inc. (d.b.a. Turn Therapeutics), a Delaware corporation, with its principal offices at 250 N Westlake Blvd, Suite 210, Westlake Village, CA 91362 (“**Turn**”), and MiMedx Group, Inc., a Florida corporation, with its principal offices at 1775 West Oak Commons Court, NE, Marietta, GA 30062 (“**MIMEDX**”). MIMEDX and Turn are sometimes referred to herein, individually, as a “**Party**” or, collectively, as the “**Parties**.”

### BACKGROUND

A. Turn has developed, licensed or owns proprietary technologies and biomaterials which may be used in wound care, burn care and surgical care, including as related to or comprising the FleX Product (as defined below);

B. The Parties entered into that certain License Agreement dated as of May 21, 2022 (“**Original Effective Date**”) under which Turn granted to MIMEDX certain exclusive and nonexclusive licenses to certain Turn technology and intellectual property rights associated with the FleX Product (the “**FleX License**”);

C. The Parties desire to terminate the FleX License and enter into this Agreement to grant to MIMEDX rights and licenses to Turn intellectual property, technologies and biomaterials including as relating to the FleX Product in order to allow MIMEDX to develop and commercialize the FleX Product and other products in the Field (as defined below), all in accordance with the terms and conditions set forth herein; and

D. Turn desires to grant such licenses to MIMEDX, all upon terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the covenants, conditions and obligations expressed herein, the sufficiency of which is hereby acknowledged by the Parties, and intending to be legally bound thereby, the Parties hereto agree as follows:

### ARTICLE 1 DEFINITIONS

Capitalized terms used in this Agreement have the meaning given thereto in this Article 1 or elsewhere in this Agreement.

1.1 “**Affiliate**” means, with respect to each Party, any company or other entity which directly or indirectly controls or is controlled by or is under common control with that Party. An entity shall be regarded as in control of another entity for purposes of this definition if it owns or controls fifty percent (50%) or more of the shares of the subject entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, for the election of the corresponding managing authority).

1.2 “**Calendar Quarter**” means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; provided, that (a) the first Calendar Quarter of the Term shall begin on the Effective Date and end on the first to occur of March 31, June 30, September 30 or December 31 thereafter and the last Calendar Quarter of the Term shall end on the last day of the Term and (b) the first Calendar Quarter of a Royalty Term for the Product in a country shall begin on the Launch Date of the Product in such country and end on the first to occur of March 31, June 30, September 30 or December 31 thereafter and the last Calendar Quarter of a Royalty Term shall end on the last day of such Royalty Term.

1.3 “**Calendar Year**” means each successive period of twelve (12) months commencing on January 1 and ending on December 31; provided, that (a) the first Calendar Year of the Term shall begin on the Effective Date and end on the first December 31 thereafter and the last Calendar Year of the Term shall end on the last day of the Term.

1.4 “**Commercialization**” or “**Commercialize**” means any and all activities directed to Manufacturing, having Manufactured, marketing, promoting, distributing, importing, exporting, using, offering to sell and/or selling a product, including the conduct of Post-Approval Studies, and activities directed to obtaining pricing and reimbursement approvals, as applicable.

1.5 “**Commercially Reasonable Efforts**” means the carrying out of obligations in good faith and in a diligent and sustained manner using such effort and employing such resources as MIMEDX would and does employ for other wholly new products (not modifications to existing products, *i.e.*, “soft launch”) it markets, distributes and sells; provided, that it is no less than what would normally be exerted or employed by a similarly situated life sciences company with similar resources for a product of similar market or profit potential or strategic value at a similar stage of its product life. For purposes

of the above, all relevant factors as measured by the facts and circumstances at the time such efforts are due shall be taken into account, including, as applicable and without limitation, mechanism of action; efficacy and safety; product profile; actual or anticipated Regulatory Agency approval and labeling; the nature and extent of market exclusivity (including patent coverage, proprietary position and regulatory exclusivity); costs; time required for and likelihood of obtaining Marketing Approval; expected competitive position of the Product vis-à-vis other therapies that have been or are reasonably expected to be developed, marketed and sold or used for the same or similar indications; the presence of third-party Patent Rights and Technology that is reasonably expected to impact the marketability of any such products; regulatory landscape; anticipated pricing and reimbursement for the Product; and actual or projected profitability.

1.6 “**Control**” means, with respect to Intellectual Property Rights, possession by the Party granting the applicable license to the other Party as provided herein of the power and authority, whether arising by ownership, license or other authorization, to grant such license without giving rise to (i) any payment or other consideration becoming due to a Third Party as a result of the grant or exercise of such license; or (ii) a violation of the terms of any written agreement with any Third Party.

1.7 “**Development,**” “**Developing**” or “**Develop**” means the research and development activities related to the generation, characterization, optimization, construction, expression, use and production of a product, any other research and development activities related to the pre-clinical testing and qualification of a product for clinical testing, and such other tests, studies and activities as may be required or recommended from time to time by any Regulatory Agency to obtain Marketing Approval of a product.

1.8 “**Exclusive Licensed Trademark**” means those of Turn’s trademarks, trade names and logos that are set forth on Exhibit B-1 attached hereto.

1.9 “**Field**” means biological products, including human or animal collagen, tissue, biologic or cellular-based materials (whether alone or in combination with a synthetic material), for use in the wound care, burn care, and surgical care field.

1.10 “**FDA**” means the United States Food and Drug Administration, or any successor agency thereto.

1.11 “**GAAP**” means generally accepted accounting principles in the United States, or internationally, as appropriate, consistently applied.

1.12 “**Intellectual Property Rights**” means all intellectual property rights worldwide arising under statutory or common law or otherwise including all (i) Patent Rights; (ii) rights associated with works of authorship including copyrights and mask work rights; (iii) rights relating to the protection of trade secrets and confidential information; (iv) trademarks, service marks, trade dress and trade names; and (v) any right analogous to those set forth herein and any other proprietary rights relating to intangible property.

1.13 “**Invention**” means any idea, invention, formulae, discovery, design, utility model, process, method, development, improvement, schematic or concept, whether patentable or not.

1.14 “**Launch Date**” means, with respect to a Product in a country, the date of the first commercial sale of the Product by or under authority of MIMEDX to a Third-Party customer in any part of the Territory after Marketing Approvals in such country.

1.15 “**Law**” means, individually and collectively, any and all laws, ordinances, orders, rules, rulings, directives and regulations of any kind whatsoever of any governmental authority or Regulatory Agency within the applicable jurisdiction.

1.16 “**Licensed Assets**” means any and all information and tangible materials comprising proprietary Inventions and Technology, regulatory approvals, data packages and files, including actual, pending and draft supplements thereto, supply agreements, clinical and regulatory information, marketing/ sales/ distribution information, manufacturing rights, and inventory, in each case pertaining to FleX, Licensed Patents, Turn Inventions or any Product, and in each case that is Controlled by Turn and reasonably necessary for the Commercialization of a Product by MIMEDX in accordance with this Agreement.

1.17 **“Licensed Patents”** means the Patent Rights listed in Exhibit A and any Patent Rights covering a Turn Invention (including all reissues, extensions, substitutions, confirmations, re-registrations, re-examinations, invalidations, supplementary protection certificates and patents of addition) and continuation patent applications (including all provisional applications, requests for continuation, continuations, continuations-in-part and divisionals) and all PCT applications, including any corresponding national stage applications.

1.18 **“Licensed Technology”** means, individually and collectively, without duplication, the Licensed Patents and Licensed Assets.

1.19 **“Licensed Trademarks”** means the Exclusive Licensed Trademarks and the Non-Exclusive Licensed Trademarks.

1.20 **“Manufacturing” or “Manufacture”** means, as applicable, all activities associated with the production, manufacture, processing, filling, finishing, packaging, labeling, shipping, and storage of a product, including process and formulation development, process validation, stability testing, manufacturing scale-up, pre-clinical, clinical and commercial manufacture and analytical development, product characterization, quality assurance and quality control development, testing and release.

1.21 **“Marketing Approval”** means, with respect to the Product in a jurisdiction, approval from the relevant Regulatory Agency to commence marketing and sales of the Product in such jurisdiction, including, without limitation, 510(k) clearance in the United States from the FDA.

1.22 **“MIMEDX Inventions”** means any Invention or Technology, whether or not patentable, discovered, developed, conceived or reduced to practice by MIMEDX or its Affiliates or sublicensees during the Term, including without limitations, any improvements of MIMEDX Background IP or any new Product Developed by MIMEDX hereunder.

1.23 **“Net Sales”** means the total of the gross revenue received and recognized by MIMEDX from commercial sales of the Product(s) sold to Third Parties in the Territory in a particular Calendar Quarter, less the following deductions:

- (i) transport, freight and value added (or like) tax;
- (ii) regular trade and quantity and cash discounts, allowances and credits;
- (iii) any credits, allowances or chargebacks given or made for rejection or returns of Product or for retroactive price reductions and billing errors;
- (iv) any price protections, rebates and cash discounts to place inventory in trade;
- (v) freight, postage, insurance and other transportation charges paid by MIMEDX;
- (vi) bad debt written off by MIMEDX;
- (vii) sales and commissions paid by MIMEDX to distributors or selling agents; and
- (viii) applicable taxes paid by MIMEDX (other than taxes based on net income) or withheld from amounts payable to MIMEDX.

All calculations shall be made in accordance with GAAP and based on or valued as based on bona fide arm’s length transactions.

1.24 **“Non-Exclusive Licensed Trademarks”** means those of Turn’s trademarks, trade names and logos that are set forth on Exhibit B-2 attached hereto.

1.25 **“Patent Rights”** means all domestic and international patents (including all reissues, extensions, substitutions, confirmations, re-registrations, re-examinations, invalidations, supplementary protection certificates and patents of addition) and patent applications (including all provisional applications, requests for continuation, continuations, continuations-in-part and divisionals) and all PCT applications, including any corresponding national stage applications.

