

**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, 2015

**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)

**26-2792552**

(I.R.S. Employer Identification Number)

**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: Common Stock, par value \$0.001 per share

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

(Title of class)

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark whether the registrant is not required to file reports pursuant to Section 13 or Section 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 and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§229,405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting Company

(Do not check if a smaller reporting company)

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

The aggregate market value of Common Stock held by non-affiliates on June 30, 2015, based upon the last sale price of the shares as reported on the NASDAQ on such date, was approximately \$1,135,614,000.

There were 107,810,490 shares of Common Stock outstanding as of February 10, 2016.

**Documents Incorporated by Reference**

Portions of the proxy statement relating to the 2016 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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## PART I

This Form 10-K and certain information incorporated herein by reference contain forward-looking statements and information within the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934. This information includes assumptions made by, and information currently available to management, including statements regarding future economic performance and financial condition, liquidity and capital resources, acceptance of our products by the market, and management’s plans and objectives. In addition, certain statements included in this and our future filings with the Securities and Exchange Commission (“SEC”), in press releases, and in oral and written statements made by us or with our approval, which are not statements of historical fact, are forward-looking statements. Words such as “may,” “could,” “should,” “would,” “believe,” “expect,” “expectation,” “anticipate,” “estimate,” “intend,” “seeks,” “plan,” “project,” “continue,” “predict,” “will,” “should,” and other words or expressions of similar meaning are intended by us to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are found at various places throughout this report and in the documents incorporated herein by reference. These statements are based on our current expectations about future events or results and information that is currently available to us, involve assumptions, risks, and uncertainties, and speak only as of the date on which such statements are made.

Forward-looking statements include, but are not limited to, the following:

- the advantages of our products;
- the regulatory pathway for our products;
- our belief regarding the growth of our direct sales force resulting in increased revenues;
- expectations regarding Government and other third-party reimbursement for our products;
- our beliefs regarding our relationships with significant distributors;
- expectations regarding future revenue growth;
- our ability to procure sufficient supplies of human tissue to manufacture and process our products;
- market opportunities for our products and future products;
- prospects for obtaining additional patents covering our proprietary technology as well as successfully defending our existing patents and prohibiting infringement thereof by third-parties;
- the outcome of pending litigation and investigations; and
- our ability to compete effectively.

Actual results and outcomes may differ materially from those expressed or implied in these forward-looking statements. Factors that may cause such a difference include, but are not limited to, those discussed in Part I, Item 1A, "Risk Factors," below. Except as expressly required by the federal securities laws, we undertake no obligation to update any such factors, or to publicly announce the results of, or changes to any of the forward-looking statements contained herein to reflect future events, developments, changed circumstances, or for any other reason.

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.

## **Item 1. Business**

### **Overview**

MiMedx® is an integrated developer, processor and marketer of patent protected and proprietary regenerative biomaterial products and bioimplants processed from human amniotic membrane and other birth tissues and human skin and bone. "*Innovations in Regenerative Biomaterials*" is the framework behind our mission to give physicians products and tissues to help the body heal itself. Our biomaterial platform technologies are AmnioFix®, EpiFix®, OrthoFlo, Physio™, AlloBurn™, and CollaFix™. AmnioFix and EpiFix are our tissue technologies processed from human amniotic membrane derived from donated placentas. Elected in advance of delivery through our donor program, a mother delivering a healthy baby via scheduled full-term Caesarean section birth may donate the placenta in lieu of having it discarded as medical waste. We process the human amniotic membrane utilizing our proprietary PURION® Process, to produce a safe and effective implant. MiMedx is the leading supplier of amniotic tissue, having supplied over 500,000 allografts to date for application in the Wound Care, Burn, Surgical, Orthopedic, Spine, Sports Medicine, Ophthalmic and Dental sectors of healthcare. We recently introduced OrthoFlo, an amniotic fluid derived allograft for homologous use. Amniotic fluid is donated by a consenting mother delivering a full-term healthy baby by scheduled Caesarean section. Through the recent acquisition of Stability Biologics, our newest proprietary platforms include Physio, a unique bone grafting material comprised of 100% bone tissue with no added carrier, a demineralized bone matrix (DBM) to complement our product portfolio offerings within the Orthopedic market and AlloBurn, a skin product for burns. CollaFix, our next technology platform we plan to commercialize, is our collagen fiber technology designed to mimic the natural composition, structure and mechanical properties of musculoskeletal tissues in order to augment their repair. CollaFix is the only known biological, biodegradable, biomimetic technology that matches human tendon in strength and stiffness.

### **Our History**

Our current business began on February 8, 2008, when Alynx, Co., our predecessor company, acquired MiMedx, Inc., a Florida-based, privately-held, development-stage medical device company, the assets of which included licenses to two development-stage medical device technology platforms—HydroFix® and CollaFix. On March 31, 2008, Alynx, Co. merged

into MiMedx Group, Inc., a Florida corporation and wholly-owned subsidiary that had been formed on February 28, 2008, for purposes of the merger. MiMedx Group, Inc. was the surviving corporation in the merger. In 2010, we commercialized the first medical device product using our HydroFix technology. In 2011 and 2012, we launched additional versions of our HydroFix® product line. In January 2011, the Company acquired all of the outstanding equity interests of Surgical Biologics, LLC (“Surgical Biologics”). The acquisition of Surgical Biologics expanded our business by adding allografts and other products processed from human amniotic membrane to our existing medical device product lines based on our HydroFix technology. In 2013, we changed the name of Surgical Biologics to MiMedx Tissue Services, LLC. Due to the relatively small size of the addressable market for our HydroFix product line, we decided to discontinue that product line in the fourth quarter of 2013. Although we have yet to commercialize any products using our CollaFix technology, we continue to believe that technology presents a significant opportunity in the orthopedic and sports medicine markets.

On January 13, 2016, we acquired all of the outstanding common stock of Stability Inc. d/b/a Stability Biologics. During its five year history, Stability Biologics evolved from its initial focus as a distributor of allografts, to its current position as an integrated provider in the surgical, spine and orthopedics sectors of healthcare specializing in human tissue and bone product design and development, tissue processing and sales and distribution. The acquisition of Stability was effected by the merger of Stability Inc. into a newly created wholly owned subsidiary of the Company. The new subsidiary was the surviving company in the merger and was subsequently renamed Stability Biologics, LLC (“Stability”). The Company is working to integrate Stability's product offerings with the Company's existing surgical, spine and orthopedics portfolio.

For financial information concerning our operating performance, please refer to Management’s Discussion and Analysis of Financial Condition and Results of Operations in Part II, Item 7 of this report and our Consolidated Financial Statements in Part II, Item 8 of this report.

## **Our Technology and Products**

### ***AmnioFix, EpiFix and other Tissue-Based Allografts***

The Company is the leading supplier of allografts processed from amniotic tissue, having supplied over 500,000 allografts to date for application in the Wound Care, Surgical, Sports Medicine, Ophthalmic, and Dental sectors of healthcare. Our amniotic membrane products include our own brands, AmnioFix and EpiFix, as well as products that we supply on a private label or “OEM” basis. We continue to research new opportunities for amniotic tissue, and currently have several additional offerings in various stages of conceptualization and development.

Amniotic membrane is considered immunoprivileged and does not elicit an immune response. Natural human amniotic membrane is composed of multiple layers that contain:

- Structural proteins; including:
  - Collagen types I, III, IV, V, and VII
  - Elastin
- Specialized extracellular matrix proteins; including:
  - Fibrillin
  - Fibronectin
  - Laminins
- TIMPs 1,2,4, Tissue Inhibitor of Metalloproteinase 1, 2, 4
- At least 226 Growth Factors; including but not limited to:
  - Epidermal Growth Factor (EGF)
  - Transforming Growth Factor Beta (TGF-B)
  - Fibroblast Growth Factor (FGF)
  - Platelet Derived Growth Factors AA & BB (PDGF AA&BB)

We believe our proprietary technique for processing allografts from amniotic tissue preserves more of the natural characteristics of the tissue than the processes used by our competitors. We operate a licensed tissue bank that is registered as a tissue establishment with the United States Food and Drug Administration (“FDA”). We are an accredited member of the American Association of Tissue Banks (“AATB”). We partner with physicians and hospitals to recover donated placental tissue. After consent for donation is obtained, donors are screened for eligibility and the donated tissue is tested for safety in

compliance with federal regulations and AATB standards on communicable disease transmission. All donor records and test results are reviewed by our Medical Director prior to the release of the tissue for processing.

Over several years, we have developed a unique and proprietary technique for processing allografts from the donated placental tissue. The PURION Process produces an allograft that is easy to use and effective. This unique processing technique specifically focuses on preserving the tissue's bioactive growth factor content, and maintaining the structure and collagen matrix of the tissue. The PURION Process also allows the allograft to be stored at room temperature and have a five-year shelf life. Additionally, each sheet allograft incorporates specialized visual embossments that assist the health care practitioner with proper allograft placement and orientation.

Our management team is dedicated to providing easy to use, effective allografts that exceed customer expectations. To better satisfy the requirements and expectations of our customers, we maintain strict controls on quality at each step of the process beginning at the time of procurement. We have developed and implemented a Quality Management System in compliance with both FDA regulations and AATB standards.

#### EpiFix

Our EpiFix allograft is configured for external use. It is used to enhance healing as well as to modulate inflammation. The EpiFix platform has been used to treat chronic wounds, including diabetic foot ulcers, venous stasis ulcers, arterial ulcers and pressure ulcers, burns and surgical wounds. We offer EpiFix in a sheet form as well as a micronized powder form. The powder can be packed into wounds and is particularly useful for tunneling wounds. Some physicians also choose to mix the powder with saline to inject it into the wound bed and wound margins.

#### AmnioFix

Our AmnioFix allografts are configured for internal use. Currently, our AmnioFix product line consists of three main configurations, AmnioFix, AmnioFix Wrap and AmnioFix Injectable:

- AmnioFix is provided in a sheet form. It is used to modulate inflammation, enhance healing and to minimize scar tissue formation. It has been used in spine, urology and general surgeries.
- AmnioFix Wrap also is supplied in a sheet form and is configured for the same purposes as AmnioFix®, but is optimized for use as a “wrap” for nerves, tendons or ligaments.
- AmnioFix Injectable is supplied in micronized powder form used to reduce inflammation while enhancing healing. AmnioFix Injectable has been used to treat conditions such as tendonitis, including plantar fasciitis, lateral epicondylitis, and medial epicondylitis, bursitis, strains and sprains.

#### OEM Products

Currently, allografts for ophthalmic surgery and dental applications are sold on an OEM basis pursuant to agreements whereby we have granted third parties exclusive licenses to some of our technology for use in those fields in specified markets. As further discussed below, the Company also sells products on a non-exclusive OEM basis to Medtronic for spinal procedures and Zimmer Biomet for spine and orthopedic procedures.

#### OrthoFlo

OrthoFlo is a unique human tissue allograft that is derived from amniotic fluid, donated by mothers delivering healthy babies by scheduled Caesarean section. It is for homologous use to (a) protect and cushion, (b) provide lubrication, and (c) reduce inflammation. Amniotic fluid, in utero, naturally functions to protect, cushion and enhance mobility. Key elements of amniotic fluid include growth factors, carbohydrates, proteins, lipids, electrolytes, and other nutrients, as well as hyaluronic acid (HA), a principal component of viscosity and lubrication in synovial fluid. A multitude of regulatory factors have been identified in amniotic fluid and synovial fluid, including the following which are some of the most notable:

- Interleukin 1 Receptor Antagonist (IL-1ra): Antagonist of IL-1 signaling which is known to be involved in cartilage degeneration
- Tissue Inhibitor of Metalloproteinases (TIMPs): inactivates a number of matrix metalloproteinases responsible for cartilage degradation

### ***Medical Device Technologies***

Our CollaFix technology combines an innovative means of creating fibers from soluble collagen and a specialized cross-linking process. Initial laboratory and animal testing shows that the cross-linked collagen fibers produce a very strong, biocompatible, and durable construct that can be transformed into biomechanical constructs intended to treat a number of orthopedic soft-tissue trauma and disease disorders. The technology is licensed from Shriners Hospitals for Children and University of South Florida Research Foundation, Inc. pursuant to an exclusive, world-wide license to practice and use the technology and to manufacture, have manufactured, market, offer for sale and sell products incorporating the technology. The license of the technology is perpetual, except that the license terminates on a country-by-country basis as to any patent or portion thereof included in the licensed technology upon the expiration of such patent or portion thereof in the applicable country. We are currently working to develop and commercialize products using our CollaFix technology and continue to evaluate how best to exploit this technology. We may license rights to specific aspects of our collagen technology to third parties for use in applications and indications that we choose not to exploit ourselves.

We are required to pay a royalty of 3% on all commercial sales revenue from the sale of products incorporating the licensed technology. We also are obligated to pay a \$50,000 minimum annual royalty payment over the life of the license.

### **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. Furthermore, we require employees, consultants and advisors to sign Proprietary Information and Inventions Agreements, as well as Nondisclosure Agreements that assign to us and protect the intellectual property existing and generated from their work or that we may otherwise use or own. 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***

Because of 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 this Form 10-K, we own 20 U.S. patents related to our amniotic tissue technology and products. Over 80 additional patent applications covering aspects of this technology are pending at the United States Patent and Trademark Office and with various international patenting agencies.

Worldwide, our CollaFix and HydroFix technologies are protected with 34 and 14 issued patents, respectively. Additionally, in the U.S. and internationally, there are 30 patent applications pending covering our CollaFix technology.

See discussion below- "Risk Factors" under the heading "***Risks Related to Our Intellectual Property.***"

### **Market Overview**

We currently are focused primarily on the U.S. market, but we are actively working towards international expansion opportunities. In the U.S., the key areas of focus for the products we market currently are (a) Wound Care; and (b) Surgical, Sports Medicine and Orthopedics (SSO). We believe Stability's spine and orthopedic related product line is a perfect complement to the Company's existing SSO products, and will serve to expedite the growth of our SSO product offerings.

#### ***Wound Care***

The number of chronic and acute wounds in the United States is estimated at 8.1 million, with hard to heal wounds (applicable for advanced wound care allografts) estimated at 2.9 million<sup>1</sup>. Our placental tissue-based allografts help heal acute and chronic wounds. Chronic wounds are defined as wounds that are delayed in closing compared to healing in an otherwise healthy individual. Some of the most common types of chronic wounds are diabetic foot ulcers, venous leg ulcers, pressure ulcers, arterial ulcers, and surgical wounds that become infected. Acute wounds can be caused by surgical intervention, trauma or burns. Our amniotic tissue platforms have the potential to reduce scar tissue formation in a variety of applications, including the chronic wound types listed above and acute wounds such as those occurring in the estimated 1.6 million patients annually undergoing elective aesthetic plastic surgery<sup>2</sup>, as well as the estimated 1.3 million patients annually undergoing Cesarean section births<sup>3</sup>, where scarring can limit flexibility, generate post-operative pain and can be unattractive. In both acute and chronic wounds, the physician's goal during treatment is to heal the wound while allowing the patient to retain natural function in the area of the wound with minimal scarring and infection. If a wound becomes infected, it can lead to a loss of limb or life,

and physicians want to close the wound as quickly as possible to minimize this risk. Patients with chronic wounds likely have comorbidities, such as diabetes or poor circulation, that complicate or delay the healing cascade. According to BioMedGPS, LLC SmartTRAK Business Intelligence, the 2014 U.S. Wound Biologics segment (comprised of skin/dermal substitutes (which includes the Company's allografts), topical delivery/drugs and collagen/active dressings) of the Advanced Wound Care Market reached approximately \$865 million and is expected to increase to approximately \$1.38 billion in 2019, a compounded annual growth rate of 9.8%.

Our EpiFix allografts are used for the treatment of chronic and acute, partial and full-thickness wounds. EpiFix contains essential wound healing factors, extracellular matrix proteins and inflammatory mediators to help modulate inflammation, enhance healing, and reduce scar tissue formation. Unlike some competing technologies, the use of EpiFix is not limited to a specific wound type. EpiFix stores at ambient temperature for up to five years. Certain cultured skin substitutes currently on the market require cryogenic freezer storage and expire only six months from time of processing. Another leading skin substitute is delivered on demand and has strict temperature controls between 20° and 23° Celsius with a ten-day shelf-life. We believe the complicated logistics associated with the use of those products highlight the distinct advantages of EpiFix.

In addition, the Company markets multiple sizes of allografts (from 1.5cm<sup>2</sup> to 49cm<sup>2</sup>) which minimizes product waste. Two former market leading competitor products come in only one size each, 2 inch x 3 inch (38 cm<sup>2</sup>) and a 75 mm disc (44 cm<sup>2</sup>). Since the majority of diabetic foot ulcers are less than 5cm<sup>2</sup>, using either one of these products results in significant waste on average.

### ***Surgical, Sports Medicine and Orthopedics***

Our AmnioFix tissue allografts have been used to enhance healing in patients undergoing surgical procedures to help to reduce scar tissue formation in a variety of applications including, but not limited to, plastic surgery, general surgery, gynecological, urology, orthopedics, spine, and sports medicine.

AmnioFix is used as a barrier membrane in procedures where scar tissue formation may be problematic. AmnioFix Wrap is applied by wrapping target tissues (ligaments, tendons, and or nerves) to create a barrier, which performs two functions: it acts as a neo-sheath to protect the target tissue and provides extracellular matrix proteins, cytokines and chemokines to enhance the wound healing process. AmnioFix provides additional benefits, including anti-inflammatory agents and growth factors that may assist with healing.

#### **Spine/Orthopedics**

There are approximately 1.47 million spinal surgeries per year<sup>4</sup> and most of them potentially could use AmnioFix to reduce scarring and modulate inflammation during the primary procedure, which may reduce time during revisions or follow-up surgeries. A reduction of scar tissue is beneficial if the patient needs to have an additional surgical procedure in the future, as it may facilitate the re-access to the surgical site, as well as help with minimizing scar attachment to the spinal dura in spine surgery. In addition to spinal surgeries, the AmnioFix offerings have been used in Arthroplasty (total joint replacement) of the knee, hip, shoulder, ankle, hand and elbow.

#### **Sports Medicine**

There are an estimated 90,000<sup>5</sup> peripheral nerve injuries which require repair each year and an estimated 8.4<sup>6</sup> million patients who have tendinopathy associated with inflammation that potentially could benefit from our AmnioFix products. AmnioFix Wrap is a surgical implant that has multiple features desired by surgeons to support the repair and replacement of ligaments, tendons grafts and repaired nerves. AmnioFix Injectable and AmnioFix Sports Med address the chronic sports/work soft tissue injury market, including but not limited to tennis elbow, golfers elbow, plantar fasciitis, tendonitis, bursitis and sprains. Soft tissue injuries are often caused by either trauma or overuse of the affected area. Micro-tears in the tissue form and become inflamed. Scar tissue may form and impede a full recovery. Steroids are often used as a first line to help the patient cope with the pain and assist with recovery. There are a number of patients who do not get relief with steroids or do not want to use steroids, and over-use of steroids can cause long-term damage to the tissue. AmnioFix Injectable and AmnioFix Sports Med modulate inflammation and reduce scar tissue formation, while enhancing healing. Additionally, OrthoFlo has recently been launched to address an estimated 26.9 million U.S. adults faced with Osteoarthritis of the joints.<sup>7</sup>

Market overview numbers derived from the following sources:

1. BioMedGPS SmartTRAK Business Intelligence

2. American Society of Plastic Surgeons “2012 Plastic Surgery Statistics Report” <http://www.plasticsurgery.org/news-and-resources/2012-plastic-surgery-statistics.html>
3. CDC Report - National Hospital Discharge Surgery: 2010 Table, Procedures by Selected patient characteristic - Number by procedure category and age (/nchs/data/nhds/4procedures/2010pro4\_numberprocedureage.pdf)
4. iData 2012, U.S. Market for Spinal Implants
5. Stabenfeldt, SE, Garcia, AJ, LaPlaca, MC. Thermoreversible laminin-functionalized hydrogel for neural tissue engineering. J of Bio Materials Research. Part A, 2006. 77: p. 718-725
6. Millenium 2013, clinical articles and management internal estimates
7. Lawrence RC, Felson DT, Helmick CG, et al. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States. Part II. Arthritis Rheum. 2008;58(1):26-35.

## **Marketing and Sales**

As of February 2016, our field sales force is comprised of over 230 sales professionals who call on hospitals, wound care clinics, physician offices and federal health care facilities such as Department of Veterans Affairs and Department of Defense Hospitals. Our direct sales force focuses on the Wound Care market and the SSO market, though, on the SSO side, we have continued to maintain a network of independent sales agents and distributors to sell sports medicine and orthopedic spine specialties lines. In addition, Stability's sales distribution organization consists of about 100 independent sales representatives that are focused in specific orthopedic/spine areas.

We continue to pursue private label or “OEM” relationship, to date the most notable of which are Medtronic and Zimmer Biomet. In September 2013, we entered into a non-exclusive distribution agreement with Medtronic, Inc. and its wholly-owned subsidiary, SpinalGraft Technologies, LLC (SGT). Under the agreement, MiMedx provides our PURION Processed grafts to Medtronic to be marketed by SGT under the RDX2® brand name for spinal applications throughout the United States.

In September 2014, we entered into a non-exclusive distribution agreement with Zimmer Biomet to distribute AmnioFix under its private label brand, AmnioRepair®. Under the agreement, Zimmer markets AmnioRepair for reconstructive, sports medicine, trauma, extremities and spine applications in the U.S. These partnerships allow us to leverage the sales and distribution resources of significant industry companies. In the ophthalmic and dental markets, our products are still marketed exclusively through licensee companies in each such field.

## **Reimbursement**

In 2015, approximately 26% of our products were purchased for U.S. Government accounts, which do not depend on reimbursement from third parties. With the exception of Government accounts, most users of our products are doctors, hospitals or ambulatory surgery centers 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. In the U.S., such payers include U.S. Governmental programs (e.g., Medicare and Medicaid), private insurance plans, managed care programs and workers’ compensation plans. Governmental payment 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 often have negotiated payment levels for medical products, services and procedures. In addition, in the U.S., an increasing percentage of insured individuals are receiving their medical care through managed care programs, which monitor and may require pre-approval of the products and services that a member will receive.

### ***EpiFix Sheet Products***

#### **Medicare Coverage**

By far, 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 the disabled. The Medicare program is administered by the Centers for Medicare and Medicaid Services (CMS). CMS has appointed eight Medicare Administrative Contractors (MACs), which are private insurance companies that serve as agents of CMS in the administration of the Medicare program, including paying claims and making coverage decisions for the Medicare-assigned jurisdiction for which they are responsible. Each MAC has its own process and standards for determining whether it will cover and reimburse a procedure or particular 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 reimbursement coverage for a new product.

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 sub regulatory coverage and reimbursement determinations. Ultimately, however, each of the MACs determines whether and on what conditions they will provide coverage for the product. Such decisions are based on their assessments of the efficacy and cost effectiveness of the applicable product. As noted below under the heading "Research and Development," we have devoted significant resources to clinical studies to be able to provide data to the MACs, as well as other payers, in order to demonstrate the efficacy and clinical effectiveness of our EpiFix sheet products. As of the date of this report, our EpiFix sheet products are eligible for coverage by all eight of the Medicare intermediaries.

For Medicare reimbursement purposes, our EpiFix sheet products are classified as "skin substitutes." Prior to 2014, providers that administered EpiFix allografts and other skin substitutes were reimbursed for the products based on the size of the graft, computed on a per square centimeter basis. The payment rate was calculated using the manufacturer's average sales price ("ASP") information. This payment methodology applied to physician offices, hospital outpatient and ambulatory surgery centers. We and other manufacturers of skin substitutes are required to provide ASP information to CMS on a quarterly basis. The Medicare payment rates are updated quarterly based on this ASP information. The skin substitutes Medicare payment rate, which is established by statute, was ASP plus 6%.

Beginning on April 1, 2013 and continuing through 2016, Medicare payments for all items and services, including EpiFix sheet products, were reduced by 2% under the sequestration required by the Budget Control Act of 2011, Pub. L. No. 112-25, as amended by the American Taxpayer Relief Act of 2012, Pub. L. 112-240.

Our EpiFix sheet allografts come in many sizes that are appropriate to the size of the wounds they are used to treat. Some competitive products come in only one size that is, on average, significantly larger than the wounds they are used to treat. The provider has to cut these products to size and the rest of the product is discarded, and, therefore, wasted. Because reimbursement for these products was based on the size of the graft, the Medicare payment for these grafts was costly. In part to combat this wastage, in November 2013, CMS announced a new reimbursement methodology for skin substitutes in the hospital outpatient and ambulatory surgical center setting effective in 2014. Under the new Hospital Outpatient Prospective Payment System ("OPPS") Final Rule, skin substitutes are no longer reimbursed based on the size of the graft. Rather the new rule "bundles" or "packages" the reimbursement for skin care substitutes, including EpiFix, with the reimbursement for the related medical procedure under a two-tier payment system. Thus, in the OPSS setting providers receive a single payment that covers the application of the product as well as the product itself. In 2014, skin substitutes with an average sales price above the weighted average mean unit cost of \$32 per sq. cm. were classified in the high cost group and were reimbursed at a higher packaged rate; those at or below the weighted average per sq. cm. were classified in the low cost group and are reimbursed at a lower packaged rate. In 2015, the weighted average mean unit cost to determine the high and low cost group was \$27 per sq. cm. The national average packaged rate was \$1,371 in 2014, \$1,407 in 2015 and \$1,411 in 2016. All skin substitutes products administered in the OPSS setting are bundled except for those that have been approved by CMS for pass-through status. This "bundled" payment structure only applies to the hospital outpatient and ambulatory surgery settings. Physician office payment structure remains at ASP plus 6%.

Section 1833(t)(6) of the Social Security Act provides for temporary additional payments or "transitional pass-through payments" for certain "new" drugs, devices and biological agents. Under the statute, transitional pass-through payments can be made for at least 2 years but not more than 3 years.

During the pass-through period, biologicals are eligible for separate payment computed as ASP plus 6%, less an offset (reduction) equal to the portion of the packaged payment determined to be attributed to the cost of the product (as opposed to the related procedure). The offset is designed to ensure that the total payment for the grafts does not exceed ASP plus 6%. In 2014, CMS determined that approximately 56% of the packaged payment is associated with the product and that is the amount reduced from the total product payment. The effect of the offset was that only larger size grafts were eligible for additional payments.

Our EpiFix sheet allografts were granted pass-through status through the end of 2014, allowing separate reimbursement for EpiFix sheet allografts administered in hospital outpatient departments and ambulatory surgery centers at ASP plus 6%, subject to the offset. The pass-through status for EpiFix expired in 2014. The Company prepared for this change by offering additional sizes of its grafts at prices below the bundled rate beginning in 2015. The new CMS reimbursement packaged policy does not apply to products applied in physician offices, which will continue to be reimbursed using the ASP plus 6% payment methodology. CMS has not changed the payment methodology as it relates to MiMedx products for calendar year 2016. The methodology under which CMS establishes reimbursement rates is subject to further change.

As discussed below under the heading "Competition," management believes this methodology will provide us with opportunities to increase market share.

#### Private Payers

We continue to devote considerable resources to clinical trials to support coverage and reimbursement of our products and we are aware of an increasing number of private payers that are reimbursing for EpiFix administered in the physician office or the hospital outpatient and ambulatory surgery center settings. Even when a payer is convinced of the clinical and cost-effectiveness of our product, coverage and reimbursement varies according to the individual or group plan or policy under which the patient has coverage. More than 180 health plans currently provide coverage for EpiFix for the treatment of Diabetic Foot Ulcers (DFU) and Venus Leg Ulcer (VLU) wounds. We have established and continue to grow a reimbursement support group to educate and assist providers and patients with regard to reimbursement for our products.

#### Hospital Use

EpiFix products administered in the hospital setting generally are bundled as part of the hospital's bill for a diagnosis-related group (DRG). In these cases, we continue to educate the hospital that the product is both efficacious and cost-effective.

#### **AmnioFix Sheet Products**

Our AmnioFix surgical products generally are bundled as part of a hospital's bill for a DRG. As noted above with respect to EpiFix, the ability to sell products to the hospital market is dependent upon demonstrating to the hospital that the product is both efficacious and cost-effective.

#### **EpiFix and AmnioFix Micronized Products**

Currently, our micronized products are available for coverage by only a limited number of commercial and state Medicaid plans.

#### **Other Products**

There is currently no third-party reimbursement available for OrthoFlo or any of the products manufactured and processed by Stability, except to the extent such products are bundled as part of a hospital's bill for a DRG. However, the Company is actively investigating all reimbursement options from third-party payers with respect to these products.

See discussion below- "Risk Factors" under the heading "***Our revenues depend on adequate reimbursement from public and private insurers and health systems.***"

#### **Customer Concentration**

The Company provides products to Government accounts, including the Department of Veteran's Affairs, through a distributor relationship with AvKARE, Inc. ("AvKARE"), which is a veteran-owned General Services Administration Federal Supply Schedule (FSS) Contractor. In addition, in 2014, the Company applied for, and in early 2015 received, its own FSS contract with a term through 2020, which allows the Company to sell directly to Government accounts. The initial term of the distribution agreement with AvKARE was due to expire in April 2015 but it has been extended via amendment through June 30, 2017, with the ability to further extend under certain circumstances. The agreement with AvKARE, as amended, allows the Company to sell its products directly on the FSS. Ultimately, the Company intends to transition all of its Government sales to sales sold directly to Government accounts on the FSS. In 2015, sales to AvKARE represented approximately 24% of total revenue.

See discussion below- "Risk Factors" under the heading "***A significant portion of our revenues and accounts receivable come from Government accounts.***"

#### **Competition**

Competition in the regenerative medicine field is intense and subject to rapid technological change. Companies within the industry compete on the basis of product efficacy, pricing, and ease of handling/logistics. However, the most 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 for our products is a significant competitive advantage.

The Company competes in multiple areas of clinical treatment where regenerative biomaterials may be employed to modulate inflammation, enhance healing and reduce scar tissue formation: advanced wound care treatment, spine, orthopedic, surgery and sports medicine. The EpiFix product line is promoted primarily for external use such as advanced wound healing, while the AmnioFix products are positioned for healing of surgical wounds and have been used in spine, orthopedics, surgical and sports medicine applications.

Advanced wound care therapies employ technologies to aid in wound healing in cases where the healing has stalled or stopped. The primary competitive products in this space include other amniotic membrane allografts, tissue-engineered living skin equivalents, and porcine- or bovine-derived collagen matrix products, among others. In 2015, our main competitor was Organogenesis, Inc., the manufacturer of Dermagraft® and Apligraf®. These products are tissue-engineered living skin equivalents that require special shipping and/or storage in freezers. The Organogenesis products also come in only one large size, which is significantly larger than the median wound size for the wounds they are used to treat, resulting in a high cost product, much of which is wasted. We have competed effectively against Dermagraft® and Apligraf® based on clinical efficacy, cost effectiveness, ease of use and storage of our products. Other smaller competitors include the Osiris Therapeutics, Inc. product Graftix® and other single-layer amnion products.

Smith & Nephew's Oasis® is the primary competitive product among the porcine- or bovine- derived collagen matrix products. As a collagen it can help with providing a matrix in the wound; however, it offers limited growth factors to enhance healing and due to the porcine origin may cause an immune response in the patient.

The primary competitive products in the SSO market are other amniotic membrane allografts and injectable solutions.

See discussion below- "Risk Factors" under the heading "*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.*"

## **Government Regulation**

### *FDA Premarket Clearance and Approval Requirements*

#### Tissue Products

The products manufactured and processed by the Company are derived from human tissue. As discussed below, some tissue-based products are regulated solely under Section 361 of the Public Health Service Act as human cells, tissues and cellular and tissue-based products, or HCT/Ps, which do not require premarket clearance or approval by the FDA. Other tissue products are regulated as biologics and, in order to be lawfully marketed in the United States, require an FDA-approved biologics application (BLA).

#### *Products Regulated as HCT/Ps*

The FDA has specific regulations governing human cells, tissues and cellular and tissue-based products, or HCT/Ps. An HCT/P is a product containing or consisting of human cells or tissue intended for transplantation into a human patient. HCT/Ps that meet the criteria for regulation solely under Section 361 of the Public Health Service Act (so-called "361 HCT/Ps") are not subject to any premarket clearance or approval requirements but are subject to post-market regulatory requirements.

To be a 361 HCT/P, a product generally must meet all four of the following criteria:

- 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.

If an HCT/P meets all the above criteria, no FDA review for safety and effectiveness under a drug, device, or biological product marketing application is required. MiMedx believes that its amniotic tissue allografts are 361 HCT/Ps, including the micronized versions of EpiFix and AmnioFix.

However, on August 28, 2013, the FDA issued an Untitled Letter alleging that the Company's micronized amniotic tissue allografts do not meet the criteria for regulation solely under Section 361 of the Public Health Service Act and that, as a result, MiMedx would need a biologics license to lawfully market those micronized products. Since the issuance of the Untitled Letter, the Company has been in discussions with the FDA to communicate its disagreement with the FDA's assertion that the Company's allografts are more than minimally manipulated. To date, the FDA has not changed its position that the Company's micronized products are not eligible for marketing solely under Section 361 of the Public Health Service Act, but discussions are continuing. The Company continues to market its micronized products but is also pursuing the Biologics License Application ("BLA") process for certain of its micronized products.