1.26 **“Post-Approval Study”** means a clinical study of the Product initiated in a country after receipt of Marketing Approval for the Product in such country.

1.27 **“Product”** means (i) Turn’s FleX™ Antimicrobial Collagen Matrix product as further described on Exhibit C attached hereto (the **“FleX Product”**) or (ii) any product that (a) is covered in whole or in part by a Valid Claim under the Licensed Patents; and/or (b) the development, manufacture, use, sale, offering for sale, or importation of which incorporates, uses, has used or is derived from, in whole or in part, the Licensed Assets.

1.28 **“Regulatory Agency”** means any governmental regulatory authority that regulates the Development, Manufacture, market approval, sale, distribution, packaging, reimbursement, pricing or use of the Product, including the FDA.

1.29 **“Royalty Term”** means, for each Product, on a country by country basis, the period beginning on the Launch Date of the Product in such country and ending on the latest to occur of the last date on which the Product is covered by a Valid Claim within the Licensed Patents in such country.

1.30 **“Sublicense Agreement”** means a written agreement between MIMEDX (or its Affiliate) and a Sublicensee in which MIMEDX grants a sublicense to such Third Party of the rights granted by Turn to MIMEDX pursuant to this Agreement.

1.31 **“Supply Agreement”** means a supply and quality agreement to be entered into between MIMEDX and a Third Party under which such Third Party will supply all of MIMEDX’s requirements for the FleX Product.

1.32 **“Sublicensee”** means a Third Party to whom MIMEDX grants a sublicense under the rights granted to MIMEDX by Turn hereunder.

1.33 **“Technology”** means any and all biological materials and other tangible materials, data, information, technology, know-how, processes, techniques, methods, skills, proprietary information, trade secrets, assays, skills, experience, techniques and results of experimentation and testing, including pre-clinical and clinical test data and quality control data, patentable or otherwise.

1.34 **“Territory”** means: (i) for the FleX Product, United States, Australia, Canada, Japan, Kuwait, New Zealand, Saudi Arabia, Singapore, South Korea, Taiwan and the UAE; (ii) for all other Products, worldwide.

1.35 **“Third Party”** means any person, corporation or other business entity, other than MIMEDX, Turn and their respective Affiliates.

1.36 **“[\*\*\*]”** means the [\*\*\*]

1.37 **“Turn Inventions”** means any Patent Rights, Technology or Inventions, conceived or reduced to practice by Turn or its Affiliates or sublicensees prior to or during the Term.

1.38 **“Valid Claim”** means a claim (i) of any issued, unexpired patent within the Licensed Patents that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through rescission, disclaimer, or otherwise or (ii) of any patent application within the Licensed Patents that was filed in good faith and is being prosecuted actively and in good faith and has not been cancelled, withdrawn, or abandoned and has not been pending for more than seven (7) years. If a claim of a patent application ceases to be a Valid Claim under item (i) because of the passage of time and later issues as part of a patent within item (ii), then it shall again be considered to be a Valid Claim effective as of the grant or issuance of such patent.

1.39 **Interpretation.** The captions and headings in this Agreement are for convenience only and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections or Exhibits mean the particular Articles, Sections and Exhibits to this Agreement and references to this Agreement include all Exhibits hereto. Unless context otherwise clearly requires, whenever used in this Agreement: (i) the words “include” or “including” shall be construed as incorporating, also, “but not limited to” or “without limitation;” (ii) the word “day” or “year” shall mean a calendar day or year unless otherwise specified; (iii) the word “notice” shall mean notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications

contemplated under this Agreement; (iv) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to this Agreement (including all Exhibits); (v) provisions that require that a Party or the Parties “agree,” “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter; or otherwise; (vi) words of either gender include the other gender; (vii) words using the singular or plural number also include the plural or singular number, respectively; and (viii) references to any specific Law or article, section or other division thereof, shall be deemed to include the then current amendments thereto or any replacement thereof. For purposes of this Agreement, neither Party shall be deemed to be acting “under authority of” the other Party.

## **ARTICLE 2 LICENSE**

### 2.1 License.

2.1.a Subject to the terms and conditions of this Agreement, Turn hereby grants to MIMEDX an exclusive, sublicensable (in accordance with Section 2.2) license in, to and under the Licensed Patents and in, to and under the Licensed Assets during the Term to Develop, Manufacture and Commercialize Products in the Field and Territory.

2.1.b Subject to the terms and conditions of this Agreement (including, without limitation, Section 4.2), Turn hereby grants to MIMEDX a license during the Term to use the Licensed Trademarks in the Territory in connection with the Commercialization of the Products pursuant to the terms and conditions of Section 4.2. The license granted to MIMEDX under this Section 2.1.b (i) with respect to the Exclusive Licensed Trademarks shall be exclusive in the Field and Territory, and (ii) with respect to the Non-Exclusive Licensed Trademarks shall be non-exclusive and used solely for the purpose of the Commercialization of the Products in the Field and Territory.

2.1.c MIMEDX shall have the right to exercise the foregoing licenses through one or more Affiliates; provided that MIMEDX shall be responsible for the acts and omissions of any such Affiliates as if such acts and omissions were those of MIMEDX.

2.1.d. Upon MIMEDX’s reasonable request, Turn shall provide MIMEDX with a list of Licensed Patents that cover the Products itself in order for MIMEDX to mark Products and/or the packaging, and labels thereof with such patent information as required by Law, and MIMEDX shall appropriately mark the Products marketed and sold by MIMEDX with reference to the Licensed Patents.

2.2 Sublicense. MIMEDX shall have the right to grant sublicenses to all or any portion of the rights granted in Section 2.1 above to a Sublicensee. Each sublicense granted by MIMEDX pursuant to this Section 2.2 shall be subject and subordinate to the terms of this Agreement and shall contain terms consistent with this Agreement, including but not limited to MIMEDX’s royalty obligations under Section 3.1. Turn will not assert the Licensed Technology against any Third Party that purchases Product directly or indirectly from MIMEDX (or its Affiliates or distributors) in full compliance with the terms of this Agreement. MIMEDX shall be fully financially responsible to Turn for the acts or omissions of any Sublicensee, including but not limited for any breach of this Agreement. For each sublicense, MIMEDX shall deliver to Turn written notice of the terms, including the proposed sublicensee’s identity, of any proposed sublicense agreement, or modification.

2.3 No Other Rights. Each Party acknowledges that the rights and licenses granted under this Article 2 and elsewhere in this Agreement are limited to the scope expressly granted. Accordingly, except for the rights and licenses expressly granted in this Agreement, neither Party is granted any right or license under any Patent Rights or Intellectual Property Rights of the other Party, nor shall any such right or license be implied or imputed, by estoppel or otherwise. All rights with respect to Patent Rights or Intellectual Property Rights that are not specifically granted herein are reserved to the owner thereof.

2.4 Right to Notice and First Refusal. During the Term, MIMEDX will be Turn’s preferred Commercialization partner in the Field, such that Turn shall afford MIMEDX the opportunity to acquire exclusive Development, Manufacture and Commercialization rights for the Flex Product in the Field for countries and jurisdictions outside of the Territory in accordance with this Section 2.4. Turn will promptly notify MIMEDX in writing (“Turn Notice”) prior to entering into *bona fide* negotiations with a Third Party for Development, Manufacture and Commercialization rights for the Flex Product outside the Territory (the “New Territory”). Similarly, Turn will promptly notify MIMEDX in writing (“Second Turn Notice”) prior to entering into any *bona fide* term sheet with a Third Party for Development, Manufacture and

Commercialization rights for the Flex Product in a New Territory. MIMEDX shall have up to thirty (30) days after receipt of the Turn Notice to notify Turn in writing of its interest in obtaining a royalty-bearing license to the Flex Product in the New Territory. If Turn received a *bona fide* proposed term sheet from Third Party, MIMEDX shall notify Turn in writing of its interest in obtaining a royalty-bearing license to the Flex Product in the New Territory within at least ten (10) days of the Second Turn Notice. If MIMEDX notifies Turn in writing within the shorter of such thirty (30) day or ten (10) day period that it is interested in such New Territory, then the Parties shall promptly commence good faith negotiations for a period of up to three (3) months after Turn's receipt of such notice if there is no *bona fide* term sheet proposed by a Third Party in an effort to reach a mutually acceptable definitive agreement (or amendment to this Agreement) for such New Territory (the "New Territory Negotiation Period"). If there is a *bona fide* term sheet proposed by a Third Party, then the Parties shall commence or continue good faith negotiations for no more than thirty (30) days in an effort to reach a mutually acceptable definitive agreement (or amendment to this Agreement) or at least a binding term sheet to continue working towards a mutually acceptable definitive agreement (or amendment to this Agreement). If (a) MIMEDX does not notify Turn in writing within the applicable time period that it is interested in the subject New Territory or (b) despite each Party's good faith efforts, Turn and MIMEDX are not able to reach agreement on and execute a definitive agreement within such three (3) month period, or at least a binding term sheet within such thirty (30) day period, then Turn may enter into a term sheet or execute an agreement with any Third Party for Development, Manufacture and Commercialization rights to, or Develop, Manufacture and Commercialize on its own, the Flex Product in the Field in the New Territory provided that any such agreement with a Third Party shall not be on more favorable terms to the Third Party than any final offer proposed by MIMEDX during the Negotiation Period (provided that MIMEDX reinstates such offer to acquire said rights).

2.5 Assignment by Turn to a Third Party. Turn acknowledges and agrees that in the event Turn sells, conveys, assigns or otherwise transfers the Licensed Technology, in whole or any portion thereof, to a Third Party, the Licensed Technology shall remain subject to the rights in such Licensed Technology granted to MIMEDX hereunder and the obligations under this Agreement applicable to such sold, conveyed, assigned or transferred Licensed Technology, including with respect to the license under such Licensed Technology granted to MIMEDX hereunder, will run with such Licensed Technology.

2.6 Bankruptcy. The Parties acknowledge and agree that all rights and licenses granted under or pursuant to this Agreement by Turn to MIMEDX are and shall otherwise be deemed to be, for purposes of 11 U.S.C. 365(n), license rights to "intellectual property" as defined under the U.S. Bankruptcy Code. In this regard, the Licensed Technology shall be deemed to be "intellectual property" within the meaning of 11 U.S.C. 365(n). The Parties hereto agree that MIMEDX, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code including, without limitation, its rights pursuant to 11 U.S.C. 365(n). The Parties further agree that (a) in the event of the commencement of bankruptcy proceedings by or against Turn under the U.S. Bankruptcy Code, MIMEDX shall be entitled to retain all of its rights under this Agreement; provided, that MIMEDX continues to perform under the Agreement; and (b) to avoid a loss of rights under this Agreement in the event of a bankruptcy proceedings by or against MIMEDX under the U.S. Bankruptcy Code, Turn hereby is granted and obtains a lien against the license rights to the "intellectual property" granted by this Agreement for continued payment as a secured creditor under the U.S. Bankruptcy Code. MIMEDX will cooperate with Turn to execute document(s) to perfect this security interest. Except as provided herein in connection with sublicensing under and subject to this Agreement, MIMEDX may not, as part of a bankruptcy proceeding, assign or transfer any of its rights or obligations under this Agreement without the prior written consent of Turn, such consent not to be unreasonably withheld, whether by operation of law or otherwise, including in connection with a change in control, merger, acquisition, consolidation, asset sale or other reorganization, and any attempt at such assignment or transfer will be void.

### **ARTICLE 3 PAYMENTS, ROYALTIES and MILESTONES**

#### 3.1 Royalty Payments on Products.

3.1.a Royalty Rate on Sales Amount. Subject to the terms and conditions of this Agreement, in further consideration of the license granted by Turn to MIMEDX under this Agreement, during the Royalty Term, MIMEDX shall pay to Turn on a quarterly basis a royalty of [\*\*\*] of Net Sales.

3.1.b Royalty Reports; Royalty Payment. Commencing in the first Calendar Quarter following the Launch Date, MIMEDX shall provide to Turn a written report within forty-five (45) days of the end of each Calendar Quarter during the Term, setting forth: (i) the MIMEDX calculation of Net Sales of each Product during such Calendar Quarter; and (ii) the total royalties payable to Turn hereunder. Simultaneously with the delivery of each such report, MIMEDX shall pay to Turn the total royalties due to Turn for the period of such report. If no royalties are due, MIMEDX shall so report. In the event that MIMEDX or its Affiliates or Sublicensees make any adjustment to such deductions after the associated Net Sales

have been reported pursuant to this Section 3.1.b, the adjustments and payment of any amounts due shall be reported with the next quarterly report.

3.1.c Records. MIMEDX shall keep, and shall require its Affiliates and Sublicensees to keep, complete and accurate records related to Product in sufficient detail to enable the royalties payable under this Agreement to be determined. Such records shall be kept at the principal place of business of MIMEDX for at least thirty-six (36) months following the end of the Calendar Year to which such books and records pertain.

3.1.d Audits. Upon Turn's reasonable request, but not more frequently than once in each Calendar Year during the Term (except as required by law or regulators), MIMEDX shall permit an independent certified public accountant selected by Turn, reasonably acceptable to MIMEDX in good faith, and operating under a confidentiality agreement acceptable to MIMEDX in its sole discretion, to have access during normal business hours to such records of MIMEDX and its Affiliates at MIMEDX's principal place of business for the purpose of and to the extent necessary to verify the accuracy of the reports provided by MIMEDX pursuant to Section 3.1.b. The independent public accountant shall disclose to Turn only (a) the accuracy of Net Sales reported and the basis for royalty payments made to Turn under this Agreement and (b) the difference, if any, by which such reported and paid amounts vary from amounts determined as a result of the audit and the details concerning such difference. Except as required by applicable law, no other information shall be provided to Turn. No record may be audited more than once and audits may not be conducted for any calendar year ending more than three (3) years prior to the date of such request. If such accounting firm identifies in its written report a discrepancy made during any period, MIMEDX shall pay to Turn any underpayment discovered by such audit within thirty (30) days after the accountant's report. If the audit reveals an overpayment by MIMEDX, then MIMEDX may take a credit for such overpayment against any future payments due to Turn. If the audit reveals either an overpayment or accurate payments by MIMEDX, then Turn's next opportunity to audit MIMEDX's royalty payments shall be delayed (*i.e.*, skip) a year. If Turn opts not to conduct an audit during any Calendar Year, or if due to a prior audit Turn's loses the right to conduct an audit during a Calendar Year, Turn does not lose the right to audit any royalty payments not previously audited by Turn. The written report from any audit shall identify the royalty payments being audited and shall be binding upon the Parties. The fees charged by such accounting firm shall be paid by Turn, unless the audit discovers an underpayment by MIMEDX of ten percent (10%) or more of the total amounts due hereunder in the audited period, in which case such fees shall be paid by MIMEDX.

3.1.e Adjustment for Third Party Royalties. If MIMEDX reasonably believes that it is necessary to obtain or maintain a license from any Third Party under any Patent Rights in order to Manufacture or Commercialize a Product in the Field and in the Territory (each, a "**Third Party License**"), then MIMEDX will have the right to credit up to fifty percent (50%) of any royalty payments actually paid by MIMEDX or its Affiliates under such Third Party License in any Calendar Quarter against any royalty payment payable to Turn for such Product; provided that Turn's contribution shall never exceed fifty percent (50%) of the royalties due and owing to Turn under this Agreement for such Product without the Third Party License. Notwithstanding the foregoing, all royalties MIMEDX is required to pay to a Third Party in connection with the [\*\*\*] may be deducted from royalty payments payable to Turn without regard to the limitations set forth in this Section 3.1e.

3.2 Milestone Payments. MIMEDX will pay Turn the non-refundable one-time payments set forth in the table below upon achievement (in the aggregate by MIMEDX itself, an Affiliate or a Sublicensee) of each milestone event set forth below.

	<u>Milestone</u>	<u>Payment</u>
I.	Execution of the Agreement	[\$***]

- I. The later of Flex Product: (i) Marketing Approval in the United States from the FDA, (ii) MIMEDX entering into the Supply Agreement, or (iii) Turn's completion of the regulatory and quality activities set forth in Exhibit D ("Turn Activities") \$[\*\*\*]
- I. Upon Launch of each Product \$[\*\*\*]
- I. First occurrence of aggregate Product(s) Net Sales in the Territory of greater than [\*\*\*] during a Calendar Year. \$[\*\*\*]
- I. First occurrence of aggregate Product(s) Net Sales in the Territory of greater than [\*\*\*] during a Calendar Year. \$[\*\*\*]
- I. First occurrence of aggregate Product(s) Net Sales in the Territory of greater than [\*\*\*] during a Calendar Year. \$[\*\*\*]

- |    |   |         |
|----|---|---------|
| I. | First occurrence of aggregate Product(s) Net Sales in the Territory of greater than [***] during a Calendar Year.                                       | \$[***] |
| I. | First occurrence of aggregate Product(s) Net Sales in the Territory of greater than Two Hundred Million Dollars (\$200,000,000) during a Calendar Year. | \$[***] |
| I. | First Occurrence of aggregate Product(s) Net Sales greater than [***] during a Calendar Year for two (2) consecutive Calendar Years.                    | \$[***] |

MIMEDX shall notify Turn in writing within sixty (60) days after the achievement of each such milestone event set forth in this Section 3.2 and each such notice shall be accompanied by the corresponding milestone payment set forth in this Section 3.2. Further each Milestone IV-IX shall only payable once upon the first occurrence of such event.

**ARTICLE 4  
DEVELOPMENT AND COMMERCIALIZATION OF PRODUCT**

4.1 Development and Commercialization of Products. MIMEDX shall use Commercially Reasonable Efforts to Develop and/or Commercialize one or more Products under this Agreement. MIMEDX shall be solely responsible for and have sole authority to conduct all Development and Commercialization activities that are required to commercialize the Product(s) in the Field in the Territory, including (i) developing and executing a commercial launch plan, (ii) developing a strategy for, and negotiating with applicable Regulatory Agencies regarding the price and reimbursement status of the Product, (iii) marketing and promotion, (iv) booking sales, and distribution and performance of related services, (v) handling all aspects of order processing, invoicing, (vi) providing customer support, and (vii) conforming its practices and procedures to applicable Law relating to the marketing and promotion of the Product in the Field in the Territory. Without limiting Section 3.2, Turn acknowledges and agrees that MIMEDX does not guarantee that it will be successful in any Development or Commercialization efforts hereunder, including, without limitation, as the result of any failure to obtain Marketing Approvals with respect to a Product in particular jurisdictions. Notwithstanding the generality of the foregoing, MIMEDX will be responsible for

complying with all applicable Laws and regulatory responsibilities, regarding its use of the Licensed Technology, Licensed Trademark, and all its activities associated with Commercialization of the Product.

#### 4.2 Licensed Trademarks.

4.2.a Use of Licensed Trademarks. During the Term, and as provided for herein, MIMEDX and its Affiliates and Sublicensees will have the right to use the Licensed Trademarks only in connection with the Commercialization of the Products, including by placing the Licensed Trademarks on all marketing and promotional materials and packaging materials for the Products (the "Permitted Use"). Unless otherwise agreed in writing, MIMEDX and its Affiliates and Sublicensees are not permitted to make any use of the Licensed Trademarks in connection with products or services other than the Permitted Use. For the avoidance of doubt, nothing under this Section 4.2.a shall be deemed to require MIMEDX or its Affiliates or Sublicensees to mark any Product with any Licensed Trademark. It is understood that the size and placement of the Licensed Trademarks may be subordinate to the trademarks of MIMEDX and its Affiliates. During the term of this Agreement and at all times following termination or expiration of this Agreement, MIMEDX and its Affiliates and Sublicensees shall not use (a) any trademark or service mark which is confusingly similar to, or a colorable imitation of, the Licensed Trademarks or any part thereof, or (b) any word, symbol, character, or set of words, symbols, or characters, which in any language would be identified as the equivalent of the Licensed Trademarks or that are otherwise confusingly similar to, or a colorable imitation of, the Licensed Trademarks. Neither Party shall knowingly engage in any conduct which may place the Licensed Trademarks in a negative light or context.