On December 22, 2014, the FDA issued for comment "Draft Guidance for Industry and FDA Staff: Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products." Essentially the Minimal Manipulation draft guidance takes the same position with respect to micronized amniotic tissue that it took in the Untitled Letter to MiMedx 16 months earlier. The Company submitted comments asserting that the Minimal Manipulation draft guidance represents agency action that goes far beyond the FDA's statutory authority, is inconsistent with existing HCT/ P regulations and the FDA's prior positions, and is internally inconsistent and scientifically unsound.

On October 28, 2015, the FDA issued for comment, "Draft Guidance for Industry and FDA Staff: Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products." The Company submitted comments on this Homologous Use draft guidance. The FDA has also indicated that it will hold a public hearing on a date in 2016 to be determined to obtain input on the Homologous Use draft guidance and the previously released Minimal Manipulation draft guidance, as well as other recently issued guidance documents on HCT/Ps. The Company has requested and been granted an opportunity to speak at this hearing.

See discussion below- "Risk Factors" under the heading "***To the extent our products do not qualify for regulation as human cells, tissues and cellular and tissue-based products under Section 361 of the Public Health Service Act, this could result in removal of the applicable products from the market, would make the introduction of new tissue products more expensive and significantly delay the expansion of our tissue product offerings and subject us to additional post-market regulatory requirements.***"

#### *Products Regulated as Biologics- The Biologics License Application (BLA) Pathway*

The typical steps for obtaining FDA approval of a BLA to market a biologic product in the U.S. include:

- Completion of preclinical laboratory tests, animal studies and formulations studies under the FDA's good laboratory practices regulations;
- Submission to the FDA of an Investigational New Drug Application (IND) for human clinical testing, which must become effective before human clinical trials may begin and which must include independent Institutional Review Board (IRB) 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 for each indication;
- Submission to the FDA of a BLA for marketing the product, which 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 Current Good Manufacturing Practices (cGMP) regulations, to assure that the facilities, methods and controls are adequate to ensure the product's identity, strength, 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 I 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 II 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 designated as Phase IIA and efficacy studies are designated as Phase IIB. Phase III 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 IV, 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. As indicated above, the Company is pursuing the Biologics License Application (“BLA”) process for certain of its micronized products. On July 22, 2014, the Company filed its first IND application with the FDA. In response to the IND application, the FDA agreed the Company had sufficient data to begin a Phase IIB clinical trial of its micronized product for a specified indication of use in anticipation of a BLA, which the Company expects to submit at a future date. The clinical trial is expected to enroll approximately 150 patients in 10 - 20 clinical sites in the U.S. The Company initiated the trial in March of 2015.

The process of obtaining an approved BLA requires the expenditure of substantial time, effort and financial resources and may take years to complete. 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.

See discussion below- “Risk Factors” under the heading “*Obtaining and maintaining the necessary regulatory approvals for certain products will be expensive and time-consuming and may impede our ability to fully exploit our technologies.*”

#### Medical Devices

Products from our CollaFix product platform are likely to be classified by the FDA as medical devices. Medical Devices are classified as I, II and III in the U.S., with Class II and III requiring either a 510(k) clearance or Premarket Approval (“PMA”) from the FDA prior to marketing. Devices deemed substantially equivalent to legally marketed devices are deemed to pose relatively less risk and are deemed Class I and II. Manufacturers are required to submit a premarket notification requesting clearance for commercial distribution. This is known as 510(k) clearance, which indicates that the device is substantially equivalent to devices already legally on the market. Most Class I devices are considered very low risk and are exempted from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or devices deemed not substantially equivalent to a previously 510(k) cleared device or a pre-amendment Class III device for which PMA applications have not been required, are placed in Class III, requiring PMA. Although we may be able to obtain approval for some products through the 510(k) clearance process, in order to fully exploit the CollaFix technology, one or more PMA applications would likely be required.

Like the process of obtaining an approved BLA, the process of obtaining a PMA requires the expenditure of substantial time, effort and financial resources and may take years to complete.

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

Tissue processors are required to register as an establishment with the FDA. As a registered establishment, we are required to comply with regulations regarding labeling, record keeping, donor eligibility, and screening and testing, process the tissue in accordance with established Good Tissue Practices, and report any adverse reactions attributed to our tissue. Our facilities are also subject to periodic inspections to assess our compliance with the regulations.

Products covered by a BLA, 510(k) clearance, or a PMA are subject to numerous additional regulatory requirements, which include, among others, compliance with cGMP, which imposes certain procedural, substantive and record keeping requirements, labeling regulations, the FDA’s general prohibition against promoting products for unapproved or “off-label” uses, and additional adverse event reporting.

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

We are accredited by the American Association of Tissue Banks (AATB), which has issued operating standards for tissue banking. Compliance with these standards is a requirement in order to become a licensed 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 National Organ Transplant Act (“NOTA”), which prohibits the transfer of certain human organs, including skin and related tissue, for valuable consideration, but permits 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, storage and transportation of donated human tissue.

See discussion below- "Risk Factors" under the heading "***Our business is subject to continuing regulatory compliance by the FDA and other authorities, which is costly and our failure to comply could result in negative effects on our business***".

#### ***Fraud, Abuse and False Claims***

We are directly and indirectly subject to various federal and state laws governing relationships with healthcare providers and pertaining to healthcare fraud and abuse, including anti-kickback laws. In particular, the federal healthcare program Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending a good or service for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. In implementing the statute, the Office of Inspector General of the U.S. Department of Health and Human Services ("OIG") has issued a series of regulations, known as the "safe harbors." These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable element of a safe harbor may result in increased scrutiny by Government enforcement authorities, such as the OIG. Many states have laws similar to the federal law.

AdvaMed is one of the primary voluntary U.S. trade associations for medical device manufacturers. This association has established guidelines and protocols for medical device manufacturers in their relationships with healthcare professionals on matters including research and development, product training and education, grants and charitable contributions, support of third-party educational conferences, and consulting arrangements. Adoption of the AdvaMed Code by a medical device manufacturer is voluntary, and while the OIG and other federal and state healthcare regulatory agencies encourage its adoption and may look to the AdvaMed Code, they do not view adoption of the AdvaMed Code as proof of compliance with applicable laws. As part of a Company-wide compliance plan, we have incorporated the principles of the AdvaMed Code in our standard operating procedures, sales force training programs, and relationships with health care professionals. Key to the underlying principles of the AdvaMed Code is the need to focus the relationships between manufacturers and healthcare professionals on matters of training, education and scientific research, and limit payments between manufacturers and healthcare professionals to fair market value for legitimate services provided and payment of modest meal, travel and other expenses for a healthcare professional under limited circumstances. We have incorporated these principles into our relationships with healthcare professionals under our consulting agreements, and our policies regarding payment of travel and lodging expenses, research and educational grant procedures and sponsorship of third-party conferences.

See discussion below- "Risk Factors" under the heading "***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 a material adverse effect on our business, financial condition and results of operations.***"

#### **Manufacturing (Processing)**

In early 2014, we expanded our production capacity from one location in Kennesaw, Georgia, by adding a second and significantly larger, manufacturing facility within our headquarters building in Marietta, Georgia. Effective January 2014, our main processing operations were relocated to the Marietta, Georgia facility. The Kennesaw facility serves as a secondary processing site. We also perform research and early stage product and process development activities in our Marietta and Kennesaw, Georgia, locations. Stability maintains a facility in San Antonio, Texas for tissue processing.

We are registered with the FDA as a tissue establishment and are subject to the FDA's quality system regulations, state regulations, and regulations promulgated by the European Union. 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.

#### **Placental Donation Program**

We have a comprehensive network of hospitals that participate in our placenta donation program. We have a dedicated staff that works at these hospitals, collecting donated placentas from mothers who undergo Cesarean section births and consent to donation. We believe that we will be able to procure an adequate supply of tissue to meet anticipated demand. However, see discussion below- "Risk Factors" under the heading "***Our products are dependent on the availability of sufficient quantities of tissue from human donors, and any disruption in supply could adversely affect our business.***"

#### **Research and Development**

Our research and development group has extensive experience in developing products related to our field of interest, 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. Clinical trials that demonstrate the safety, efficacy and cost effectiveness of our products are key to obtaining broader reimbursement for our products. In addition to our internal staff, we contract with outside labs 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 Matters**

Our tissue preservation activities generate some chemical and biomedical wastes, consisting primarily of diluted alcohols and acids, and human and animal pathological and biological wastes, including human and animal tissue and body fluids removed during laboratory procedures. The chemical and biomedical wastes generated by our tissue processing operations are placed in appropriately constructed and labeled containers and are segregated from other wastes. We contract with third parties for transport, treatment, and disposal of waste. We strive to remain compliant with applicable laws and regulations promulgated by the Resource Conservation and Recovery Act, the U.S. Environmental Protection Agency and similar state agencies.

#### **Employees**

As of December 31, 2015, we had approximately 550 employees. We consider our relationships with our employees to be satisfactory. None of our employees is covered by a collective bargaining agreement.

#### **Available Information**

Our website address is [www.mimedx.com](http://www.mimedx.com). We make available on this website under "Investors - SEC Filings," free of charge, our proxy statements, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports as soon as reasonably practicable after we electronically file or furnish such materials to the SEC. In addition, we post filings of Forms 3, 4, and 5 filed by our directors, executive officers and ten percent or more shareholders. We also make available on this website under the heading "Investors - Corporate Governance" our Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee Charters as well as our Code of Business Conduct and Ethics.

The reference to our website does not constitute incorporation by reference of any information contained at that site.

## Item 1A. Risk Factors

### Risks Related to Our Business and Industry

*Our operating results may fluctuate significantly as a result of a variety of factors, many of which are outside of our control.*

We are subject to the following factors, among others, that may negatively affect our operating results:

- The announcement or introduction of new products by our competitors;
- Failure of Government and private health plans to adequately and timely reimburse the users of our products;
- Removal of our products from the Federal Supply Schedule or change in the prices that Government accounts will pay for our products;
- Our ability to upgrade and develop our systems and infrastructure to accommodate growth;
- Our ability to attract and retain key personnel in a timely and cost effective manner;
- The amount and timing of operating costs and capital expenditures relating to the expansion of our business, operations and infrastructure;
- Regulation by Federal, State or Local Governments; and
- General economic conditions as well as economic conditions specific to the healthcare industry.

We have based our current and future expense levels largely on our investment plans and estimates of future events, although certain of our expense levels are, to a large extent, fixed. We may be unable to adjust spending in a timely manner to compensate for any unexpected revenue shortfall. Accordingly, any significant shortfall in revenue relative to our planned expenditures would have an immediate adverse effect on our business, results of operations and financial condition. Further, as a strategic response to changes in the competitive environment, we may from time to time make certain pricing, service or marketing decisions that could have a material and adverse effect on our business, results of operations and financial condition. Due to the foregoing factors, our revenue and operating results are and will remain difficult to forecast.

*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 from research and academic institutions is intense, expected to increase, subject to rapid change, and could be significantly affected by new product introductions. The presence of this competition in our market may lead to pricing pressure, which would make it more difficult to sell our products at a price that will make us profitable or prevent us from selling our products at all. Our success will depend on our ability to perfect and protect our intellectual property rights related to our technologies as well as to develop new technologies and new applications for our technologies. Our failure to compete effectively would have a material and adverse effect on our business, results of operations and financial condition.

*Rapid technological change could cause our products to become obsolete.*

The technologies underlying our products are subject to rapid and profound technological change. Competition intensifies as technical advances in each field are made and become more widely known. We can give no assurance that others will not 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 a material and adverse effect on our business, results of operations and financial condition.

*Our products are dependent on the availability of sufficient quantities 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 sufficient quantities of tissue from human donors. The availability of donated tissue could be adversely impacted by regulatory changes, public opinion of the donor process as well as our own reputation in the industry. Any disruption in the supply of donated human tissue could restrict our growth and could have a material adverse impact on our business and financial condition. We cannot



be sure that the supply of human tissue will continue to be available at current levels or will be sufficient to meet our future needs.

***The products we manufacture and 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, but not limited to, human immunodeficiency virus ("HIV"), 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.

Although we maintain strict quality controls over the procurement and processing of our tissue, there is no assurance that these quality controls will be adequate. In addition, negative publicity concerning disease transmission from other companies' improperly processed donated tissue could have a negative impact on the demand for our products.

***We depend on key personnel.***

Our success will 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 find and attract additional qualified employees to support our expected growth or retain any such personnel. Our inability to hire and retain qualified personnel or the loss of services of our key personnel may have a material and adverse effect on our business and results of operations.

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

We provide products to Government accounts, including the Department of Veterans Affairs, through a distributor that has a Federal Supply Schedule (FSS) Contract. Sales through this distributor, AvKARE, represented approximately 24% of our revenue in 2015, 34% of our revenue in 2014, and 56% of our revenue in 2013. In addition, in 2014, the Company applied for, and in early 2015 received, its own FSS contract with a term through 2020, which allows the Company to sell directly to Government accounts. The initial term of the distribution agreement with AvKARE was due to expire in April 2015 but it has been extended via amendment through June 30, 2017, with the ability to further extend under certain circumstances. The agreement with AvKARE, as amended, allows the Company to sell its products directly on the FSS. Ultimately, the Company intends to transition all of its Government sales to sales sold directly to Government accounts on the FSS. Any disruption of our products on the Federal Supply Schedule (whether we are selling our products directly to Government accounts or through our current or another distributor) or a change in the way the Government purchases products like ours or the price it is willing to pay for our products, could materially and adversely affect our business, revenues and results of operations.

***In order to grow revenues from certain of our products, we must expand our relationships with distributors and independent sales representatives.***

We derive significant revenues through our relationships with distributors and independent sales representatives, though, other than our distributor for Government accounts as discussed above, no one distributor comprised over 5% of our revenues. If such relationships were terminated for any reason, it could materially and adversely affect our ability to generate revenues and profits. We intend to obtain the assistance of additional distributors and independent sales representatives to continue our sales growth with respect to certain of our products. We may not be able to find additional distributors and independent sales representatives who will agree to market and/or distribute those products on commercially reasonable terms, if at all. If we are unable to establish new distribution and independent sales representative relationships or renew current distribution and sales agency agreements on commercially acceptable terms, our business, financial condition and results of operations could be materially and adversely affected.

***We continue to invest significant capital in expanding our internal sales force, and there can be no assurance that these efforts will continue to result in significant increases in sales.***

We are engaged in a major initiative to build and further expand our internal sales and marketing capabilities which has contributed to our increased sales. As a result, we continue to invest in a direct sales force for certain of our products to allow us to reach new customers. These expenses impact our operating results, and there can be no assurance that we will continue to be successful in significantly expanding the sales of our products.

***Our revenues depend on adequate reimbursement from public and private insurers and health systems.***

Our success depends on the extent to which reimbursement for the costs of our products and related treatments will be available from third party payers, such as public and 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 new

products. Therefore, significant uncertainty usually exists as to the reimbursement status of new healthcare products. A significant number of public and private insurers and health systems currently do not provide reimbursement for our products. If we are not successful in obtaining adequate reimbursement for our products from these third party payers, the market's acceptance of our products could be adversely affected. Inadequate reimbursement levels also likely would create downward price pressure on our products. Even if we do succeed in obtaining widespread reimbursement for our products, future changes in reimbursement policies could have a negative impact on our business, financial condition and results of operations.

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

Our results of operations are dependent upon the continued operation of our processing facilities. Risks that could impact our ability to use these facilities include the occurrence of natural and other disasters, and the need to comply with the requirements of directives from Government agencies, including the FDA. We have a secondary processing facility in Kennesaw, Georgia that also serves as a disaster recovery center. However, the unavailability of our manufacturing and processing facilities 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 convince physicians that our products are safe and effective alternatives to existing treatments and that our products should be used in their procedures.***

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

- Their lack of experience with prior procedures in the field using our products;
- Lack of evidence supporting additional patient benefits and our products over conventional methods;
- Perceived liability risks generally associated with the use of new products and procedures;
- Limited availability of reimbursement from third party payers; and
- The time that must be dedicated to training.

In addition, we believe recommendations for and support of our products by influential physicians are essential for market acceptance and adoption. If we do not receive this support or if we are unable to demonstrate favorable long-term clinical data, physicians and hospitals may not use our products, which would significantly reduce our ability to achieve expected revenue and would prevent us from sustaining profitability.

***We will need to expand our organization, and managing growth may be more difficult than expected.***

Managing our growth may be more difficult than we expect. We anticipate that a period of significant expansion will be required to penetrate and service the market for our existing and anticipated future products and to continue to develop new products. This expansion will place a significant strain on management, operational and financial resources. To manage the expected growth of our operations and personnel, we must both modify our existing operational and financial systems, procedures and controls and implement new systems, procedures and controls. We must also expand our finance, administrative, and operations staff. Management may be unable to hire, train, retain, motivate and manage necessary personnel or to identify, manage and exploit existing and potential strategic relationships and market opportunities.

***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 medical devices and 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. Defending a lawsuit, regardless of merit, could be costly, divert management attention and result in 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. Also, it is possible that claims could exceed the limits of our coverage. 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.

***We may implement a product recall or voluntary market withdrawal, which could significantly increase our costs, damage our reputation and disrupt our business.***

The manufacturing, marketing and processing of our tissue products involves an inherent risk that our tissue products or processes do not meet applicable quality standards and requirements. In that event, 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 would be costly and would 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.

***Significant disruptions of information technology systems or breaches of information security could adversely affect our business.***

We rely to a large extent upon sophisticated information technology systems to operate our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, but not limited to, personal information and intellectual property). 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 size and complexity of our information technology and information security systems, and those of our third-party vendors with whom we contract (and the large amounts of confidential information that is present on them), make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors, or from malicious attacks by third parties. Such attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives (including, but not limited to, industrial espionage and market manipulation) and expertise. While we have invested significantly in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches. Although we have cyber-insurance coverage that may cover certain events described above, this insurance is subject to deductibles and coverage limitations and we may not be able to maintain this insurance. Also, it is possible that claims could exceed the limits of our coverage. Any interruption or breach in our systems could adversely affect our business operations and/or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us or allow third parties to gain material, inside information that they use to trade in our securities.

***We may not be successful in commercializing our CollaFix Technology.***

We have invested substantial time and resources in developing various additional products using our CollaFix technology. Further commercialization of this technology will require additional development, clinical evaluation, regulatory clearance or approval, significant marketing efforts and substantial additional investment before they can provide us with any revenue. Despite our efforts, any such products may not become commercially successful products for a number of reasons, including:

- We may not be able to obtain regulatory clearance or approvals for such products, or the approved indication may be narrower than we seek;
- Such products may not prove to be safe and effective in preclinical or clinical trials;
- Physicians or hospitals may not receive any reimbursement from third party payers, or the level of reimbursement may be insufficient to support widespread adoption of such products;
- We may experience delays in our development programs;
- Any products that are approved may not be accepted in the marketplace by physicians or patients;
- We may not be able to manufacture any such products in commercial quantities or at an acceptable cost; and
- Rapid technological change may make such products obsolete.

***We may expand our business through acquisitions, licenses, investments, and other commercial arrangements in other companies or technologies, which contain significant risks.***

We periodically evaluate strategic opportunities to acquire companies, 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:

- Issue additional equity securities that would dilute our stockholders' value;
- 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;
- Be unable to secure the services of key employees related to the acquisition; and
- Be unable to succeed in the marketplace with the acquisition.

Any of these items could materially, and adversely affect our revenues, financial condition, and profitability. 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 an acquisition could materially, and adversely affect our business if we are unable to recover our initial investment, which could include the cost of acquiring licenses or distribution rights, acquiring products, purchasing initial inventory, or investments in early stage companies. Inability to recover our investment, or any write off of such investment, associated goodwill, or assets, could have a material and adverse effect on our business, results of operations and financial condition.

***Our international expansion and operations in foreign markets expose us to risks associated with international sales and operations.***

We are actively seeking to expand into foreign markets. Managing a global organization is difficult, time consuming, and expensive. Conducting international operations subjects us to risks that could be different than those faced by us in the United States. These risks include: lack of familiarity with and unexpected changes in foreign regulatory requirements; longer accounts receivable payment cycles and difficulties in collecting accounts receivable; difficulties in managing and staffing international operations; fluctuations in currency exchange rates; the burdens of complying with a wide variety of foreign laws and legal standards; increased financial reporting burdens and complexities; and political, social, and economic instability abroad. Operating in international markets also requires significant management attention and financial resources. The investment and additional resources required to operate and manage growth in other countries may not produce desired levels of revenue or profitability.

***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 a material adverse effect on our business, results of operations and financial condition.

**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 a material and adverse effect on us.***

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. We cannot ensure that any of our pending patent applications will 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. Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States.

The failure to obtain and maintain patents and/or protect our intellectual property rights could have a material and adverse effect on our business, results of operations, and financial condition. Whether a patent is valid is a complex matter of science and law, and therefore we cannot be certain that, if challenged, our patents would be upheld. If one or more of those patents are invalidated, that could reduce or eliminate any competitive advantage we might otherwise have had.

In the event a competitor infringes upon our licensed or pending patent 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. For example, the defendants in certain of our ongoing patent infringement suits have filed petitions for inter-partes review of certain of our patents with the United States Patent and Trademark Office (USPTO). We intend to defend these actions vigorously, but there is no guarantee of success, and such effort takes financial and time resources from the Company. In the event that one or more of our patents are challenged, a court or the USPTO may invalidate the patent(s) or determine that the patent(s) is not enforceable, which could harm our competitive position. If the USPTO ultimately cancels or narrows the claim in 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 future, expected revenue. See Item 3, Legal Proceedings for information regarding our ongoing patent infringement lawsuits and related inter-partes review proceedings.

***The prosecution and enforcement of patents licensed to us by third parties are not within our control, and without these technologies, our products may not be successful and our business would be harmed if the patents were infringed or misappropriated.***

We have obtained licenses from third parties for patents and patent application rights related to our CollaFix technologies, allowing us to use intellectual property rights owned by or licensed to these third parties. We do not control the maintenance, prosecution, enforcement or strategy for many of these patents or patent application rights and as such are dependent in part on the owners of the intellectual property rights to maintain their viability. Their failure to do so could significantly impair our ability to exploit those technologies.

***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 or other intellectual property involves complex 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 patents 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 patents in such claim 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 unless we could obtain licenses to use the technology covered by the patent or other intellectual property or are able to design around the patent 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

activities. Depending on the nature of the relief ordered by the court, we could become liable for additional damages to third parties.

***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 of others.***

Some of our employees were previously employed at other medical device or tissue companies. We may also hire additional employees who are currently employed at other medical device 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 against us are currently pending, we may be subject to claims that these employees or independent contractors have used or disclosed any party's trade secrets or other proprietary information. 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. 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.

***Our License Agreement for our CollaFix technology could be terminated.***

Under our license agreement with Shriners' Hospitals for Children and University of South Florida Research Foundation dated January 29, 2007, it is possible for the licensor to terminate the agreement if we breach the license agreement and all of our cure rights are exhausted. If our license agreement were to be terminated, our investment in the CollaFix technology would be lost.

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

***To the extent our products do not qualify for regulation as human cells, tissues and cellular and tissue-based products under Section 361 of the Public Health Service Act, this could result in removal of the applicable products from the market, would make the introduction of new tissue products more expensive and significantly delay the expansion of our tissue product offerings and subject us to additional post-market regulatory requirements.***

The products we manufacture and process are derived from human tissue. The FDA has specific regulations governing human cells, tissues and cellular and tissue-based products, or HCT/Ps. An HCT/P is a product containing or consisting of human cells or tissue intended for transplantation into a human patient. HCT/Ps that meet the criteria for regulation solely under Section 361 of the Public Health Service Act (so-called "361 HCT/Ps") are not subject to any premarket clearance or approval requirements and are subject to less stringent post-market regulatory requirements.

If a product is deemed not to be a 361 HCT/P, FDA regulations will require premarket clearance or approval requirements that will involve significant time and cost investments by the Company. Further, there can be no assurance that the FDA will not, at some future point, change its position on current or future products' 361 HCT/P status, and any regulatory reclassification could have adverse consequences for us and make it more difficult or expensive for us to conduct our business by requiring premarket clearance or approval and compliance with additional post-market regulatory requirements with respect to those products. Moreover, increased regulatory scrutiny within the industry in which we operate could lead to increased regulation of HCT/Ps, including 361 HCT/Ps. We also cannot assure you that the FDA will not impose more stringent definitions with respect to products that qualify as 361 HCT/Ps.

See "Government Regulation" in Item 1 for a discussion of 361 HCT/Ps and the FDA's position on our products. If the FDA does allow the Company to continue to market a micronized form of its sheet allografts without a biologics license either prior to or after finalization of the draft guidance documents, it may impose conditions, such as labeling restrictions and compliance with cGMP. Although the Company is preparing for these requirements in connection with its pursuit of a BLA for certain of its micronized products, earlier compliance with these conditions would require significant additional time and cost investments by the Company. It is also possible that the FDA will not allow the Company to market any form of a micronized product without a biologics license even prior to finalization of the draft guidance documents and could even require the Company to recall its micronized products. Revenues from micronized products comprised approximately 12% of the Company's revenues in 2015.

***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 biologic or medical device from the FDA or similar regulatory authorities outside of the United States is costly and time consuming, and there can be no assurance that such clearances or approvals will be granted on a timely basis, or at all. As discussed above, we intend to pursue approval of a Biologics License Application (BLA) for certain of our micronized products. 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 and market may require marketing clearance or approval from the FDA. There can be no assurance, however, that clearance or approval will be granted with respect to any of our products or enhancements or that FDA review will not involve delays that would adversely affect our ability to market such products or enhancements.

The process of obtaining an approved BLA requires the expenditure of substantial time, effort and financial resources and may take years to complete. 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. Additionally, there are significant costs associated with clinical trials that cannot be estimated until the IND is approved. Moreover, data obtained from clinical activities 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. 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. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Like the process of obtaining an approved BLA, the process of obtaining a PMA requires the expenditure of substantial time, effort and financial resources and may take years to complete. The FDA may not grant approval on a timely basis, or at all. 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. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

***Our business is subject to continuing regulatory compliance by the FDA and other authorities, which is costly and our failure to comply could result in negative effects on our business.***

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. The FDA's regulation of HCT/Ps includes requirements for registration and listing of products, donor screening and testing, processing and distribution ("Current Good Tissue Practices"), labeling, record keeping and adverse-reaction reporting, and inspection and enforcement.

Biologics and 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 and/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 or medical devices, 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, 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.

It is likely that the FDA's regulation of HCT/Ps will continue to evolve in the future. Complying with any such new regulatory requirements may entail significant time delays and expense, which could have a material adverse effect on our business.

The American Association of Tissue Banks (“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 National Organ Transplant Act (“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, storage and transportation of donated human tissue. Although we have independent third party appraisals that confirm that 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 would potentially be subject to criminal enforcement sanctions, which could materially and adversely affect our results of operations.

Finally, as discussed above, we and other manufacturers of skin substitutes are required to provide 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.

***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 a material adverse effect on our business, financial condition and results of operations.***

Our relationships with physicians, hospitals and other healthcare providers are subject to scrutiny under various federal anti-kickback, self-referral, false claims and similar laws, often referred to collectively as healthcare fraud and abuse laws. Healthcare fraud and abuse laws are complex, and even minor, inadvertent violations can give rise to claims that the relevant law has been violated. Possible sanctions for violation of these fraud and abuse laws include monetary fines, civil and criminal penalties, exclusion from federal and state healthcare programs, including Medicare, Medicaid, Veterans Administration health programs, workers' compensation programs and TRICARE (the healthcare system administered by or on behalf of the U.S. Department of Defense for uniformed services beneficiaries, including active duty and their dependents, retirees and their dependents), and forfeiture of amounts collected in violation of such prohibitions. Certain states have similar fraud and abuse laws, imposing substantial penalties for violations. Any Government investigation or a finding of a violation of these laws would likely result in a material adverse effect on the market price of our common stock, as well as our business, financial condition and results of operations.

Anti-kickback laws and regulations prohibit any knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for the referral of an individual or the ordering or recommending of the use of a product or service for which payment may be made by Medicare, Medicaid or other Government-sponsored healthcare programs. We have entered into consulting agreements, speaker agreements, research agreements and product development agreements with physicians, including some who may order 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 as consideration for services performed by them. While these transactions were structured with the intention of complying with all applicable laws, including state anti-referral laws and other applicable anti-kickback laws, it is possible that regulatory or enforcement agencies or courts may in the future view these transactions as prohibited arrangements that must be restructured or for which we would be subject to other significant civil or criminal penalties. As discussed above, we have incorporated the AdvaMed code principles into our relationships with healthcare professionals under our consulting agreements, and our policies regarding payment of travel and lodging expenses, research and educational grant procedures and sponsorship of third-party conferences. In addition, we have conducted training sessions on these principles. However, there can be no assurance that regulatory or enforcement authorities will view these arrangements as being in compliance with applicable laws or that one or more of our employees or agents will not 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 the market 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 and determine that we would be unable to achieve compliance with such 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 and Medicaid, for non-compliance.

The Federal False Claims Act (“FCA”) imposes civil liability on any person or entity that 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 with knowledge of past or present fraud against the Federal Government to sue on behalf of the Government to recover the civil penalties and treble damages. The U.S. Department of Justice (“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 entitlement programs such as 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 corporate integrity agreements that require, among other things, substantial reporting and remedial actions going forward.

The scope and enforcement of all of these laws is uncertain and subject to rapid change, especially in light of the lack of applicable precedent and regulations. There can be no assurance that federal or state regulatory or enforcement authorities will not 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.

***We face significant uncertainty in the industry due to Government healthcare reform.***

There have been and continue to be proposals by the Federal Government, State Governments, regulators and third party payers to control healthcare costs, and generally, to reform the healthcare system in the United States. There are many programs and requirements for which the details have not yet been fully established or the consequences are not fully understood. These proposals may affect aspects of our business. We also cannot predict what further reform proposals, if any, will be adopted, when they will be adopted, or what impact they may have on us.

**Risks Related to the Securities Markets and Ownership 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 companies that are in, or are just emerging from, the development stage, 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 regulatory applications and proceedings;
- 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 any restatements of previously reported results;
- Our ability to effectively and consistently 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 Federal Supply Schedule, or changes in how Government accounts purchase products such as ours or in the price for our products to Government accounts; and
- The other risks detailed in this Item 1A.

Further, due to the relatively fixed nature of most of our costs, which primarily include personnel costs as well as facilities costs, any unanticipated shortfall in revenue in any fiscal quarter would have an adverse effect on our results of operations in that quarter. 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. In addition, the stock market has been very volatile in the recent past. This volatility is often not related to the operating performance of companies listed thereon and will probably continue in the foreseeable future.

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

At this time, seven securities analysts provide research coverage of our common stock. However, there is no assurance that these analysts will continue to report on our common stock or that additional analysts will initiate reporting on our common stock. Rules mandated by the Sarbanes-Oxley Act and a global settlement reached in 2003 among the SEC, other regulatory agencies, and a number of investment banks led to a number of fundamental changes in how analysts are reviewed and compensated. In particular, many investment banking firms are required to contract with independent financial analysts for their stock research. If securities analysts discontinue covering our common stock, the lack of research coverage may adversely affect its actual and potential market price. The trading market for our common stock may be affected in part by the research and reports that industry 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. This could have a negative effect on the market price of our shares.

***Our charges to earnings resulting from acquisition, restructuring and integration costs may materially adversely affect the market value of our common stock.***

We account for the completion of our acquisitions using the purchase method of accounting. We allocate the total estimated purchase prices to net tangible assets, amortizable intangible assets and indefinite-lived intangible assets, and based on their fair values as of the date of completion of the acquisitions, record the excess of the purchase price over those fair values as goodwill. Our financial results, including earnings per share, could be adversely affected by a number of financial adjustments required in purchase accounting including the following:

- We will incur additional amortization expense over the estimated useful lives of certain of the intangible assets acquired in connection with acquisitions during such estimated useful lives.
- We will incur additional depreciation expense as a result of recording purchased tangible assets.
- To the extent the value of goodwill or intangible assets becomes impaired, we may be required to incur material charges relating to the impairment of those assets.
- Cost of sales may increase temporarily following an acquisition as a result of acquired inventory being recorded at its fair market value.
- Earnings may be affected by changes in estimates of future contingent consideration to be paid when an earn-out is part of the consideration.
- Earnings may be affected by transaction and implementation costs, which are expensed immediately.

***We do not intend to pay cash dividends.***

We have never declared or paid cash dividends on our capital stock. We currently expect to use available funds and any future earnings in the development, operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, the terms of our existing credit facility restrict us from paying dividends. 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.

***We and certain of our executive officers have been named as defendants in a class action lawsuit that could result in substantial costs and divert management's attention.***

As discussed in Item 3, Legal Proceedings, we, and certain of our executive officers, have been named as defendants in purported class action lawsuits that allege violations of federal securities laws related to various statements regarding our belief that our products were 361 HCT/Ps. The Court has preliminarily approved a settlement in this action and has set the final settlement hearing for April 5, 2016. We do not believe the terms of the settlement, if finally approved, will have a material adverse effect on our operating results or financial condition.

In addition, the volatility in our stock price may make us more vulnerable to future class action litigation.

Any adverse judgment in or settlement of the pending or any future litigation could require payments that exceed the limits of our available directors' and officers' liability insurance, which could have a material adverse effect on our operating results or financial condition.

***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.***

We are subject to the Florida affiliated transactions statute, which generally requires approval by the disinterested directors or supermajority approval by shareholders for "affiliated transactions" between a corporation and an "interested stockholder." Additionally our organizational documents contain provisions:

- Authorizing the issuance of preferred stock that can be created and issued by the Board of Directors without prior common stock shareholder approval, with rights senior to those of the common stock;
- Restricting persons who may call shareholder meetings;
- Electing directors on a staggered basis; and
- Allowing the Board 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**

None.