4.2.b Quality Standards. All representations of Licensed Trademarks that MIMEDX intends to use shall be in the form as set forth on Exhibits B-1 and B-2. If MIMEDX uses any of the Licensed Trademarks, MIMEDX shall cause the appropriate designation "TM" or registration symbol "®" to be placed adjacent to the Licensed Trademarks, and agrees that the nature and quality of advertising, promotional, and other uses of the Licensed Trademarks by MIMEDX shall conform to standards set by, and be under the control of, Turn. MIMEDX acknowledges and agrees that Turn may adopt reasonable standards and specifications for the use of the Licensed Trademarks (the "Quality Standards") and that MIMEDX shall abide by such Quality Standards in the use of the Licensed Trademarks, provided that no such Quality Standard prohibits or inhibits MIMEDX's use of the Licensed Marks as agreed herein. MIMEDX acknowledges and agrees that the Turn may amend the Quality Standards from time to time and that, upon written notice from Turn of any and all such amendments, MIMEDX, as soon as commercially practicable thereafter, shall conform its marketing, promoting, advertising, distributing, provision and selling of Product under Licensed Trademarks to such amended Quality Standards, provided that no such amended Quality Standard prohibits or inhibits MIMEDX's use of the Licensed Marks as agreed herein.

4.2.c Rights in Licensed Trademarks. The Licensed Trademarks will remain the exclusive property of Turn, and all use of the Licensed Trademarks and any goodwill associated therewith shall inure to the exclusive benefit of Turn. Unless otherwise agreed, Turn shall, at its sole cost and expense, register, maintain, and enforce the Licensed Trademarks at its reasonable and sole discretion. If Turn fails to continue to register, maintain, and enforce the Licensed Trademarks, Turn will provide MIMEDX with timely notice and will provide MIMEDX with a reasonable opportunity to assume responsibility for the continued register, maintain, and enforce the Licensed Trademarks.

4.3 Advertising and Promotional Materials. MIMEDX will be responsible for the creation, preparation, production, reproduction and filing with the applicable Regulatory Agencies, of relevant written sales, promotion and advertising materials relating to the Product as required by Law ("**Promotional Materials**") for use in the MIMEDX Territory. All such Promotional Materials will be compliant with all applicable laws, rules and regulations.

4.4 Launch Date. MIMEDX will use Commercially Reasonable Efforts to have a Launch Date of the Flex Product in the United States no later than four (4) months after the later of (i) the execution of the Supply Agreement, or (ii) the date of Marketing Approval in the United States from the FDA for the Product. For clarity, failure of MIMEDX to use Commercially Reasonable Efforts to achieve a Launch Date for the Flex Product in the United States as provided under this Section 4.4 shall not permit Turn to terminate the license under Licensed Technology granted to MIMEDX hereunder with respect to its license for the Flex Product unless MIMEDX fails to launch the Product within ten (10) months after the later of (i) or (ii) above. With the exception of delays to the Launch Date due to Turn's failure to complete the Turn Activities or other agreed upon regulatory and quality obligations, the Parties further agree that, if the Product is not launched within the four (4) month period, then MIMEDX shall be obligated to make monthly payment to Turn in the amount of [\*\*\*]; provided that such amounts paid to Turn by MIMEDX shall be deducted from Milestone II payment. All payments pursuant to this Section 4.4 are non-refundable.

## ARTICLE 5 INTELLECTUAL PROPERTY RIGHTS

5.1 Inventorship. Inventorship for patentable inventions conceived or reduced to practice during the course of the performance of activities pursuant to this Agreement shall be determined in accordance with the principles that are used to determine inventorship under the patent laws of the country where such invention is made; provided, however, that if Joint IP is invented in more than one country and one of such countries is the United States, such inventorship shall, if permitted by the applicable local Law, be determined by United States patent laws; provided, further, however, that any patent application filed in the United States shall comply with the United States patent laws relating to inventorship.

## 5.2 Ownership of Inventions.

5.2.a Subject to the licenses granted to MIMEDX under Section 2.1, as between the Parties, all Inventions and Technology (including all Intellectual Property Rights therein) Controlled by either Party prior to the Effective Date and/or developed, invented or conceived and reduced to practice by such Party independently from the activities contemplated under this Agreement (collectively, "**Background IP**") are and shall, as between the Parties, remain the sole property of such Party.

5.2.b Subject to the licenses granted to MIMEDX under Section 2.1, Turn shall own the entire right, title and interest in and to all Turn Inventions (and Patent Rights claiming patentable inventions therein) first made or discovered solely by employees or consultants of Turn or acquired solely by Turn.

5.2.c MIMEDX shall own the entire right, title and interest in and to all MIMEDX Inventions (and Patent Rights claiming patentable inventions therein) first made or discovered solely by employees or consultants of MIMEDX or acquired solely by MIMEDX.

5.2.d Unless otherwise agreed in a separate development or other agreement, if MIMEDX and Turn jointly develop, invent or conceive and reduce to practice any Inventions or Technology during the Term that relate to any Product(s) ("**Joint IP**"), Turn agrees that it will assign to MIMEDX all of Turn's interest in and to such Joint IP, including all Intellectual Property Rights therein, and that such Joint IP shall be deemed MIMEDX Inventions for the purposes of this Agreement. MIMEDX shall have exclusive rights under such Joint IP in the Field and shall grant, and hereby does grant, Turn exclusive rights under such Joint IP for all uses outside of the Field. Neither Party shall have any obligation to pay the other Party any royalties or other fees for exercise of its rights to the Joint IP as set forth herein.

## 5.3 Prosecution and Maintenance of Patent Rights.

5.3.a Licensed Patents. During the Term of this Agreement, Turn shall make commercially reasonable efforts to prosecute to issuance, maintain the Licensed Patents and perfect the intellectual property rights licensed to MIMEDX under this Agreement, including paying all applicable fees (including, without limitation, all taxes and maintenance fees) in its sole and reasonable discretion. If Turn fails to continue to prosecute to issuance or maintain any Licensed Patents or Patent Rights that Cover Turn Inventions pertaining to the Product, prior to abandoning such Licensed Patents or Patent Rights, Turn will provide MIMEDX with timely notice and will provide MIMEDX with a reasonable opportunity to assume responsibility for the continued prosecutions and maintenance of such Licensed Patents or Patent Rights the Cover Turn Inventions pertaining to the Product. If any of the applications for the Licensed Patents are abandoned, rejected or not maintained and such abandonment, rejection or non-maintenance has a material effect on the protection offered by the Licensed Technology to MIMEDX, the Parties will negotiate in good faith a reasonable reduction of the Royalty payable to Turn. MIMEDX may designate in writing any country or countries in which MIMEDX desires Turn to file, prosecute and maintain Patent Rights (in addition to those Licensed Patents set forth on **Exhibit A**). If Turn agrees to file such additional Patent Rights, Turn shall be responsible for paying all applicable fees and such additional Patent Rights shall be deemed Licensed Patents under this Agreement. If Turn does not wish to file, prosecute and maintain such additional Patent Rights in any country, Turn will assign all such Patent Rights in such country to MIMEDX and MIMEDX shall have the sole right to prosecute and maintain such Patent Rights in MIMEDX's name.

5.3.b MIMEDX Technology. MIMEDX has the sole right to, at its discretion and expense, to prosecute and maintain all Patent Rights comprising MIMEDX's Background IP and MIMEDX Inventions.

5.3.c Joint IP. Subject to Turn's continuing right to the timely prior review of and comment on material documents, MIMEDX has the initial right, at its sole discretion, to file, prosecute and maintain all Patent Rights comprising Joint IP in the name of MIMEDX. MIMEDX shall promptly notified Turn in writing of its intention to (or not to) file, prosecute or maintain any or all such Patent Rights, or to abandon any or all such Patent Rights. If MIMEDX opts not to file, prosecute or maintain any or all Joint IP Patent Rights, Turn shall have the right, at its sole discretion, to file, prosecute and

maintain all Patent Rights comprising Joint IP. The Parties shall use Commercially Reasonable Efforts to make available to the other Party or its authorized attorneys, agents or representatives, such of its employees, consultants and representatives as the Party filing, prosecuting or maintaining said Patent Rights deems necessary in order to assist in obtaining or maintaining patent protection for Joint IP. Each Party shall sign, or use Commercially Reasonable Efforts to have signed, all legal documents necessary to file and prosecute patent applications or to obtain or maintain patents in respect of such Joint IP, at its own cost and expense.

5.3.d Cooperation; Patent Challenges. Each Party hereby agrees: (i) to make its employees, agents and consultants reasonably available to the other Party (or to the other Party's authorized attorneys, agents or representatives), to the extent reasonably necessary to enable such Party to undertake patent prosecution for the Licensed Patents, Patent Rights in any Turn Inventions or any Joint IP; (ii) to provide the other Party with copies of all material correspondence pertaining to prosecution of the Licensed Patents, Patent Rights in any Turn Inventions or any Joint IP with the patent offices in the Territory; (iii) to cooperate, if necessary and appropriate, with the other Party in gaining patent term extensions wherever applicable to the Licensed Patents, Patent Rights in any Turn Inventions or any Joint IP; and (iv) to endeavor in good faith to coordinate its efforts with the other Party to minimize or avoid interference with the prosecution and maintenance of the other Party's patent applications. Without limiting the foregoing but excluding with respect to any Patent Rights in any MIMEDX Inventions, the Party prosecuting and maintaining the Patent Rights shall furnish to the other Party copies of substantive documents (e.g., applications, office actions and responses) relevant to any such efforts in advance with sufficient time for such other Party to review and provide comments on such documents and shall in good faith take such comments into account. The Parties acknowledge that they have a shared community of legal interest in the development of products that can be manufactured, used, sold and otherwise commercialized without infringing the intellectual property rights of any third party. The Parties may exchange confidential attorney-client communications to advance certain common legal interests in accordance with this Agreement and shall not disclose such communications to a third party, nor to employees of either party who do not have a need to know the content of such communication.

5.3.e Patent Expenses. The patent filing, prosecution and maintenance expenses incurred after the Effective Date with respect to Patent Rights shall be borne by each Party filing, prosecuting and maintaining such Patent Rights under this Article 5.

5.3.f Turn's Rights. For clarity, Turn's rights to any Background IP and Turn Inventions will be subject to the licenses granted to MIMEDX under Section 2.1 above, including with for clarity the associated exclusivity obligations with respect to the Field in the Territory for the Term of this Agreement.

5.3g MIMEDX Rights. For clarity, MIMEDX will have the sole right and authority, in its sole discretion, to file, prosecute and maintain any Patent Rights in any MIMEDX Background IP and any MIMEDX Inventions hereunder in the name of MIMEDX.

5.4 Third Party Infringement. Each party will promptly notify the other if it becomes aware of acts of infringement or misappropriation of the Licensed Technology related to any Product by a Third Party which infringement bears adversely on MIMEDX's enjoyment of the rights granted hereunder ("**Commercially Relevant Infringement**"). The Parties shall provide each other with all evidence or information relating to such Commercially Relevant Infringement which is available to it and which it is legally able to disclose. MIMEDX shall have the initial right (but not the obligation) during the Term, at its own cost and expense, to institute and conduct legal action against third-party infringers of the Licensed Technology with respect to the Product, with counsel determined by MIMEDX. MIMEDX shall notify Turn within thirty (30) days of receiving written notice of Commercially Relevant Infringement as to whether it intends to commence any legal action. If no legal action is commenced within ninety (90) days of receiving written notice of Commercially Relevant Infringement, Turn shall have the right during the Term, at its own cost and expense, to institute and conduct legal action against third-party infringers of the Licensed Technology with respect to the Product, with counsel determined by Turn.

In connection with any action to enforce any Licensed Technology, a Party will provide reasonable cooperation to the Party instituting and conducting legal action against third-party infringers (the "Enforcing Party") concerning factual matters including, for example, by becoming a named party in the litigation if reasonably required to maintain the action, answering discovery requests, and providing testimony at deposition and trial without charge to the Enforcing Party other than recovery of statutory witness fees and its actual reasonable out-of-pocket costs incurred in connection with providing such cooperation. Any and all recoveries from any suit or action instituted or prosecuted based on infringement of the Licensed Technology for the Product shall first be distributed to reimburse each Party's reasonable out-of-pocket costs and expenses incurred in connection with the suit or action. The remaining recoveries shall be shared ninety-ten percent (90%/10%) in favor of MIMEDX if MIMEDX is the Enforcing Party, and on a fifty-fifty percent (50%/50%) basis if Turn is the Enforcing Party.

5.5 Claimed Infringement. Except as provided below in Section 5.6, in the event that a Third Party at any time provides written notice of a claim to, or brings an action, suit or proceeding against, any Party, or any of their respective Affiliates or Sublicensees, claiming infringement of such Third Party's Patent Rights based upon an assertion or claim arising out of the Manufacture or Commercialization of a Product in the Field ("**Infringement Claim**"), such Party shall promptly notify the other Party thereof, enclosing a copy of the claim and all papers served. MIMEDX, in consultation with Turn, shall assume primary responsibility to defend and respond to any Infringement Claims brought against either Party or its Affiliate or Sublicensees in the Territory using legal counsel reasonably acceptable to Turn. Neither Party shall settle any Infringement Claim without the consent of the other Party, such consent not to be unreasonably withheld or delayed. All liabilities, damages, costs and expenses arising out of such Infringement Claims shall be borne by Turn; provided that with respect to the [\*\*\*], MIMEDX shall pay for the litigation expenses and shall thereafter invoice Turn for fifty percent (50%) of such litigation expenses as they are incurred, and subject to a right to reasonably audit and request reasonable evidence of such invoiced expenses, Turn shall pay such invoiced amounts to MIMEDX within thirty (30) days of receipt of such invoice. MIMEDX shall keep Turn reasonably informed of the status of such claims and any defense.

5.6 Inter Partes Review. In the event the Parties agree to file for an Inter Partes Review with respect to any Patent Rights ("**IPR**"), MIMEDX, in consultation with Turn, shall assume primary responsibility to litigate the IPR using legal counsel mutually agreed upon by the parties using reasonable efforts. MIMEDX shall pay for the litigation expenses and shall thereafter invoice Turn for fifty percent (50%) of such litigation expenses as they are incurred, and Turn shall pay such invoiced amounts to MIMEDX within thirty (30) days of receipt of such invoice.

## ARTICLE 6 MANUFACTURING AND SUPPLY

6.1 Supply Agreement. MIMEDX agrees to negotiate in good faith the Supply Agreement pursuant to which a Third Party will supply MIMEDX with its requirements for the FleX Product.

6.2 Exclusivity. During the Term, neither Turn nor its Affiliates will supply, or authorize a Third Party to supply, the FleX Product to any Third Party throughout the Territory for use within the Field, and neither Turn nor its Affiliates during the Term will use the FleX Product to Manufacture any product for sale within the Field in the Territory.

## ARTICLE 7 REGULATORY MATTERS

7.1 U.S. Marketing Approval. Turn will (i) oversee, monitor and coordinate all regulatory actions, communications and filings with, and submissions to the FDA with respect to initial Marketing Approval for the FleX Product in the United States, (ii) be responsible for interfacing, corresponding and meeting with each Regulatory Agency with respect to initial Marketing Approval for the FleX Product in the United States, (iii) until assigned to MIMEDX in accordance with Section 7.2, be responsible for maintaining all regulatory filings for the FleX Product in the United States, and (iv) apprise Turn of all material communications from Regulatory Agencies relating to the FleX Product as soon as reasonably possible but in any event within ten (10) business days after receipt thereof

7.2 Assignment and Transfer of Regulatory Documents and Approvals. Within thirty (30) days following receipt of initial Marketing Approval for the FleX Product in the United States, Turn shall transfer to MIMEDX all of Turn's right, title and interest in and to all such Marketing Approvals and all regulatory documents and applications submitted to Regulatory Agencies with respect to the FleX Product.

7.3 Other Regulatory Filings and Interactions. Except as set forth in Sections 7.1 and 7.2, as between the Parties, MIMEDX will own all Marketing Approvals and any regulatory documents and applications submitted to the applicable Regulatory Agencies with respect to a Product, and will (i) be solely responsible to oversee, monitor and coordinate all regulatory actions, communications and filings with, and submissions to, each Regulatory Agency, (ii) be solely responsible for interfacing, corresponding and meeting with each Regulatory Agency, (iii) be solely responsible for maintaining all regulatory filings, (iv) be identified as the marketing authorization holder, and (v) apprise Turn of all material communications from Regulatory Agencies relating to the FleX Product as soon as reasonably possible but in any event within ten (10) business days after receipt thereof. Without limiting the terms of this Section 7.3, Turn shall use Commercially Reasonable Efforts to complete the Turn Activities as soon as practicable, and the Parties shall use Commercially Reasonable Efforts to cooperate to complete the regulatory and quality activities set forth in Exhibit E attached hereto as soon as practicable (the "**Cooperative Activities**").

## **ARTICLE 8 ADVERSE EVENTS; RECALLS**

8.1 Notice of Adverse Events. Each Party will maintain a record of any and all complaints it or its Affiliates and Sublicensees receive with respect to FleX Product. Each Party will notify the other Party in reasonable detail of any such complaints within sufficient time to allow the other Party and its Affiliates and Sublicensees (if applicable) to comply with any and all regulatory and other requirements imposed upon them in any jurisdiction in which the FleX Product is being marketed. MIMEDX will maintain at its own expense a common adverse event database for the FleX Product, and Turn will have access to all data in such adverse event database. MIMEDX shall be responsible, at its own expense, for submitting adverse event reports with respect to the FleX Product to the applicable Regulatory Agency. The Parties will cooperate in good faith in the exchange of safety data and the collection, investigation, reporting, and exchange of information concerning any adverse experiences, and any product quality and product complaints involving adverse experiences, related to the FleX Product, such that each Party is able to comply with its legal and regulatory obligations.

8.2 Recalls, Market Withdrawals or Corrective Actions. In the event that any Regulatory Agency issues or requests a recall or takes a similar action in connection with the FleX Product, the Party notified of such recall or similar action, shall within twenty-four (24) hours advise the other Party thereof by telephone, or by email or facsimile together with telephone confirmation. MIMEDX, in its sole discretion, shall decide whether to conduct a recall and the manner in which any such recall shall be conducted (except in the case of a government mandated recall, when MIMEDX may act without such advance notice but shall notify Turn as soon as possible). MIMEDX shall bear the expense of any such recall in the Field in the Territory ("**Recall Expenses**"); provided, however, that Turn shall bear the expense of any such recall to the extent the recall is the result of Turn's breach of its obligations under this Agreement.

## **ARTICLE 9 PAYMENT**

9.1 Payment Method. All payments due to Turn under this Agreement shall be made by bank check or wire transfer in immediately available funds to an account designated by Turn. All payments hereunder shall be made in the legal currency of the United States of America, and all references to "\$" or "Dollars" shall refer to United States dollars (*i.e.*, the legal currency of the United States). MIMEDX is responsible for all taxes other than taxes imposed with respect to Turn's income.