## **Item 2. Properties**

Our corporate headquarters are located in Marietta, Georgia, where we lease approximately 80,000 square feet of office, laboratory, tissue processing and warehouse space. We also lease (a) approximately 21,000 square feet for a facility in Kennesaw, Georgia, which primarily consists of laboratory, tissue processing and warehouse space; and (b) approximately 26,000 square feet of additional office space in Marietta, Georgia. In addition, Stability leases approximately 3,000 square feet for its corporate offices in Nashville, Tennessee and approximately 11,000 square feet in San Antonio, Texas which consists of its tissue processing center.

## **Item 3. Legal Proceedings**

### **Securities Class Action**

Following the publication of an Untitled Letter from the FDA regarding the Company's micronized products in September 2013, the trading price of the Company's stock declined and several putative shareholder class action lawsuits were filed against the Company and certain of its executive officers asserting violations of the Securities Exchange Act of 1934. The cases were consolidated in the United States District Court for the Northern District of Georgia. On November 17, 2015, the parties entered into a stipulation of settlement to settle the consolidated case in its entirety. The stipulation of settlement was filed with the Court on November 18, 2015. On November 19, 2015, the Court preliminarily approved the settlement and has set the final settlement hearing for April 5, 2016. The Company does not believe the terms of the settlement, if finally approved, will have a material adverse effect on its operating results or financial condition.

### **OIG Investigation**

In the fourth quarter of 2014, the Company received a subpoena from the Office of Inspector General, U.S. Department of Health and Human Services, or OIG, in connection with a civil investigation into matters primarily related to the Company's sales and marketing activities. In March 2015, the Company received notice from the Department of Justice that it declined at that time to intervene in the qui tam action that gave rise to the issuance of the subpoena. The qui tam plaintiff had 120 days from the date of the Department of Justice's notice to proceed with the case. The 120 day period passed without initiation of the lawsuit. The plaintiff, who is an executive at the Company's competitor Organogenesis, Inc., voluntarily dismissed the lawsuit in July 2015. This dismissal was approved by the Court on October 6, 2015.

### **Patent Infringement Litigation**

MiMedx continues to diligently enforce its intellectual property against several entities. Currently, there are three actions pending, as described below:

#### ***The Liventa Action***

First, there is an action pending against several entities in the in the United States District Court for the Northern District of Georgia, i.e., "the Liventa Action". On April 22, 2014, the Company filed a patent infringement lawsuit against Liventa Bioscience, Inc. ("Liventa"), Medline Industries, Inc. ("Medline") and Musculoskeletal Transplant Foundation, Inc. ("MTF") for permanent injunctive relief and unspecified damages. In addition to the allegations of infringement of MiMedx's patents, the lawsuit asserts that Liventa and Medline knowingly and willfully made false and misleading representations about their respective products to providers, patients, and in some cases, prospective investors. The Liventa Action was filed in the United States District Court for the Northern District of Georgia.

MiMedx asserts that Liventa (formerly known as AFCCell Medical, Inc.), Medline and MTF infringed and continue to infringe certain of the Company's patents relating to the MiMedx dehydrated human amnion/chorion membrane ("dHACM") allografts. MTF is the tissue processor while Liventa and Medline are the distributors of the allegedly infringing products. On May 30, 2014, defendants filed answers to the Complaint, denying the allegations in the Complaint. They also raised affirmative defenses of non-infringement, invalidity, laches and estoppel. MTF and Medline also filed counterclaims seeking declaratory judgments of non-infringement and invalidity.

On June 30, 2014, fact discovery began and the parties have engaged in extensive fact discovery.

MiMedx served Infringement Contentions on August 29, 2014, and Defendants served Invalidity Contentions and Responses to Infringement Contentions on September 29, 2014. After a protracted series of meet and confers, MiMedx

required Defendants to supplement their invalidity contentions in view of parallel Inter Partes Review ("IPR")(see further discussion, *infra*) proceedings. MTF complied on June 26, 2015.

In September 2015, the Defendants filed a renewed Motion to Stay in light of the Patent Trial and Appeal Board's ("PTAB") decisions to institute IPRs on the '437 and '687 Patents, seeking a partial stay of the litigation as to the '437, '687, and '494 Patents (i.e., the '437 Patent family). MiMedx opposed the Motion to Stay with respect to the '494 Patent and once again successfully defeated Defendants' motion to stay.

Claim Construction proceedings began in October 2014. The parties submitted proposed constructions for key terms for the '701, '092, '437, '687, '207, and '494 Patents. Briefing was completed in March 2015.

On December 22, 2015, a Markman Hearing was held before Special Master Sumner C. Rosenberg. Over thirty disputed claim terms were at issue. One week later, on December 30, 2015, the Special Master issued its Report and Recommendation. Except for one term, the Special Master's Report essentially adopted MiMedx's proposed constructions. The parties are awaiting a final Court decision pending their respective objections.

#### ***The Bone Bank Action***

On May 16, 2014, the Company also filed a patent infringement lawsuit against Transplant Technology, Inc. d/b/a Bone Bank Allografts ("Bone Bank") and Texas Human Biologics, Ltd. ("Biologics") for permanent injunctive relief and unspecified damages (the "Bone Bank Action"). The Bone Bank Action was filed in the United States District Court for the Western District of Texas. This lawsuit similarly asserts that Bone Bank and Biologics infringed certain of the Company's patents through the manufacturing and sale of their placental-derived tissue graft products. On July 10, 2014, defendants filed an answer to the Complaint, denying the allegations in the Complaint. They also raised affirmative defenses of non-infringement and invalidity and filed counterclaims seeking declaratory judgments of non-infringement and invalidity. The Bone Bank Action is in an advanced stage. The parties have (i) substantially completed document production; (ii) taken several fact depositions (both party and non-party); and (iii) completed claim construction briefing. The Markman hearing in this case was held on October 2, 2015. Except for one term, the Court adopted MiMedx's proposed construction of the disputed terms. The parties have submitted a proposed scheduling order to the Court and are awaiting the Court's order in this regard. Meanwhile, the parties continue with fact discovery in view of recent depositions.

#### ***The NuTech Action***

Finally, on March 2, 2015, the Company filed a patent infringement lawsuit against NuTech Medical, Inc. ("NuTech") and DCI Donor Services, Inc. ("DCI") for permanent injunctive relief and unspecified damages. This lawsuit was filed in the United States District Court for the Northern District of Alabama. The lawsuit alleges that NuTech and DCI have infringed and continue to infringe the Company's patents through the manufacture, use, sale, and/or offering of their tissue graft product. The lawsuit also asserts that NuTech knowingly and willfully made false and misleading representations about its products to customers and/or prospective customers.

On April 17, 2015, NuTech filed a motion to dismiss the case purportedly for lack of patentable subject matter, which the Company opposed. NuTech also filed a motion to stay the case pending disposition of the motion to dismiss, which MiMedx also opposed, and on which the Court declined to rule. Hearing on the motion to dismiss occurred on August 20, 2015. On November 24, 2015, the court ruled on NuTech's Motion to Dismiss, granting in part, and denying in part. MiMedx still has claims against NuTech for infringement of the '494 and '687 patents, as well as violations of the Lanham Act; these claims shall proceed.

On December 30, 2015, the parties submitted a Joint Rule 26(f) Report of Parties' Planning Meeting and Proposed Case Management Order to the Court. In the Report, the parties requested that the Court stay the proceedings with respect to the '687 patent pending the completion of the inter partes review on that patent.

On January 8, 2016, MiMedx served its infringement contentions. Discovery has recently begun.

#### ***Pending IPRs***

In addition to defending the claims in the pending district court litigations, defendants in the Liventa and Bone Bank cases have challenged certain of the Company's patents in several IPR proceedings to avoid the high burden of proof of proving invalidity by "clear and convincing evidence" in the district court litigations. An inter partes review (or "IPR") is a request for a specialized group within the United States Patent and Trademark Office to review the validity of a plaintiff's patent claims. The

defendants in the Bone Bank Action have challenged the validity of the Company's 8,597,687 and 8,709,494 patents (the "'687" and "'494" patents, respectively); while the defendants in the Liventa Action have challenged the validity of the Company's 8,372,437 and 8,323,701 patents (the "'437" and "'701" patents, respectively).

On June 29, 2015, the Patent Trial and Appeals Board ("PTAB") denied defendants' request for institution of an IPR with respect to the '494 patent on all seven challenged grounds. On August 18, 2015, the PTAB also denied defendants' request for institution of an IPR with respect to the '701 patent on all six challenged grounds. That is, the PTAB decided in each case that the defendants failed to establish a reasonable likelihood that defendants would prevail in showing any of the challenged claims of the '494 or the '701 patent were unpatentable.

On July 10, 2015 the PTAB issued an opinion allowing a review of the '687 patent to proceed, although on only two of the five challenged grounds. The PTAB also adopted MiMedx's construction of the claims which will govern the Board's review of the '687 patent. On August 18, 2015, the PTAB issued an opinion allowing a review of the '437 patent to proceed, although only on one of the seven challenged grounds. Briefing and expert discovery is ongoing.

Following the PTAB decisions, the defendants in the Bone Bank Action moved to stay the district court litigation, despite the Court's previous denial of such a stay, pending the outcome of the '687 patent inter partes review. The parties agreed to stay the case with respect to the '687 patent only and the Court denied Bone Bank's motion to stay the litigation with respect to the '494 patent. The Company has also successfully defeated an attempt by defendants in the Liventa Action to stay that litigation -- also pending the outcome of the IPR of the patents at issue in that case.

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

Not applicable.

## PART II

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

Our common stock was approved for quotation on the OTC Bulletin Board on July 19, 2007. Only a limited number of shares were traded after the approval of the quotation in July 2007. The common stock was traded with the trading symbol of "AYXC." Our common stock began trading under the symbol "MDXG" on April 2, 2008. On April 25, 2013, our common stock was approved for trading on the NASDAQ.

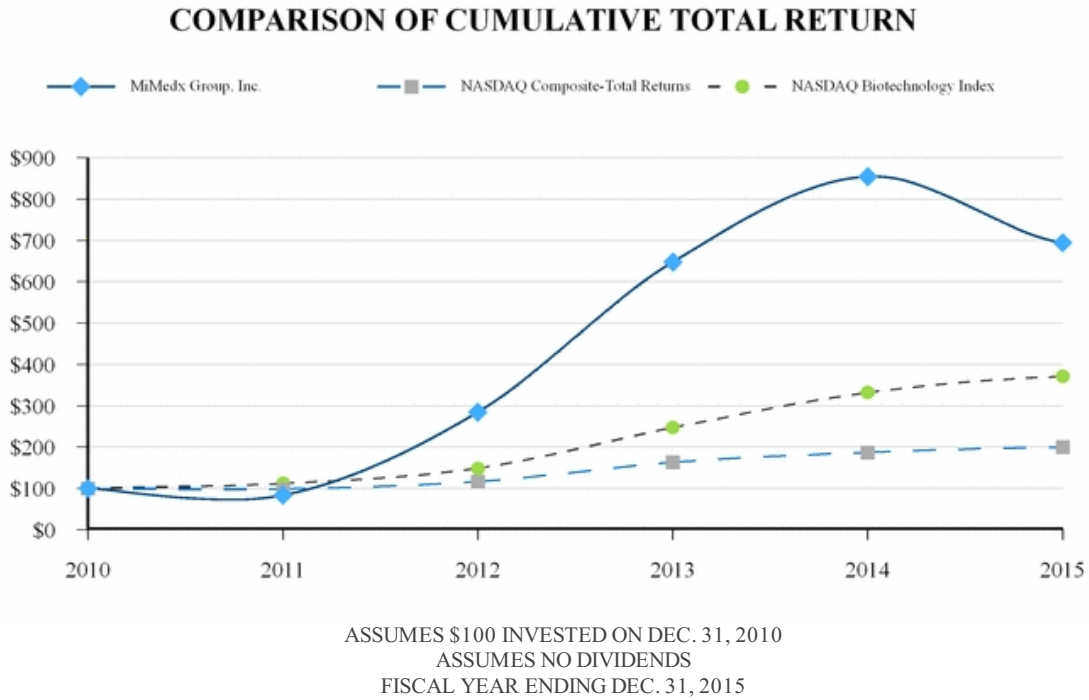
The following table sets forth, for the periods indicated, the range of high and low sale prices per share of common stock on NASDAQ for the fiscal years ended December 31, 2014 and 2015.

Year ended December 31, 2015	High	Low
First Quarter	\$ 11.33	\$ 7.92
Second Quarter	11.93	8.97
Third Quarter	13.20	8.52
Fourth Quarter	10.14	6.71
Year ended December 31, 2014	High	Low
First Quarter	\$ 8.68	\$ 5.56
Second Quarter	7.63	4.88
Third Quarter	7.90	6.10
Fourth Quarter	11.97	6.81

Based upon information supplied from our transfer agent, there were approximately 739 shareholders of record of our common stock as of February 10, 2016.

### 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 and the Nasdaq Biotechnology Index and assumes an investment of \$100.00 on December 31, 2010, in each of the common stock, the stocks comprising the Nasdaq Composite Index and the stocks comprising the Nasdaq Biotechnology Index.



### Unregistered Sales of Equity Securities and Use of Proceeds

In November of 2015, we issued approximately 42,000 unregistered shares of common stock in connection with the exercise of warrants at an exercise price of \$1.09 per share. These issuances were exempt under Section 4(a)(2) of the Securities Act of 1933 since the issuance of shares did not involve a public offering.



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

On May 12, 2014, our Board of Directors authorized the repurchase of up to \$10 million of our common stock from time to time, through December 31, 2014. The Board subsequently extended the program until December 31, 2016. In December 2014, the Board increased the authorization to a total of \$20 million and further increased the authorization in 2015 to a total of \$60 million. The timing and amount of repurchases will depend upon the Company's stock price, economic and market conditions, regulatory requirements, and other corporate considerations. The Company may initiate, suspend or discontinue purchases under the stock repurchase program at any time. Below is a summary of the Company's stock repurchases, before brokerage commissions of approximately \$70,000, for the quarter ended December 31, 2015. All shares were purchased pursuant to the Company's publicly announced repurchase program.

	Total Number of Shares Purchased	Average Price Paid per Share	Total Amount Spent Under the Plan	Remaining Amount to be Spent Under the Plan
Total amount remaining October 1, 2015			\$	3,414,850
October 2015 increased spending authorization			\$	20,000,000
October 1, 2015 - October 31, 2015	1,282,757	\$ 8.53	\$ 10,940,681	\$ 12,474,169
November 1, 2015 - November 30, 2015	912,456	\$ 7.65	\$ 6,980,399	\$ 5,493,770
December 2015 increased spending authorization			\$	10,000,000
December 1, 2015 - December 31, 2015	141,000	\$ 8.65	\$ 1,220,131	\$ 14,273,639
Total for the quarter	<u>2,336,213</u>	\$ 8.19	<u>\$ 19,141,211</u>	

**Item 6. Selected Financial Data**

The following selected consolidated financial data was derived from our consolidated financial statements. The data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 and Consolidated Financial Statements and notes in Item 8.

	As of December 31, in thousands				
	2015	2014	2013	2012	2011
<b>Statement of Operations Data:</b>					
Net sales	\$ 187,296	\$ 118,223	\$ 59,181	\$ 27,054	\$ 7,760
Gross margin	167,094	105,558	49,853	21,865	4,403
Operating income (loss)	24,364	7,100	(2,639)	(5,355)	(9,761)
Net income (loss)	\$ 29,446	\$ 6,220	\$ (4,112)	\$ (7,662)	\$ (10,194)
Net income (loss) per common share - basic	\$ 0.28	\$ 0.06	\$ (0.04)	\$ (0.09)	\$ (0.14)
Net income (loss) per common share - diluted	\$ 0.26	\$ 0.05	\$ (0.04)	\$ (0.09)	\$ (0.14)

	As of December 31, in thousands				
	2015	2014	2013	2012	2011
<b>Balance Sheet Data:</b>					
Total assets	\$ 135,913	\$ 109,259	\$ 84,694	\$ 35,183	\$ 27,096
Working capital	69,533	67,272	55,781	13,072	2,149
Long term liabilities	1,148	1,526	1,518	10,158	10,468
Stockholders' equity	107,988	89,329	73,568	20,007	11,897

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

The following discussion and analysis should be read in conjunction with the Consolidated Financial Statements and the corresponding notes included in Item 8. Certain percentages presented in this discussion and analysis are calculated from the underlying whole dollar amounts and therefore may not recalculate from the rounded numbers used for disclosure purposes. Some of the information contained in this discussion and analysis or set forth elsewhere in this report includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" section of this report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

The discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires making estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue, and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

### Overview

MiMedx® is an integrated developer, processor and marketer of patent protected and proprietary regenerative biomaterial products and bioimplants processed from human amniotic membrane and other birth tissues and human skin and bone. "*Innovations in Regenerative Biomaterials*" is the framework behind our mission to give physicians products and tissues to help the body heal itself. Our biomaterial platform technologies are AmnioFix®, EpiFix®, OrthoFlo, Physio™, AlloBurn™, and CollaFix™. AmnioFix and EpiFix are our tissue technologies processed from human amniotic membrane derived from donated placentas. Elected in advance of delivery through our donor program, a mother delivering a healthy baby via scheduled full-term Caesarean section birth may donate the placenta in lieu of having it discarded as medical waste. We process the human amniotic membrane utilizing our proprietary PURION® Process, to produce a safe and effective implant. MiMedx is the leading supplier of amniotic tissue, having supplied over 500,000 allografts to date for application in the Wound Care, Burn, Surgical, Orthopedic, Spine, Sports Medicine, Ophthalmic and Dental sectors of healthcare. We recently introduced OrthoFlo, an amniotic fluid derived allograft for homologous use. Amniotic fluid is donated by a consenting mother delivering a full-term healthy baby by scheduled Caesarean section. Through the recent acquisition of Stability Biologics, our newest proprietary platforms include Physio, a unique bone grafting material comprised of 100% bone tissue with no added carrier, a demineralized bone matrix (DBM) to complement our product portfolio offerings within the Orthopedic market and AlloBurn, a skin product for burns. CollaFix, our next technology platform we plan to commercialize, is our collagen fiber technology designed to mimic the natural composition, structure and mechanical properties of musculoskeletal tissues in order to augment their repair. CollaFix is the only known biological, biodegradable, biomimetic technology that matches human tendon in strength and stiffness.