9.2 Currency Conversion. In the case of Net Sales made or expenses incurred by MIMEDX and its Affiliates and Sublicensees, the rate of exchange to be used in computing the amount of currency equivalent in United States dollars due shall be made at the rate of exchange utilized by such person in its worldwide accounting system and calculated in accordance with GAAP (or in accordance with MIMEDX's accounting methods applied in the Territory consistent with applicable law), prevailing on the third to the last business day of the month preceding the month in which such sales or expenses are recorded, as the case may be.

9.3 Withholding Taxes. MIMEDX may deduct the amount of any taxes imposed on Turn that are required to be withheld or collected by MIMEDX or its Affiliates or Sublicensees on amounts owing from hereunder to the extent MIMEDX or its Affiliates or Sublicensees pay such withholding taxes to the appropriate governmental authority on behalf of Turn. MIMEDX will promptly deliver to Turn proof of payment of such taxes together with copies of all communications from or with such governmental authority with respect thereto.

## **ARTICLE 10 REPRESENTATIONS AND WARRANTIES AND COVENANTS**

10.1 Mutual Representations and Warranties. Each Party represents and warrants to the other Party that as of the Effective Date:

10.1.a It is duly organized and validly existing under the laws of its jurisdiction of incorporation, and has full corporate power and authority to enter into this Agreement, and to carry out the provisions hereof.

10.1.b It is duly authorized to execute and deliver this Agreement, and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action.

10.1.c This Agreement is legally binding upon it and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party and by which it may be bound, or with its charter or by-laws.

10.1.d It has not granted, and will not grant, during the Term, any right to any Third Party that would conflict with the rights granted to the other Party hereunder.

10.1.e Neither Party nor any of its Affiliates has been debarred or is subject to debarment and neither Party nor any of its Affiliates will use in any capacity, in connection with the exercise of its rights and the performance of its obligations under this Agreement, any person or entity that has been debarred pursuant to Section 306 of the United States Federal Food, Drug, and Cosmetic Act or any similar law in any foreign jurisdiction, or that is the subject of a conviction described in such section or similar law in any foreign jurisdiction. Each Party agrees to inform the other Party in writing immediately if it or any person or entity that is performing activities under this Agreement, is debarred or is the subject of a conviction described in Section 306 or similar law in any foreign jurisdiction, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of the notifying Party's knowledge, is threatened, relating to the debarment or conviction of the notifying Party or any person or entity used in any capacity by such Party or any of its Affiliates in connection with the performance of its obligations under this Agreement.

10.2 Representations and Warranties of Turn. Turn makes the following representations and warranties to MIMEDX:

10.2.a Turn is the rightful, sole, exclusive and beneficial owner of the Licensed Technology and Licensed Trademarks, including as necessary to Develop, Manufacture and Commercialize the FleX Product.

10.2.b The Licensed Technology and Licensed Trademarks are valid and enforceable and, to the best of Turn's knowledge, the practice and use of the foregoing as set forth under this Agreement will not infringe or violate any Intellectual Property Rights of any third party in the Territory.

10.2.c There are no claims pending against or, to the best of Turn's knowledge, threatened challenging Turn's ownership or control or making any adverse claim of ownership of the exclusively licensed Intellectual Property Rights in the Territory.

10.2.d Except for the [\*\*\*], Turn has not received any written notice from any Third Party asserting or alleging that any Development, Manufacture or Commercialization of a Product by Turn prior to the Effective Date infringed or misappropriate the Patent Rights or other Intellectual Property Rights of such Third Party.

10.2.e There are no Third-Party rights that could interfere with or materially conflict with the grant of rights by Turn to MIMEDX under this Agreement.

EXCEPT AS EXPRESSLY SET FORTH IN SECTION 10.2, TURN DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, WHETHER WRITTEN, ORAL, EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE, CONCERNING THE VALIDITY, ENFORCEABILITY, AND SCOPE OF THE LICENSED TECHNOLOGY, THE ACCURACY, COMPLETENESS, SAFETY, USEFULNESS FOR ANY PURPOSE, OR LIKELIHOOD OF SUCCESS (COMMERCIAL, REGULATORY OR OTHER) OF THE PRODUCTS, LICENSED TECHNOLOGY, AND ANY OTHER TECHNICAL INFORMATION, TECHNIQUES, MATERIALS, METHODS, PRODUCTS, PROCESSES, OR PRACTICES AT ANY TIME MADE AVAILABLE BY TURN, INCLUDING ALL IMPLIED WARRANTIES OF MERCHANTABILITY, QUALITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, AND WARRANTIES ARISING FROM A COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE, OR TRADE PRACTICE.

10.3 MIMEDX Warranties/Disclaimer. Turn acknowledges and agrees that, other than as expressly provided herein, MIMEDX does not make any representation or warranty or guarantee as to the amount of royalties or milestone payments or fees to be made by MIMEDX or the income that Turn will derive from this Agreement. EXCEPT AS EXPRESSLY SET FORTH IN SECTION 10.1, MIMEDX DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, WHETHER WRITTEN, ORAL, EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE, INCLUDING ALL IMPLIED WARRANTIES OF MERCHANTABILITY, QUALITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, AND WARRANTIES ARISING FROM A COURSE OF DEALING, COURSE OF PERFORMANCE, USAGE, OR TRADE PRACTICE.

10.4 Employee Inventions. Prior to performing any activities in connection with this Agreement, the Parties shall ensure that its and its Affiliates' employees, agents and consultants have executed valid and binding agreements with it that assign and otherwise effectively vest in them any and all rights that such employees, agents and/or consultants might otherwise have in any invention made by such employees, agents and/or consultants. Should any royalties or other consideration become payable to such employees, agents and/or consultants, the respective Party shall remain solely responsible for making such payments.

## ARTICLE 11 INDEMNIFICATION; SET-OFF

11.1 By MIMEDX. MIMEDX shall indemnify, protect, defend and hold harmless Turn, Affiliates and their respective directors, officers, employees, successors and assigns from and against any and all liabilities, damages, harm, loss, costs, penalties and expenses (including reasonable attorneys' fees) (collectively, "**Liabilities**"), arising out of any claim, complaint, suit, proceeding, or cause of action brought or claimed by any Third Party (each, a "**Claim**") to the extent arising out of, relating to or resulting from (i) MIMEDX's breach of any representation or warranty made to Turn under this Agreement; (ii) the acts or omissions of any Sublicensee; or (iii) use by MIMEDX of the Licensed Technology or Licensed Trademarks, the Manufacture, Commercialization or any sale of the Products by MIMEDX, but excluding any Claim arising out of a Product or Licensed Technology or Licensed Trademarks for which Turn is liable under this Agreement or obligated to indemnify, protect, defend and hold MIMEDX harmless in accordance with Section 11.2.

11.2 By Turn. Turn agrees to indemnify, protect, defend and hold harmless MIMEDX, its Affiliates and their respective directors, officers, employees, successors and assigns from and against any Liabilities, arising out of any Claim to the extent arising out of or resulting from: (i) Turn's breach of any obligation under this Agreement or any representation or warranty made by Turn to MIMEDX under this Agreement; (ii) a Claim that the Flex Product or any Licensed Technology as delivered by Turn to MIMEDX, or the Development, Manufacture or Commercialization thereof, by MIMEDX or any of its sublicensees, distributors or customers, or the use by MIMEDX of the Licensed Trademarks (as authorized by Turn under Section 4.2) infringes upon the U.S. Intellectual Property Right of a Third Party; and (iii) the [\*\*\*].

11.3 Indemnification Procedure. A Party, its director, officer, employee, successor or assign that intends to claim indemnification ("**Indemnitee**") under this Article 11 shall promptly notify the indemnifying Party ("**Indemnitor**") in writing of any Claim with respect to which the Indemnitee intends to claim such indemnification, and, subject to Section 5.5, the Indemnitor shall have sole control of the defense and settlement of the Claim; provided that the Indemnitor shall not enter into any settlement that admits the fault of Indemnitee without the prior written consent of Indemnitee, such consent not to be unreasonably withheld. The Indemnitee shall have the right to participate, at its own expense, with counsel of its own choosing in the defense or settlement of the Claim. The indemnification obligations under this Article 11 shall not apply to amounts paid in settlement of any Claim if such settlement is effected without the consent of the Indemnitor. The Indemnitee and its employees, at the Indemnitor's request and expense, shall provide full information and reasonable assistance to Indemnitor and its legal representatives with respect to Claims.

11.4 Set-Off. MIMEDX may set off any amounts owed to Turn hereunder, including any royalties or milestone payments, against any amounts owed by Turn to MIMEDX under this Agreement or the Supply Agreement.

## ARTICLE 12 CONFIDENTIAL INFORMATION

12.1 Definition. Each Party may from time to time disclose to the other Party Confidential Information. As used herein, "**Confidential Information**" means any information and data disclosed by one Party to the other Party in connection with this Agreement, including all scientific, pre-clinical, clinical, regulatory, manufacturing, marketing, financial, trade secret and commercial information or data, whether communicated orally or by any other method. Notwithstanding the foregoing, Confidential Information shall not include any information to the extent that such information, as demonstrated by written documentation: (i) is or becomes generally available to the public through no fault of the receiving Party; (ii) is known by the receiving Party, other than under an obligation of confidentiality, at the time of its disclosure by the other Party; (iii) is demonstrably independently developed by the receiving Party after the date of disclosure without the application or use of the disclosing Party's Confidential Information; or (iv) becomes known to the receiving Party without an obligation of confidentiality from a source other than the disclosing Party without breach of this Agreement by such Party, provided, that such source has the lawful right to disclose such Confidential Information to such Party.

12.2 Confidentiality. Except as reasonably necessary to fulfill its obligations or exercise its rights under this Agreement, each Party and its respective employees and agents shall not use or disclose to any Third Parties any

Confidential Information of the other Party. Nothing contained in this Article 12 shall prevent either Party from disclosing any Confidential Information of the other Party to the extent necessary in complying with applicable Laws or orders; provided that if a Party is required by Law to make any such disclosure of the other Party's Confidential Information, other than pursuant to a confidentiality agreement, it will, to the extent legally permissible, give reasonable advance notice to the other Party of such disclosure and will use its reasonable efforts to secure confidential treatment of such Confidential Information. Notwithstanding the foregoing: a Party may disclose the other Party's Confidential Information to the extent required by Regulatory Agencies in connection with Product.