Our EpiFix allografts are configured for external use. We offer EpiFix® in a sheet form as well as a micronized powder form. Currently, the EpiFix platform is being used to treat chronic wounds, including diabetic foot ulcers, venous stasis ulcers, arterial ulcers and pressure ulcers, burns and surgical wounds (such as wounds following plastic surgery).

Our AmnioFix allografts consist of three configurations, all configured for internal use:

- AmnioFix is provided in a sheet form. It is used to modulate inflammation, enhance soft tissue healing and to minimize scar tissue formation. It has been used in spine, urology and general surgeries.
- AmnioFix Wrap also is supplied in a sheet form and is configured for the same purposes as AmnioFix®, but is optimized for use as a "wrap" for nerves, tendons or ligaments.
- AmnioFix Injectable is supplied in micronized powder form used to reduce inflammation while enhancing healing of soft tissue. AmnioFix Injectable has been used to treat conditions such as tendonitis, including plantar fasciitis, lateral epicondylitis, and medial epicondylitis, bursitis, strains and sprains.

We also process allografts for ophthalmic surgery and dental applications, which are sold on an OEM basis.

Our assets also include licenses to two medical device technology platforms- HydroFix and CollaFix. Although we had commercialized some products based on the HydroFix technology, due to the relatively small size of the addressable market for those products, we decided to discontinue that product line in the fourth quarter of 2013. We are currently working to develop products using our CollaFix technology and continue to assess how best to exploit that technology.

Our distribution model is comprised of direct sales, third party sales agents and stocking distributors that market MiMedx-branded products. We also have several OEM relationships targeting the spine, orthopedic, ophthalmic and dental markets. Our primary focus is in the U.S. market, but we are currently exploring international expansion opportunities. In 2015 approximately 3% of our revenues were from sales outside the U.S. to stocking distributors compared with less than 1% of revenues in 2014.

## **Recent Events**

### ***FDA Guidance***

On December 22, 2014, the FDA issued for comment "Draft Guidance for Industry and FDA Staff: Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products." Essentially, the Minimal Manipulation draft guidance takes the same position with respect to micronized amniotic tissue that it took in the Untitled Letter to the Company 16 months earlier. The Company submitted comments to the Minimal Manipulation draft guidance asserting that the Minimal Manipulation draft guidance represents agency action that goes far beyond the FDA's statutory authority, is inconsistent with existing HCT/ P regulations and the FDA's prior positions, and is internally inconsistent and scientifically unsound. On October 28, 2015, the FDA issued for comment, "Draft Guidance for Industry and FDA Staff: Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products." The Company submitted comments on this Homologous Use draft guidance. The FDA has also indicated that it will hold a public hearing on a date in 2016 to be determined to obtain input on the Homologous Use draft guidance and the previously released Minimal Manipulation draft guidance, as well as other recently issued guidance documents on HCT/Ps. The Company has requested, and has been granted an opportunity to speak at this hearing.

### ***Acquisition of Stability***

On January 13, 2016, the Company completed the acquisition of Stability Inc., d/b/a Stability Biologics, a provider of human tissue products to surgeons, facilities, and distributors serving the surgical, spine, and orthopedic sectors of the healthcare industry. The acquisition of Stability was effected by the merger of Stability Inc. into a newly created wholly owned subsidiary of the Company. The new subsidiary was the surviving company in the merger and was subsequently renamed Stability Biologics, LLC ("Stability"). The Company paid \$10 million at the closing, comprised of 60% cash and 40% in shares of common stock of MiMedx Group, Inc., assumed approximately \$800,000 in debt and eliminated a \$2.4 million receivable related to Company products sold to Stability prior to the acquisition. The Company will also pay future contingent consideration through a two-year earn out arrangement based on the 2016 and 2017 performance of Stability's business. The Company expects the earn out will be the larger portion of the overall consideration for the transaction. The earn out will also be paid in the form of 60% cash and 40% in shares of stock of MiMedx Group, Inc.

## **Critical Accounting Policies**

We believe that of our significant accounting policies, which are described in Note 2 to our financial statements appearing elsewhere in this report, the following accounting policies involve a greater degree of judgment and complexity.

### ***Revenue Recognition and Sales Returns, Discounts, and Allowances Accruals***

The Company sells its products primarily through a combination of a direct sales force, independent stocking distributors and third - party representatives in the U.S. and independent distributors in international markets. The Company recognizes revenue when title to the goods and risk of loss transfers to customers, provided there are no material remaining performance obligations required of the Company or any matters of customer acceptance. In cases where the Company utilizes distributors or ships products directly to the end user, it recognizes revenue according to the shipping terms of the agreement provided all revenue recognition criteria have been met. A portion of the Company's revenue is generated from inventory maintained at hospitals or with field representatives. For these products, revenue is recognized at the time the product has been

used or implanted. The Company records estimated sales returns, discounts and allowances as a reduction of net sales in the same period revenue is recognized.

#### *Goodwill and Impairment of Long-Lived Assets*

Goodwill is the excess of the purchase price over the fair value of net assets of acquired businesses. Goodwill is tested for impairment annually or whenever an event occurs or circumstances change that would indicate that the carrying amount may be impaired. The test for impairment requires us to make several estimates about fair value, most of which are based on projected future cash flows. Our estimates associated with the goodwill impairment test are considered critical due to the amount of goodwill recorded on our consolidated balance sheets and the judgment required in determining fair value, including projected future cash flows. No goodwill impairment has been recognized during 2015, 2014 or 2013.

Other intangible assets include patents, trademarks, and purchased technology. Intangible assets with a definite life are amortized on a straight-line or accelerated basis, as appropriate, with estimated useful lives ranging from ten to fourteen years, and are tested for impairment whenever events or changes in circumstances indicate that the carrying amount of an intangible asset may not be recoverable. Indefinite-lived intangible assets are tested for impairment annually or whenever events or changes in circumstances indicate that the carrying amount of an intangible asset may not be recoverable. Refer to Note 8 to the consolidated financial statements in Item 8 for additional information. Our 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, asset groupings, and other assumptions and estimates. We use estimates that are consistent with our business plans and a market participant view of the assets being evaluated. Actual results may differ from our estimates. In 2012, because our impairment test indicated that the carrying value of the intangible assets related to HydroFix exceeded its fair value, an impairment loss of approximately \$1,798,000 was recognized and the intangible asset carrying amount was adjusted to its new basis. During the fourth quarter of 2013 we chose to discontinue the HydroFix product line. This action resulted in an impairment charge of approximately \$368,000. This item is included in our Statement of Operations for the year ended December 31, 2013.

#### *Fair Value Measurements*

We record certain financial instruments at fair value, including: cash equivalents and contingent consideration. We may make an irrevocable election to measure other financial instruments at fair value on an instrument-by-instrument basis; although as of December 31, 2015 we have not chosen to make any such elections. Fair value financial instruments are recorded in accordance with the fair value measurement framework.

We also measure 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 applying accounting for business combinations. We use the fair value measurement framework to value these assets and report the fair values in the periods in which they are recorded or written down.

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; and*
- *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 requires judgment. Level 3 valuations often involve a higher degree of judgment and complexity. Level 3 valuations may require the use of various cost, market, or income valuation methodologies applied to unobservable 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. We may also engage external advisors to assist us in determining fair value, as appropriate.

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

### *Share-based Compensation*

We follow the provisions of FASB Accounting Standards Codification (“ASC”) 718, “Compensation — Stock Compensation” (ASC 718), previously referred to as Statement of Financial Accounting Standards No. 123R — Share-based Payments which requires the measurement and recognition of compensation expense for all share-based payment awards either modified or granted to employees and directors based upon estimated fair values. The Black-Scholes-Merton option-pricing model, consistent with the provisions of ASC 718, was used to determine the fair value of each option granted. Option valuation models require the input of highly subjective assumptions, including the expected stock price volatility. We use projected volatility rates, which are based upon historical volatility rates, trended into future years. Because our stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management’s opinion, the existing models do not necessarily provide a reliable single measure of the fair value of our options.

### *Income Taxes*

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, we determine deferred tax assets and liabilities on the basis of the differences between the financial statement and tax bases of assets and liabilities by 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 income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that we believe that these assets are more likely than not to be realized. In making such a determination, we consider all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If we determine that we would be able to realize our deferred tax assets in the future in excess of their net recorded amount, we would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions in accordance with ASC 740 on the basis of a two-step process in which (1) we determine 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, we recognize the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority.

### **Recently Adopted Accounting Pronouncements**

See Note 2 to the consolidated financial statements in Item 8 for recently adopted accounting pronouncements.

### **Results of Operations for the year ended December 31, 2015, compared to the year ended December 31, 2014**

#### *Revenue*

Total revenue increased \$69.1 million, or 58%, from approximately \$118.2 million in 2014 to \$187.3 million in 2015. This growth in revenue was driven by increases in our direct sales force, taking market share from other suppliers of wound care technologies, as well as market expansion due to the clinical and cost benefits of our EpiFix platform. Growth was also driven by expansion into several new surgical applications with our AmnioFix platform. Wound Care revenue in 2015 grew by \$47.5 million, or approximately 51%, compared with 2014. Surgical, Sports Medicine, and Orthopedics (SSO) revenue in 2015 grew by \$21.5 million or approximately 87%, compared with 2014.

#### *Tissue Processing Costs and Cost of Products Sold*

Cost of sales as a percentage of revenue was 10.8% versus 10.7% when compared to the prior year. The increase is due to the expiration of pass through status of our wound care products for Medicare patients in hospital out-patient clinics and ambulatory surgery centers, product sales mix, mostly offset by an increase in direct sales revenue and higher production rates that absorb a greater percentage of fixed manufacturing costs, and continued improvements in manufacturing efficiencies. SSO sales have lower gross margins than Wound Care sales, so the Company expects cost of sales as a percentage of revenue to increase as SSO sales become a larger percentage of total company sales.

### ***Research and Development Expenses***

Our research and development expenses increased approximately \$1.4 million, or 19%, to \$8.4 million in 2015, compared to approximately \$7.0 million in the prior year. The increase is primarily related to increased investments in clinical trials, personnel costs, lab supplies, and consulting fees. The Company expects research and development expenses to remain in line with current spending on a percentage of sales basis moving forward.

### ***Selling, General and Administrative Expenses***

Selling, General and Administrative expenses for 2015 increased approximately \$42.9 million, or 47%, to \$133.4 million compared to \$90.5 million for 2014. Selling expense increases were driven primarily by costs associated with building our direct sales organization for both the Wound Care and SSO markets, where headcount grew by 65 during the year, as well as increased commissions due to higher sales volume. General and administrative expense increases were driven primarily by costs associated with adding personnel to support continued growth, as well as increased patent litigation costs.

Selling, General and Administrative expenses consist of personnel costs, professional fees, sales commissions, sales training costs, industry trade show fees and expenses, product promotions and product literature costs, facilities costs and other sales, marketing and administrative costs, depreciation and amortization, and share-based compensation. Share-based compensation included in SG&A for the years ended December 31, 2015 and 2014, was approximately \$15.8 million and \$10.5 million, respectively, an increase of approximately \$5.3 million, or 50%.

Amortization expense related to intangible assets remained flat at \$0.9 million for the year ended December 31, 2015 as compared to the prior year. We amortize our intangible assets over a period of 10 to 17 years, which we believe represents the remaining useful lives of the patents underlying the licensing rights and intellectual property. We do not amortize goodwill but we test our goodwill at least annually for impairment and periodically evaluate other intangibles for impairment based on events or changes in circumstances as they occur.

### ***Net Interest Expense***

We recorded financing and net interest expense of approximately \$86,000 during the year ended December 31, 2015, compared with approximately \$48,000 of financing and net interest expense during the year ended December 31, 2014. The increase is due to the amortization of deferred financing costs incurred during 2015 related to our \$50 million revolving credit facility. See Note 9 in the consolidated financial statements in Item 8 for further details.

### **Results of Operations for the year ended December 31, 2014, compared to the year ended December 31, 2013**

#### ***Revenue***

Total revenue increased \$59 million, or 100%, from approximately \$59.2 million in 2013 to \$118.2 million in 2014. The increase in revenue as compared to the prior year is due primarily to increased wound care sales of EpiFix in both commercial and Government accounts. Commercial revenue growth was driven by expanded Medicare and private insurance coverage.

#### ***Tissue Processing Costs and Cost of Products Sold***

Cost of products sold as a percentage of revenue were 10.7% versus 15.8% when compared to the prior year. The improvement was due primarily to the increase in direct sales revenue, favorable product mix and higher production rates that absorb a greater percentage of fixed manufacturing costs.

### ***Research and Development Expenses***

Our research and development expenses increased approximately \$2.2 million, or 46%, to \$7.0 million in 2014, compared to approximately \$4.8 million in the prior year. The increase is primarily related to increased investments in clinical trials, personnel costs, lab supplies, and testing costs. Our research and development expenses consist primarily of internal personnel costs, clinical trials, fees paid to external consultants, and supplies and instruments used in our laboratories. Additionally, during 2014, we were granted seven U.S. patents for the amnion technology, one U.S. patent for the collagen technology (under license agreement), and four international patents for the collagen technology (three under license agreements).

### ***Selling, General and Administrative Expenses***

Selling, General and Administrative expenses for 2014 increased approximately \$44.3 million, or 96%, to \$90.5 million compared to \$46.2 million for 2013. Selling expense increases were driven by costs associated with building our direct sales organization for Government and commercial accounts, where headcount grew by 94 during the year, as well as increased commissions due to higher sales volume.

Additional increases included spending on support costs related to medical reimbursement, including our reimbursement hotline; our information technology infrastructure to help manage the growth of the business; increased share-based compensation expense, and a provision for anticipated costs associated with the management incentive program.

Selling, General and Administrative expenses consist of personnel costs, professional fees, sales commissions, sales training costs, industry trade show fees and expenses, product promotions and product literature costs, facilities costs and other sales, marketing and administrative costs, depreciation and amortization, and share-based compensation. Share-based compensation included in SG&A for the years ended December 31, 2014 and 2013, was approximately \$10.5 million and \$5.3 million, respectively, an increase of approximately \$5.2 million, or 98%.

We recorded approximately \$.9 million and \$1.1 million in amortization expense related to intangible assets in the years ended December 31, 2014 and 2013, respectively. The decrease of approximately \$0.2 million is attributable to the impairment related to our HydroFix product line which we elected to discontinue in the fourth quarter of 2013. We amortize our intangible assets over a period of 10 to 17 years, which we believe represents the remaining useful lives of the patents underlying the licensing rights and intellectual property. We do not amortize goodwill but we test our goodwill at least annually for impairment and periodically evaluate other intangibles for impairment based on events or changes in circumstances as they occur.

#### **Net Interest Expense**

We recorded financing and net interest expense of approximately \$48,000 during the year ended December 31, 2014, compared with approximately \$1.4 million of financing and net interest expense during the year ended December 31, 2013, which represented the amortization of debt discount in connection with convertible senior secured promissory notes issued in 2011.