12.3 Prior Agreements. This Agreement supersedes the Letter of Intent between MIMEDX and Turn dated January 21, 2022, the Letter of Intent between MIMEDX and Turn dated February 28, 2022 (collectively, the "**Prior LOIs**"), the Non-Disclosure Agreement between MIMEDX and Turn and dated August 16, 2021 (the "**Prior NDA**") and the FleX License with respect to information disclosed thereunder. All information exchanged between the Parties under the Prior LOIs and the Prior NDA shall be deemed to have been disclosed under this Agreement and shall be subject to the terms of this Article 12 from and after the Effective Date.

12.4 Confidential Terms. Each Party shall treat the terms of this Agreement as the Confidential Information of the other Party. Notwithstanding anything to the contrary, however, each Party may disclose the terms of this Agreement (i) to advisors, actual or potential investors, acquisition partners and others on a need-to-know basis under circumstances that reasonably ensure the confidentiality thereof, or (ii) as required by securities or other applicable Laws or regulations, such as SEC regulations.

12.5 FOIA. In the event either Party receives a request under the United States Freedom of Information Act (5 U.S.C. §552) or similar Law related to the Licensed Technology, any Marketing Approval or this Agreement, such Party shall promptly deliver a copy of such request to the other Party. The Parties agree to work in good faith in responding to such request, including, by redacting any information not required by such Laws.

## **ARTICLE 13 TERM AND TERMINATION**

13.1 Term of Agreement. The initial term of this Agreement shall be effective as of the Effective Date and, unless earlier terminated pursuant to this Article 13, shall remain in effect until the last date on which any Product is covered by a Valid Claim within the Licensed Patents (the "**Term**"). Upon expiration of the Term, all licenses granted under Article 2 then in effect shall become fully paid-up, perpetual (exclusive or non-exclusive as applicable pursuant to Article 2) licenses provided, however, that to the extent MIMEDX thereafter continues to Commercialize the FleX Product and such Commercialization requires the use of Turn's trade secrets to Commercialize the FleX Product after the Term, MIMEDX shall pay Turn a royalty of [\*\*\*] of Net Sales for the FleX Product made after the Term for a period expiring ten (10) years after Launch of the FleX Product.

### 13.2 Termination.

13.2.a By Either Party. This Agreement may be terminated by either Party as follows:

(i) Upon ninety (90) days prior written notice to the other Party, in the event of a material breach of this Agreement by such other Party, which breach is not cured within such ninety (90) day period; or

(ii) Upon prior written notice to the other Party: (i) if the other Party is declared bankrupt by a court of competent jurisdiction, (ii) if a voluntary or involuntary petition in bankruptcy is filed in any court of competent jurisdiction against the other Party and such petition is not dismissed within sixty (60) days after filing, or (iii) if the other Party shall make or execute an assignment of substantially all of its assets related to this Agreement for the benefit of creditors.

13.2.b By MIMEDX. MIMEDX may terminate this Agreement, or any license(s) granted herein, in whole or in part, for convenience upon three (3) months' prior written notice to Turn. In addition, MIMEDX may terminate the license to the FleX Product and the related FleX Product obligations in this Agreement in the event that: (i) the FleX Product does not receive Marketing Approval in the United States from the FDA by March 31, 2023 or (ii) has not completed the Turn Activities set forth in Exhibit D by March 31, 2023.

13.2.c By Turn. Turn may terminate this Agreement solely with respect to rights granted for the FleX Product if (i) MIMEDX fails to launch the FleX Product within ten (10) months after the later of (i) the execution of the

Supply Agreement, or (ii) the date of Marketing Approval in the United States from the FDA for the Product. If Turn terminates this license with respect to the FleX Product under this Section 13.2, all rights to the FleX Product will revert to Turn as contemplated in Section 13.3(b) and the obligations of Turn in Section 6.2 shall terminate.

### 13.3 Effect of Termination.

13.3.a Termination Dispute. If Turn provides MIMEDX with a notice of a termination for material breach pursuant to Section 13.2a(i) and MIMEDX disputes whether it has materially breached this Agreement or whether the applicable breach has been cured, then MIMEDX may pursue resolution of such dispute in accordance with Section 15.7. If MIMEDX provides written notice of such dispute in accordance with Section 15.7, this Agreement and licenses herein will remain in full force and effect for so long as MIMEDX pursues resolution of such dispute in accordance with Section 15.7 (including the pendency of any arbitration or dispute resolution proceedings), and the cure period will be tolled during pendency of the dispute. If as a result of any dispute resolution proceeding it is determined that MIMEDX did not materially breach the Agreement, or that any material breach was cured during the cure period), then no termination will be effective and this Agreement and the licenses herein will continue in full force and effect.

13.3.b Reversion of Rights. In the event that this Agreement is terminated only with respect to certain of the licenses granted herein as permitted herein, the remaining rights and licenses shall remain in full force and effect in accordance with and subject to the terms set forth in this Agreement. In the event that this Agreement is terminated in its entirety by Turn pursuant to Section 13.2 due to uncured material breach by MIMEDX (and subject to Section 13.3.a) or by MIMEDX under Section 13.2(b), the licenses granted by Turn to MIMEDX under this Agreement shall terminate and all rights in the Licensed Technology and Licensed Trademarks shall revert to Turn. In addition if this Agreement is terminated in its entirety or with respect to the FleX Product, MIMEDX shall as promptly as practicable transfer to Turn or Turn's designee (A) possession and ownership of all governmental or regulatory correspondence, conversation logs, filings and approvals (including without limitation all Marketing Approvals and pricing and reimbursement approvals) relating to the FleX Product and execute any and all documents and carry out any other actions as may be requested by Turn to assist Turn with all regulatory filings with the applicable Regulatory Agencies required in connection with the termination of this Agreement to ensure that all Marketing Approvals for the FleX Product in the MIMEDX Territory can be transferred or issued to Turn or Turn's designee if necessary, and (B) copies of all data, reports, records and materials in MIMEDX's possession or Control relating to the FleX Product, including without limitation all non-clinical and clinical data relating to the Product, including without limitation customer lists and customer contact information and all adverse event data in MIMEDX's possession or Control. Upon termination of this Agreement, MIMEDX shall have the right for a period of no more than six (6) months after the effective date of such termination to sell off any existing Products in its inventory or in the process of Manufacture, in each case as of the effective date of such termination (the "Sell-Off Period") and the licenses granted under Section 2.1 shall survive for such period of time for MIMEDX to exercise its rights under this Section 13.3.b; provided that MIMEDX shall remain obligated to make payment of royalties to Turn for such Product in accordance with Section 3.1.

13.3.c Accrued Liability. Termination or expiration of this Agreement shall not relieve a Party from any liability that, at the time of such termination or expiration, has already accrued to the other Party.

13.3.d Survival. The provisions of Articles 1, 8, 10, 11, 12, 13, 14 and 15 and, with respect to infringement occurring during the Term, Sections 5.4 and 5.5 of this Agreement shall survive the expiration or termination of this Agreement for any reason.

## **ARTICLE 14 LIMITATION OF LIABILITY/ INSURANCE**

14.1 Limitation of Liability. EXCEPT AS OTHERWISE PROVIDED HEREIN, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY, OR ANY THIRD PARTY, FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING DAMAGES FOR LOSS OF BUSINESS OR PROFITS) ARISING FROM ANY CLAIM RELATED TO THIS AGREEMENT OR THE SUBJECT MATTER HEREOF, WHETHER SUCH CLAIM IS BASED ON CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT LIABILITY) OR OTHERWISE, EVEN IF SUCH PARTY IS ADVISED OF THE POSSIBILITY OR LIKELIHOOD OF THE SAME. THE LIMITATIONS OF LIABILITY UNDER THIS SECTION 14.1 SHALL NOT APPLY TO ANY CLAIMS, DAMAGES OR LIABILITIES ARISING FROM (I) BREACH OF ARTICLE 12, (II) BREACH BY TURN OF THE EXCLUSIVITY OBLIGATIONS SET FORTH IN THIS AGREEMENT, (III) A PARTY'S INDEMNIFICATION OBLIGATIONS UNDER THIS ARTICLE 11, (IV) WILFULL MISCONDUCT OR GROSS NEGLIGENCE OF A PARTY; OR (V) WILFULL MISCONDUCT OR GROSS NEGLIGENCE OF A SUBLICENSEE OR IN THE SUBLICENSING OR MONITORING OF A SUBLICENSEE.

14.2 Insurance. During the Term and for a period of at least five (5) years after the last commercial sale of the Product under this Agreement, each Party shall obtain and/or maintain in full force and effect general commercial liability insurance that names the other Party as an additional insured with a reputable, solvent insurer in an amount appropriate for its business and products of the type that are the subject of this Agreement, but in no event with coverage levels of less than \$2,000,000 per occurrence and \$10,000,000 in annual aggregate, and in the geographical market in which the relevant insurable activity is being performed, and for its obligations under this Agreement. Upon request, each Party shall provide the other Party with evidence of the existence and maintenance of such insurance coverage.

## ARTICLE 15 MISCELLANEOUS

15.1 Entire Agreement; Amendment. This Agreement, including all Exhibits hereto, sets forth the entire agreement and understanding between the Parties and supersedes all previous agreements, promises, representations, understandings and negotiations, whether written or oral, between the Parties, with respect to the subject matter hereof, including the Prior LOIs, the Prior NDA and the Flex License. Upon execution of this Agreement, the Flex License shall be automatically terminated. None of the terms of this Agreement shall be amended or modified except in writing signed by the Parties hereto.

15.2 Assignment. This Agreement shall not be assignable by either Party without the prior written consent of the other Party. Notwithstanding the foregoing, either Party may assign this Agreement without such consent to a successor to all or substantially all of its business or assets to which this Agreement relates, whether by way of merger, consolidation, sale of stock, sale of assets, operation of Law or otherwise; provided that such assignee assumes in writing the assignor's obligations under this Agreement and agrees to be bound by the terms and conditions hereof.

15.3 Severability. If, and solely to the extent that, any provision of this Agreement shall be invalid or unenforceable, or shall, if kept effective in this Agreement, render this entire Agreement to be invalid or unenforceable, such offending provision shall be of no effect and shall not affect the validity of the remainder of this Agreement or any of its provisions; provided, however, the Parties shall use their respective reasonable efforts to renegotiate the unenforceable provisions to best accomplish the original intentions of the Parties with respect to such provisions.

15.4 Waivers. Any waiver of the terms and conditions hereof must be explicitly in writing. A waiver by any Party of any term or condition of this Agreement in any one instance shall not be deemed or construed to be a waiver of such term or condition for any similar instance in the future or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be a limitation of any other remedy, right, undertaking, obligation or agreement.

15.5 Force Majeure. Neither Party shall be liable to the other for failure or delay in the performance of any of its obligations under this Agreement (except for an obligation to pay) for the time and to the extent such failure or delay is directly caused by earthquake, riot, civil commotion, war, terrorist acts, strike, flood, plague, epidemic, pandemic or governmental acts or restriction, or other cause that is beyond the reasonable control of the respective Party ("**Force Majeure Event**"). The Party affected by such force majeure will provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities) and will use Commercially Reasonable Efforts to overcome the difficulties created thereby and to resume performance of its obligations as soon as practicable. If the performance of any such obligation under this Agreement is delayed owing to such a force majeure for any continuous period of more than ninety (90) days, the Parties will consult with respect to an equitable solution, including the possibility of the mutual termination of this Agreement.

15.6 Governing Law. This Agreement shall be governed by the Laws of the State of Delaware, without reference to conflict of Laws principles and excluding the 1980 U.N. Convention on Contracts for the Biosciences Sale of Goods.

15.7 Disputes. In the event of any dispute or claim arising out of or in connection with this Agreement, or the performance, breach or termination thereof, either Turn or MIMEDX may, by written notice to the other Party, have such dispute referred to the Chief Executive Officers (or designee) of Turn and MIMEDX, for attempted resolution by good faith negotiations. The Parties will negotiate in good faith and reasonably for a period of not less than ninety (90) days. If the Parties are unable to resolve such dispute within such ninety (90) day period, such dispute shall be finally settled by binding arbitration by the American Arbitration Association (the "AAA") under its rules of arbitration, by a single arbitrator selected by the mutual agreement of the Parties; provided that if the Parties are unable to agree on an arbitrator, the arbitrator shall be appointed in accordance with the AAA rules. The decision and/or award rendered by the arbitrator shall be written, final and non-

appealable, and judgment on such decision and/or award may be entered in any court of competent jurisdiction. The arbitral proceedings and all pleadings and evidence shall be in the English language. The place of arbitration shall be in the State of Delaware, U.S.A. The costs of any arbitration, including administrative fees and fees of the arbitrator(s), shall be shared equally by the Parties to the dispute, unless otherwise determined by the arbitrator(s). Each Party shall bear the cost of its own attorneys' and expert fees. The Parties agree that, any provision of applicable Law notwithstanding, they will not request, and the arbitrator shall have no authority to award, punitive or exemplary damages against any Party.

15.8 Notices. Any notice, consent or approval permitted or required under this Agreement shall be in writing sent by registered or certified airmail (postage prepaid), overnight courier or by facsimile (receipt confirmed) and addressed as follows:

If to Turn:  
Turn Therapeutics  
250 N Westlake BLVD, Suite 210  
Westlake Village, CA 91362

If to MIMEDX:

Attn: General Counsel  
MiMedx Group, Inc.  
1775 W Oak Commons Ct  
Marietta, Georgia 30062  
Fax: (770) 590-3567

All notices shall be deemed to be effective on the business day after delivery of such notice to the overnight courier, the day such notice is received by addressee via registered or certified mail, or the day on which such notice is sent by facsimile. In case any Party changes its address at which notices are to be received, written notice of such change shall be given as soon as practicable to the other Party.

15.9 Implied Obligations. This Agreement sets forth all of the rights and obligations of the Parties with respect to the subject matter hereof.

15.10 Relationship of the Parties. The relationship hereby established between MIMEDX and Turn is solely that of independent contractors; this Agreement shall not create an agency, partnership, joint venture or employer/employee relationship, and nothing hereunder shall be deemed to authorize either Party to act for, represent or bind the other except as expressly provided in this Agreement.

15.11 Third Party Beneficiaries. Except solely on behalf of Indemnitees with respect to the enforcement of Article 11 on behalf of themselves, nothing herein shall be deemed to create (by implication or otherwise) any right on behalf of any Third Party to enforce any provision of this Agreement or any other right.

15.12 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall constitute an original, and all of which together shall constitute a single instrument.

15.13 Remedies. In addition to any other relief afforded under the terms of this Agreement or by law, each Party has the right to seek enforcement this Agreement by injunction issued against the other Party, it being understood that both damages and an injunction may be proper modes of relief and are not to be considered as alternative remedies.

15.14 Publicity. Neither Party may issue or release any announcement, statement, press release, or other publicity or marketing materials relating to this Agreement or, unless expressly permitted under this Agreement, otherwise use the other party's trademarks, service marks, trade names, logos, domain names, or other indicia of source, association, or sponsorship, in each case, without the prior written consent of the other Party.

[remainder of page left blank intentionally; signature page follows]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed as of the Effective Date by their duly authorized officers.

**GLOBAL HEALTH SOLUTIONS, INC. MIMEDX GROUP, INC.**

By: /s/ Bradley Burnam By: /s/ K. Todd Newton  
Name: Bradley Burnam Name: K. Todd Newton  
Title: CEO Title: Interim Chief Executive Officer

List of Exhibits:

Exhibit A Licensed Patents  
Exhibit B-1 Exclusive Licensed Trademarks  
Exhibit B-2 Non-Exclusive Licensed Trademarks  
Exhibit C Product Description  
Exhibit D Turn Activities  
Exhibit E Cooperative Activities  
Exhibit F [\*\*\*]

**[\*\*\*] Certain information in this document has been excluded pursuant to Regulation S-K, Item 601(b)(10). Such excluded information is not material and is the type that the registrant treats as private or confidential.**

**Exhibit 21.1**

MiMedx Group, Inc.

List of Subsidiaries

<b>Company</b>	<b>Jurisdiction of Organization</b>
MiMedx Tissue Services, LLC	Georgia
MiMedx Processing Services, LLC	Florida
MiMedx Japan, Godo Kaisha	Japan

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-259103 on Form S-3 and Registration Statement Nos. 333-251434, 333-211900, 333-199841, 333-189784, 333-183991, 333-153255 and 333-265689 on Form S-8 of our reports dated February 28, 2023, relating to the financial statements of MiMedx Group, Inc. and subsidiaries and the effectiveness of MiMedx Group, Inc. and subsidiaries' internal control over financial reporting appearing in this Annual Report on Form 10-K for the year ended December 31, 2022.

/s/ Deloitte & Touche LLP  
Atlanta, Georgia  
February 28, 2023

Consent of Independent Registered Public Accounting Firm

MiMedx Group, Inc.  
Marietta, Georgia

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-259103) and Form S-8 (No. 333-153255, 333-183991, 333-189784, 333-199841, 333-211900, 333-251434 and 333-265689) of MiMedx Group, Inc. of our reports dated March 8, 2021, except with respect to our opinion on the consolidated financial statements insofar as it relates to the change in reportable segments discussed in Notes 2 and 13, as to which the date is February 28, 2023, relating to the consolidated financial statements and schedule, which appear in this Form 10-K.

/s/ BDO USA, LLP  
Atlanta, Georgia  
February 28, 2023

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
PURSUANT TO RULES 13a-14(A) AND 15d-14(A)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Joseph H. Capper, certify that:

1. I have reviewed this Annual Report on Form 10-K of MiMedx Group, Inc. (the "Report");
2. Based on my knowledge, this Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Report;
3. Based on my knowledge, the financial statements, and other financial information included in this Report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Report based on such evaluation; and
  - (d) Disclosed in this Report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2023

/s/ Joseph H. Capper  
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Joseph H. Capper  
Chief Executive Officer

**CERTIFICATION OF CHIEF FINANCIAL OFFICER  
PURSUANT TO RULES 13a-14(A) AND 15d-14(A)  
OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Peter M. Carlson, certify that:

1. I have reviewed this Annual Report on Form 10-K of MiMedx Group, Inc. (the “Report”);
2. Based on my knowledge, this Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Report;
3. Based on my knowledge, the financial statements, and other financial information included in this Report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Report;
4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this Report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this Report based on such evaluation; and
  - (d) Disclosed in this Report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: February 28, 2023

/s/ Peter M. Carlson

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Peter M. Carlson  
Chief Financial Officer

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED  
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

The undersigned Joseph H. Capper, the Chief Executive Officer of MiMedx Group, Inc. (the "Company"), has executed this certification in connection with the filing with the Securities and Exchange Commission of the Company's Annual Report on Form 10-K for the period ending December 31, 2022 (the "Report"). Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned hereby certifies, to his knowledge, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 28, 2023

/s/ Joseph H. Capper

Joseph H. Capper  
Chief Executive Officer

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED  
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

The undersigned Peter M. Carlson, the Chief Financial Officer of MiMedx Group, Inc. (the “Company”), has executed this certification in connection with the filing with the Securities and Exchange Commission of the Company’s Annual Report on Form 10-K for the period ending December 31, 2022 (the “Report”). Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned hereby certifies, to his knowledge, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 28, 2023

/s/ Peter M. Carlson

Peter M. Carlson  
Chief Financial Officer