#### **Contractual Commitments**

The table below sets forth our known contractual obligations as of December 31, 2015 (in thousands):

Contractual Obligations	TOTAL	less than 1 year	1-3 years	3-5 years	More than 5 years
Capital lease obligations	\$ 133	\$ 102	\$ 31	\$ —	\$ —
Operating lease obligations	7,542	1,804	3,623	2,115	—
Charitable contribution obligations	250	250	—	—	—
Meeting space commitments	1,247	764	483	—	—
	<u>\$ 9,172</u>	<u>\$ 2,920</u>	<u>\$ 4,137</u>	<u>\$ 2,115</u>	<u>\$ —</u>

#### **Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements.

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

Our net working capital at December 31, 2015, increased \$2.2 million to \$69.5 million from \$67.3 million at December 31, 2014. The increase in working capital was primarily due to our revenue growth resulting in an increase in accounts receivable, mostly offset by cash used for share repurchases. The current ratio (current assets divided by current liabilities) decreased to 3.6 as of December 31, 2015, as compared to 4.6 at December 31, 2014.

On October 12, 2015, the Company and its subsidiaries entered into a Credit Agreement (the "Credit Agreement") with certain lenders and Bank of America, N.A., as administrative agent. The Credit Agreement establishes a senior secured revolving credit facility in favor of the Company, with an aggregate lender commitment of up to \$50 million at any time



outstanding. As of the date hereof, there are no outstanding revolving loans under the Credit Agreement. The Credit Agreement also provides for an uncommitted incremental facility of up to \$35 million, which can be exercised as one or more revolving commitment increases or new term loans, all subject to certain customary terms and conditions set forth in the Credit Agreement. The obligations of the Company under the Credit Agreement are guaranteed by the Company's subsidiaries. Borrowings under the Credit Agreement bear interest at a rate equal to, at the Company's option, the base rate or LIBOR, in each case plus an applicable margin. The base rate under the Credit Agreement equals the highest of (i) the agent's prime rate, (ii) the Federal Funds rate plus 0.50%, or (iii) LIBOR for a one month interest period plus 1.0%. The initial applicable margin is 0.50% with respect to base rate borrowings and 1.50% with respect to the LIBOR borrowings. The applicable margin is subject to quarterly pricing adjustments based on the Company's consolidated leverage ratio. In addition to paying interest on outstanding principal under the facility, the Company is required to pay a commitment fee in respect of committed but unutilized commitments equal to 0.25% per annum initially. The commitment fee is subject to quarterly adjustments based on the Company's consolidated leverage ratio. The Company must pay a fee on outstanding letters of credit under the facility at a rate equal to the applicable margin in respect of LIBOR borrowings plus certain fronting and administrative fees. The maturity date of the revolving credit facility is October 12, 2018. The Credit Agreement provides that the maturity date may be extended up to twice for one additional year each, subject to certain customary terms and conditions set forth in the Credit Agreement, if requested by the Company and agreed-upon by the lenders. The Credit Agreement contains customary covenants and events of default for senior secured credit agreements of this type. The covenants include (a) a requirement for the Company to maintain a maximum consolidated leverage ratio of 2.50:1.00; (b) a requirement for the Company to maintain a minimum consolidated fixed charge coverage ratio of 2.00:1.00; and (c) a requirement for the Company to maintain minimum liquidity of \$10 million.

As of December 31, 2015, we had approximately \$28.5 million of cash and cash equivalents. In addition, we had short term investments in FDIC insured certificates of deposit at various U.S. financial institutions that totaled, approximately \$3.0 million. We believe that our anticipated cash from operating activities, existing cash and cash equivalents and availability under the Credit Agreement will enable us to meet our operational liquidity needs and fund our planned investing activities for the next year.

#### **Discussion of cash flows**

Net cash from operations during the year ended December 31, 2015, increased approximately \$2.0 million to \$18.8 million, compared to \$16.8 million from operating activities for the year ended December 31, 2014, and was primarily attributable to the increase in Net Income (net of non cash items), partially offset by an increase in accounts receivable.

Net cash used in investing activities during the year ended December 31, 2015, decreased approximately \$11.5 million to \$0.7 million compared to \$12.2 million used in investing activities for the year ended December 31, 2014. The decrease was primarily due to maturing certificates of deposit.

Net cash flows used in financing activities during the year ended December 31, 2015, was approximately \$36.2 million compared to \$2.1 million during the year ended December 31, 2014. The increase is primarily due to an increase in share repurchases, partially offset by an increase in proceeds received from the exercise of stock options and warrants.

Due to the material amount of non-cash related items included in our results of operations, we have developed an Adjusted EBITDA metric that provides management with a clearer view of operational use of cash (see the table below). Our Adjusted EBITDA for the year ended December 31, 2015, was approximately \$44.0 million which is an improvement of approximately \$23.3 million as compared to 2014 and an improvement of \$38.5 million compared to 2013. These year-over-year improvements were the result of improved operating results.

Adjusted EBITDA is a non-GAAP measure. Non-GAAP financial measures are commonly used in the industry and are presented because management believes they provide relevant and useful information to investors. However, there are limitations to using these non-GAAP financial measures. Adjusted EBITDA is not indicative of cash provided or used by operating activities and may differ from comparable information provided by other companies. Adjusted EBITDA should not be considered in isolation, as an alternative to, or more meaningful than measures of financial performance determined in accordance with U.S. GAAP. The following table presents a reconciliation of Adjusted EBITDA to Net Income (loss), the most comparable financial measure reported under GAAP, for the years ended December 31, 2015, 2014 and 2013.

Years Ended December 31 (in thousands)

	2015	2014	2013
Net Income (Loss) (Per GAAP)	\$ 29,446	\$ 6,220	\$ (4,112)
Add back (deduct):			
Income Taxes	(5,168)	832	100
Financing expense associated with beneficial conversion of Senior Secured Promissory Notes	—	—	1,328
Other interest expense, net	86	48	45
Depreciation Expense	1,799	1,197	637
Loss on fixed asset disposal	—	—	37
Amortization Expense	933	928	1,054
Share-Based Compensation	16,896	11,453	6,010
Impairment of Intangible Assets	—	—	368
Income Before Interest, Taxes, Depreciation, Amortization and Share -Based Compensation (Adjusted EBITDA)	\$ 43,992	\$ 20,678	\$ 5,467

**Inflation**

We do not believe that the rate of inflation has had a material effect on our operating results. However, inflation could adversely affect our future operating results.

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

Based on our lack of market risk sensitive instruments outstanding at December 31, 2015, we have determined that there was no material market risk exposure to our consolidated financial position, results of operations or cash flows as of such date.

## Item 8. Financial Statements and Supplementary Data

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of MiMedx Group, Inc. and subsidiaries ( the "Company") as of December 31, 2015 and 2014, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years ended in the period ended December 31, 2015. We have also audited the accompanying consolidated financial statement schedule for each of the three years in the period ended December 31, 2015 listed in the index at Item 15. These consolidated financial statements and schedules are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of MiMedx Group, Inc. and subsidiaries as of December 31, 2015 and 2014, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2015 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the related consolidated financial statement schedule for each of the three years in the period ended December 31, 2015, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), MiMedx Group, Inc.'s internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control—Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 29, 2016 expressed an unqualified opinion.

/s/ Cherry Bekaert LLP

Atlanta, Georgia

February 29, 2016

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited MiMedx Group, Inc.'s internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). MiMedx Group, Inc.'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 Management's 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 conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States of America). 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 of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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.

In our opinion, MiMedx Group, Inc maintained, in all material respects, effective internal control over financial reporting as of December 31, 2014, based on criteria established in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of MiMedx Group, Inc. and subsidiaries as of December 31, 2015 and 2014, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2015 and the related consolidated financial statement schedules as of December 31, 2015, 2014 and 2013, and our report dated February 29, 2016 expressed an unqualified opinion.

/s/ Cherry Bekaert LLP

Atlanta, Georgia

February 29, 2016

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

	December 31,	
ASSETS	2015	2014
Current assets:		
Cash and cash equivalents	\$ 28,486	\$ 46,582
Short term investments	3,000	5,750
Accounts receivable, net	53,755	26,672
Inventory, net	7,460	5,133
Prepaid expenses and other current assets	3,609	1,540
Total current assets	96,310	85,677
Investments	—	3,250
Property and equipment, net of accumulated depreciation	9,475	5,447
Goodwill	4,040	4,040
Intangible assets, net of accumulated amortization	10,763	10,845
Deferred tax asset, net	14,838	—
Deferred financing costs and other assets	487	—
Total assets	\$ 135,913	\$ 109,259
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 6,633	\$ 3,661
Accrued compensation	15,034	11,523
Accrued expenses	4,644	2,504
Other current liabilities	466	716
Total current liabilities	26,777	18,404
Other liabilities	1,148	1,526
Total liabilities	27,925	19,930
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Preferred stock; \$.001 par value; 5,000,000 shares authorized and 0 shares issued and outstanding	—	—
Common stock; \$.001 par value; 150,000,000 shares authorized; 109,467,416 issued and 107,361,471 outstanding at December 31, 2015 and 108,776,247 issued and 107,789,611 outstanding at December 31, 2014	109	108
Additional paid-in capital	163,133	162,433
Treasury stock at cost: 2,105,945 shares at December 31, 2015 and 986,636 shares at December 31, 2014	(17,125)	(5,637)
Accumulated deficit	(38,129)	(67,575)
Total stockholders' equity	107,988	89,329
Total liabilities and stockholders' equity	\$ 135,913	\$ 109,259

See notes to consolidated financial statements

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

	Years Ended December 31,		
	2015	2014	2013
Net sales	\$ 187,296	\$ 118,223	\$ 59,181
Cost of sales	20,202	12,665	9,328
Gross margin	167,094	105,558	49,853
<b>Operating expenses:</b>			
Research and development expenses	8,413	7,050	4,843
Selling, general and administrative expenses	133,384	90,480	46,227
Impairment of intangible assets	—	—	368
Amortization of intangible assets	933	928	1,054
Operating income (loss)	24,364	7,100	(2,639)
<b>Other income (expense), net</b>			
Amortization of debt discount	—	—	(1,328)
Interest expense, net	(86)	(48)	(45)
Income (loss) before income tax provision	24,278	7,052	(4,012)
Income tax provision	5,168	(832)	(100)
Net income (loss)	\$ 29,446	\$ 6,220	\$ (4,112)
Net income (loss) per common share - basic	\$ 0.28	\$ 0.06	\$ (0.04)
Net income (loss) per common share - diluted	\$ 0.26	\$ 0.05	\$ (0.04)
Weighted average shares outstanding - basic	105,929,205	105,793,008	96,285,504
Weighted average shares outstanding - diluted	113,628,482	113,295,504	96,285,504

See notes to consolidated financial statements

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

	Common Stock		Additional	Treasury Stock		Accumulated	Total
	Shares	Amount	Paid-in Capital	Shares	Amount	Deficit	
Balances, December 31, 2012	88,423,169	\$ 88	\$ 89,627	50,000	\$ (25)	\$ (69,683)	\$ 20,007
Share-based compensation expense	—	—	6,010	—	—	—	6,010
Exercise of stock options	1,958,674	2	1,979	—	—	—	1,981
Exercise of warrants	1,844,352	2	2,106	—	—	—	2,108
Common stock issued for 5% convertible note	5,272,004	5	5,267	—	—	—	5,272
Common stock issued for earn - out liability	1,174,915	1	5,791	—	—	—	5,792
Issuance of restricted stock	2,500	—	—	—	—	—	—
Public offering of common stock, net of expenses	5,750,000	6	36,504	—	—	—	36,510
Net income (loss)	—	—	—	—	—	(4,112)	(4,112)
Balances, December 31, 2013	104,425,614	\$ 104	\$ 147,284	50,000	\$ (25)	\$ (73,795)	\$ 73,568
Share-based compensation expense	—	—	11,453	—	—	—	11,453
Exercise of stock options	1,653,690	2	2,468	—	—	—	2,470
Exercise of warrants	1,242,416	1	1,112	—	—	—	1,113
Issuance of restricted stock	1,438,569	1	(1)	—	—	—	—
Shares issued for services performed	15,958	—	117	—	—	—	117
Stock repurchase	—	—	—	936,636	(5,612)	—	(5,612)
Net income	—	—	—	—	—	6,220	6,220
Balance December 31, 2014	108,776,247	\$ 108	\$ 162,433	986,636	\$ (5,637)	\$ (67,575)	\$ 89,329
Share-based compensation expense	—	—	16,896	—	—	—	16,896
Tax benefit of share-based compensation expense	—	—	7,757	—	—	—	7,757
Exercise of stock options	647,656	1	(9,792)	(1,573,225)	14,420	—	4,629
Exercise of warrants	—	—	(379)	(42,400)	425	—	46
Issuance of restricted stock	34,250	—	(14,547)	(1,940,009)	14,547	—	—
Restricted stock shares canceled/forfeited	(2,058)	—	652	69,949	(652)	—	—
Shares issued for services performed	11,321	—	113	(5,172)	51	—	164
Stock repurchase	—	—	—	4,610,166	(40,279)	—	(40,279)
Net income	—	—	—	—	—	29,446	29,446
Balances, December 31, 2015	109,467,416	\$ 109	\$ 163,133	2,105,945	\$ (17,125)	\$ (38,129)	\$ 107,988

See notes to consolidated financial statements



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

	Years Ended December 31,		
	2015	2014	2013
Cash flows from operating activities:			
Net income (loss)	\$ 29,446	\$ 6,220	\$ (4,112)
Adjustments to reconcile net income (loss) to net cash from operating activities:			
Depreciation	1,799	1,197	637
Loss on fixed asset disposal	—	—	37
Amortization of intangible assets	933	928	1,054
Impairment of intangible assets	—	—	368
Amortization of debt discount and deferred financing costs	42	—	1,328
Share-based compensation	16,896	11,453	6,010
Change in deferred income taxes	(7,081)	—	—
Increase (decrease) in cash resulting from changes in:			
Accounts receivable	(27,083)	(10,579)	(8,439)
Inventory	(2,327)	(1,252)	(858)
Prepaid expenses and other assets	(2,094)	(203)	(637)
Accounts payable	3,136	1,287	1,209
Accrued compensation	3,511	5,935	2,836
Accrued expenses	2,140	1,098	353
Accrued interest	—	—	(42)
Other liabilities	(511)	718	(28)
Net cash flows from operating activities	<u>18,807</u>	<u>16,802</u>	<u>(284)</u>
Cash flows from investing activities:			
Purchases of equipment	(5,827)	(2,558)	(2,337)
Maturity (purchases) of fixed maturity securities	6,000	(9,000)	—
Patent application costs	(851)	(594)	(689)
Net cash flows from investing activities	<u>(678)</u>	<u>(12,152)</u>	<u>(3,026)</u>
Cash flows from financing activities:			
Proceeds from exercise of stock options	4,629	2,470	1,981
Proceeds from exercise of warrants	46	1,113	2,108
Proceeds from public offering, net of expenses	—	—	36,602
Deferred financing costs	(504)	—	—
Stock repurchase	(40,279)	(5,612)	—
Principal payments of equipment leases	(117)	(117)	(57)
Net cash flows from financing activities	<u>(36,225)</u>	<u>(2,146)</u>	<u>40,634</u>
Net change in cash	(18,096)	2,504	37,324
Cash and cash equivalents, beginning of period	46,582	44,078	6,754
Cash and cash equivalents, end of period	<u>\$ 28,486</u>	<u>\$ 46,582</u>	<u>\$ 44,078</u>

See notes to consolidated financial statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE FISCAL YEARS ENDED DECEMBER 31, 2015 AND 2014

**1. Nature of Business**

MiMedx Group, Inc. ("MiMedx," "the Company," "we," or "us") operates in one business segment, Regenerative Biomaterials, which includes the development, processing and marketing of regenerative biomaterial products and bioimplants processed from human amniotic membrane and other birth tissues in the Wound Care, Surgical, Sports Medicine, Ophthalmic and Dental market categories. The Company's biomaterial platform technologies include tissue technologies, AmnioFix and EpiFix, amniotic fluid derived allograft, OrthoFlo, and anticipated device technology CollaFix, which the Company has yet to commercialize.

The Company is focused primarily on the United States but is actively exploring international expansion opportunities. The adoption of the technologies may vary depending on each country's regulations, but the opportunities to help individuals in the different disease states remain similar and large.

**2. Significant Accounting Policies**

*Use of Estimates*

The preparation of financial statements in conformity with generally accepted accounting principles ("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 financial statements and the reported consolidated statements of operations during the reporting period. Actual results could differ from those estimates.

*Principles of Consolidation*

The accompanying financial statements include the accounts of MiMedx Group, Inc. and its wholly-owned subsidiaries MiMedx, Inc., MiMedx Processing Services, LLC (formerly known as SpineMedica, LLC), and MiMedx Tissue Services, LLC (formerly known as Surgical Biologics, LLC). All significant inter-company balances and transactions have been eliminated.

*Segment Reporting*

ASC 280, "Segment Reporting" requires use of the "management approach" model for segment reporting. The management approach model is based on the way a company's management organizes segments within the company for making operating decisions and assessing performance. The Company has determined it has one operating segment. Disaggregation of the Company's operating results is impracticable, because the Company's research and development activities and its assets overlap, and management reviews its business as a single operating segment. Thus, discrete financial information is not available for more than one operating segment.

*Market Concentrations and Credit Risk*

The Company places its cash and cash equivalents on deposit with financial institutions in the United States. In July 2010, the Federal Deposit Insurance Corporation ("FDIC") increased coverage to \$250,000 for substantially all depository accounts. As of December 31, 2015 and 2014, the Company had cash and cash equivalents of approximately \$27,700,000 and \$44,600,000, respectively, in excess of the insured amounts.

The Company's principal market concentration of risk is related to its limited distribution channels. The Company's revenues include the distribution efforts of several independent companies as well as the Company's internal sales force. Significant revenues are derived from the Company's relationship with one of its distributors, AvKare, Inc. which sells our products to the Federal Government. For the years ended December 31, 2015, 2014 and 2013, AvKare revenue was approximately 24%, 34%, and 56%, of total revenue, respectively. Related receivables for the years ended December 31, 2015 and 2014 were approximately 26%, and 33%, of total accounts receivable, respectively.

*Cash and Cash Equivalents*

Cash and cash equivalents include cash and FDIC insured certificates of deposit held at various banks with an original maturity of three months or less.

*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.

The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses in the Company's existing receivables. The Company determines the allowance based on factors such as historical collection experience, customers' current creditworthiness, customer concentrations, age of accounts receivable balance and general economic conditions that may affect the customers' ability to pay.

#### *Investments*

Investments consist of FDIC insured certificates of deposit held at various banks and are classified as either Short term investments or Investments depending on their maturity date and are valued at cost, which approximates market value.

#### *Inventories*

Inventories are valued at the lower of cost or market, using the first-in, first-out (FIFO) method. Inventory is tracked through Raw Material, WIP, and Finished Good 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. Reserves for inventory obsolescence are utilized to account for slow-moving inventory as well as inventory no longer needed due to diminished market demand.

#### *Goodwill and Purchased Intangible Assets*

Goodwill and purchased intangible assets with indefinite useful lives are not amortized but are tested for impairment at least annually. The Company reviews goodwill and purchased intangible assets with indefinite lives for impairment annually at the beginning of its fourth fiscal quarter and whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. Potential impairment indicators include a significant change in the business climate, legal factors, operating performance indicators, competition, and the sale or disposition of a significant portion of the business. The Company first assesses certain qualitative factors to determine whether the existence of events or circumstances would indicate that it is more likely than not that the fair value of the Company was less than its carrying amount. If after assessing the totality of events or circumstances, the Company were to determine that it is more likely than not that the fair value of the Company is less than its carrying amount, then the Company would perform a two-step quantitative impairment testing. In the first step, the Company compares the fair value of the Company to its carrying value. The Company determines the fair value utilizing the market approach. Under the market approach, the Company uses its market capitalization which is calculated by taking the Company's share price times the number of outstanding shares. If the fair value of the Company exceeds the carrying value of the net assets, goodwill is not impaired, and no further testing is required. If the fair value of the Company is less than the carrying value, the Company must perform the second step of the impairment test to measure the amount of impairment loss, if any. In the second step, the Company's value is allocated to all of the assets and liabilities, including any unrecognized intangible assets, in a hypothetical analysis that calculates the implied fair value of goodwill in the same manner as if the Company was being acquired in a business combination. If the implied fair value of the reporting unit's goodwill is less than the carrying value, the difference is recorded as an impairment loss.

#### *Impairment of Intangible Assets with Finite Lives*

The Company reviews purchased intangible assets with finite lives for impairment whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable using a two-step impairment test. In step one, we determine the sum of the undiscounted future cash flows of the assets based on management's estimates and compare it to the carrying value of the assets. If the carrying amount is greater than the sum of the undiscounted cash flows, then the asset is impaired and step two is required. In step two, the impairment loss is calculated as the difference between the fair value of the assets and the carrying value of the assets.

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, asset groupings, and other assumptions and estimates. The Company uses estimates that are consistent with our business plans and a market participant view of the assets being evaluated. Actual results may differ from our estimates.

During the fourth quarter of 2013, the Company chose to discontinue the HydroFix product line. This action resulted in an impairment charge of approximately \$368,000 related to the Licenses for SaluMedica LLC, Spine Repair and Polyvinyl

Alcohol Cryogel. This item is included in our Statement of Operations for the year ended December 31, 2013. An impairment charge of approximately \$1,800,000 had previously been booked in 2012.

#### *Property and Equipment*

Property and equipment are recorded at cost and depreciated on a straight-line basis over their estimated useful lives, principally three to seven years. Leasehold improvements are depreciated on a straight-line basis over the lesser of the estimated useful lives or the life of the lease. The Company is party to various lease arrangements for its facility space and equipment. These arrangements include interest, scheduled rent increases and rent holidays which are included in the determination of minimum lease payments when assessing lease classification, and are included in rent expense on a straight line basis over the lease term. See Notes 7 and 16 for further information regarding capital leases, operating leases and rent expense.

#### *Patent Costs*

The Company incurs certain legal and related costs in connection with patent applications for tissue based products and processes. 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 alternative future use is available to the Company. The Company capitalized approximately \$851,000 of patent costs during 2015, \$594,000 of patent costs during 2014 and \$689,000 of patent costs during 2013.

#### *Impairment of Long-lived Assets*

The Company evaluates the recoverability of its long-lived assets (property and equipment) whenever adverse events or changes in business climate indicate that the expected undiscounted future cash flows from the related assets may be less than previously anticipated. If the net book value of the related assets exceeds the expected undiscounted future cash flows of the assets, the carrying amount would be reduced to the present value of their expected future cash flows and an impairment loss would be recognized. During the fourth quarter of 2013, the Company chose to discontinue the HydroFix product line. This action resulted in a disposal loss of approximately \$30,000. This item is included in the Consolidated Statements of Operations for the year ended December 31, 2013, as Selling, General and Administrative expenses.

#### *Grant Income*

The Company received a Regional Economic Business Assistance ("REBA") grant in the amount of \$250,000 from the State of Georgia to help the Company defray certain expenses and capital expenditures related to the Company's expansion of manufacturing activities in the State. In order to retain the grant monies the Company was required to add a certain number of full time positions and spend a certain amount on capital and operations expenditures by December 31, 2014. As of December 31, 2013, the Company had satisfied the grant requirements. Accordingly, the Company recorded the \$250,000 as a reduction of Selling, General and Administrative expenses in the accompanying 2013 Consolidated Statements of Operations.

#### *Revenue Recognition*

The Company sells its products primarily through a combination of a direct sales force, independent stocking distributors and third - party representatives in the U.S. and independent distributors in international markets. The Company recognizes revenue when title to the goods and risk of loss transfers to customers, provided there are no material remaining performance obligations required of the Company or any matters of customer acceptance. In cases where the Company utilizes distributors or ships products directly to the end user, it recognizes revenue according to the shipping terms of the agreement provided all revenue recognition criteria have been met. A portion of the Company's revenue is generated from inventory maintained at hospitals or with field representatives. For these products, revenue is recognized at the time the product has been used or implanted. The Company records estimated sales returns, discounts and allowances as a reduction of net sales in the same period revenue is recognized.

#### *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.

#### *Income Taxes*

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, we determine deferred tax assets and liabilities on the basis of the differences between the financial statement and tax bases of assets and liabilities by 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 income in the period that includes the enactment date.

The Company recognizes deferred tax assets to the extent that we believe that these assets are more likely than not to be realized. In making such a determination, we consider all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. If we determine that we would be able to realize our deferred tax assets in the future in excess of their net recorded amount, we would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company records uncertain tax positions in accordance with ASC 740 on the basis of a two-step process in which (1) we determine 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, we recognize the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority.

#### *Share-based Compensation*

The Company accounts for its share-based compensation plans in accordance with FASB ASC topic 718 "Compensation- Stock compensation". FASB ASC 718 requires the measurement and recognition of compensation expense for all share-based awards made to employees and directors, including employee stock options, restricted stock and warrants. Under the provisions of FASB ASC 718, and U. S. Securities and Exchange Commission Staff Accounting Bulletin No. 107, share-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense on a straight line basis over the requisite service period of the entire award (generally the vesting period of the award).

#### *Fair Value of Financial Instruments*

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, short term investments, accounts payable and accrued expenses. The carrying cost of the Company's investments also reflects their fair values due to the type of these investments and the fair value of capital leases approximates their carrying value based upon current rates available to the Company.

#### *Fair Value Measurements*

The Company records certain financial instruments at fair value, including: cash equivalents, short term investments and investments. The Company may make an irrevocable election to measure other financial instruments at fair value on an instrument-by-instrument basis; although as of December 31, 2015, the Company has not chosen to make any such elections. Fair value financial instruments are recorded in accordance with the fair value measurement framework.

The Company also 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.

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 cost, market, or income valuation methodologies applied to unobservable 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.

#### *Recently Issued Accounting Pronouncements*

The Company considers the applicability and impact of all Accounting Standards Updates ("ASUs"). In May 2014, the Financial Accounting Standards Board issued ASU 2014-09, "Revenue Recognition - Revenue from Contracts with Customers" (ASU 2014-09) that requires companies to recognize revenue when a customer obtains control rather than when companies have transferred substantially all risks and rewards of a good or service. This update is effective for annual reporting periods beginning on or after December 15, 2017 and interim periods therein and requires expanded disclosures. The Company is currently assessing the impact the adoption of ASU 2014-09 will have on its consolidated financial statements.

In November 2015, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2015-17, Balance Sheet Classification of Deferred Taxes. ASU 2015-17 simplifies the presentation of deferred taxes by requiring deferred tax assets and liabilities be classified as noncurrent on the balance sheet. ASU 2015-17 is effective for public companies for annual reporting periods beginning after December 15, 2016, and interim periods within those fiscal years. The guidance may be adopted prospectively or retrospectively and early adoption is permitted. The Company has adopted this standard, prospectively, at the beginning of the fourth quarter 2015 to simplify reporting with the release of the valuation allowance as disclosed in Note 13. Prior periods were not retrospectively adjusted.

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, Leases (Topic 842). The core principle of Topic 842 is that a lessee should recognize the assets and liabilities that arise from leases. ASU 2016-02 is effective for public companies for annual reporting periods beginning after December 15, 2018, and interim periods within those fiscal years. The guidance may be adopted prospectively or retrospectively and early adoption is permitted. The Company is currently assessing the impact the adoption of ASU 2016-02 will have on its consolidated financial statements.

All other ASUs issued and not yet effective for the year ended December 31, 2015, 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 financial position or results of operations.

### **3. Liquidity and Capital Resources**

#### **Net Working Capital**

As of December 31, 2015, the Company had approximately \$28,486,000 of cash and cash equivalents. The Company reported total current assets of approximately \$96,310,000 and current liabilities of approximately \$26,777,000 and had net working capital of approximately \$69,533,000.

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

The Company's largest cash requirement for the twelve months ended December 31, 2015 was cash for general working capital needs. In addition, the Company's other cash requirements included capital expenditures, and repurchases of the Company's common stock. The Company funded its cash requirements through its existing cash reserves, and its operating activities which generated approximately \$18,807,000 during the period. The Company believes that its anticipated cash from operating and financing activities and existing cash and cash equivalents as well as its investments in FDIC insured certificates of deposit will enable the Company to meet its operational liquidity needs and fund its planned investing activities for the next year. In addition, on October 12, 2015, the Company entered into a new three-year \$50 million senior secured revolving credit facility, which provides additional liquidity.

### **4. Cash Equivalents and Short Term Investments**

Included in Cash and cash equivalents as of December 31, 2014, were approximately \$1,250,000 of FDIC insured certificates of deposit held with various U.S. financial institutions. Short term investments at December 31, 2015 and 2014 consist of approximately \$3,000,000 and \$5,750,000, respectively, of FDIC insured certificates of deposits held with various financial institutions. The cost of these instruments approximates their fair market value.

## 5. Inventories

Inventories consisted of the following items as of December 31, 2015 and 2014 (in thousands):

	December 31,	
	2015	2014
Raw materials	\$ 602	\$ 255
Work in process	3,850	3,419
Finished goods	3,405	1,986
Inventory, gross	7,857	5,660
Reserve for obsolescence	(397)	(527)
Inventory, net	\$ 7,460	\$ 5,133

## 6. Investments

Investments consisted of FDIC insured certificates of deposit with various U.S. financial institutions. The balance as of December 31, 2015 was zero and the balance as of December 31, 2014 was approximately \$3,250,000 and the cost approximated fair market value. Maturities of these instruments range to May of 2016.

## 7. Property and Equipment

Property and equipment consist of the following as of December 31, 2015 and 2014 (in thousands):

	December 31,	
	2015	2014
Leasehold improvements	\$ 2,684	\$ 2,559
Lab and clean room equipment	4,564	3,040
Furniture and equipment	4,577	2,398
Construction in Progress	2,629	949
Property and equipment, gross	14,454	8,946
Less accumulated depreciation	(4,979)	(3,499)
Property and equipment, net	\$ 9,475	\$ 5,447

Included in property and equipment is approximately \$427,000 of capital leases. The corresponding liability of approximately \$133,000 is included in other liabilities in the accompanying condensed consolidated balance sheet. Also included is approximately \$1,000,000 in leasehold improvements paid for by the landlord of our main operating facility with a corresponding liability included in long term liabilities, which is amortized over the term of the lease.

Depreciation expense for the years ended December 31, 2015, 2014, and 2013 was approximately \$1,799,000, \$1,197,000, and \$637,000, respectively.

## 8. Intangible Assets and Royalty Agreement

Intangible assets are summarized as follows (in thousands):

	Weighted Average Amortization Lives	December 31,	
		2015	2014
		Cost	Cost
Licenses (a) (b)	10 years	\$ 1,009	\$ 1,009
Patents & Know How (b)	17 years	8,001	7,891
Customer & Supplier Relationships (b)	14 years	3,761	3,761
Tradenames & Trademarks (b)	indefinite	1,008	1,008
In Process Research & Development (b)	n/a	25	25
Patents in Process (c)	n/a	1,823	1,082
Total		15,627	14,776
Less Accumulated amortization		(4,864)	(3,931)
Net		\$ 10,763	\$ 10,845

(a) On January 29, 2007, the Company acquired a license from Shriners Hospitals for Children and University of South Florida Research Foundation, Inc. in the amount of \$996,000. Within 30 days after the receipt by the Company of approval by the FDA allowing the sale of the first licensed product, the Company is required to pay an additional \$200,000 to the licensor. Due to its contingent nature, this amount is not recorded as a liability. The Company will also be required to pay a royalty of 3% on all commercial sales revenue from the licensed products. The Company is also obligated to pay a \$50,000 minimum annual royalty payment over the life of the license. As of December 31, 2015, this license had a remaining net book value of approximately \$110,000.

(b) On January 5, 2011, the Company acquired Surgical Biologics, LLC. As a result, the Company recorded intangible assets for Customer & Supplier Relationships of \$3,761,000, Patents & Know-How of \$7,690,000, Licenses of \$13,000, Trade Names & Trademarks of \$1,008,000 and In-Process Research & Development of \$25,000. During 2015 approximately \$110,000 of additional costs associated with patents granted during the year were capitalized and included in Patents & Know-How subject to amortization.

(c) Capitalized external legal and other registration costs in connection with internally developed tissue-based patents that are pending. Once issued, the costs associated with a given patent will be included in Patents & Know-How under intangible assets subject to amortization.

Amortization expense for the years ended December 31, 2015, 2014, and 2013, was approximately \$933,000, \$928,000, and \$1,054,000, respectively.



Expected future amortization of intangible assets as of December 31, 2015, is as follows (in thousands):

Year ending December 31,	Estimated Amortization Expense
2016	\$ 936
2017	846
2018	836
2019	836
2020	836
Thereafter	5,465
	<u>\$ 9,755</u>

## 9. Long-Term Debt

### *Senior Secured Promissory Notes*

From December 27 to December 31, 2011, the Company sold 5% Convertible Senior Secured Promissory Notes (the "Notes") to individual accredited investors for aggregate proceeds of \$5,000,000. The aggregate proceeds included \$500,000 of Notes sold to the Company's Chairman of the Board and CEO. In total, the principal of the Notes were convertible into up to 5,000,000 shares of common stock of the Company ("Common Stock") plus accrued but unpaid interest at \$1.00 per share at any time upon the election of the holder of the note.

In conjunction with the sale of the Notes, the Company incurred a placement fee of \$32,800 and issued 42,400 common stock warrants to the placement agents at an exercise price of \$1.09 per share. These warrants were exercised in November 2015. The fair value of the warrants was determined to be approximately \$15,000 using the Black-Scholes-Merton valuation technique. The total direct costs of approximately \$47,800 were recorded as deferred financing costs and were amortized over the term of the Notes using the effective interest method. Further, the placement agent warrants are classified in stockholders' equity because they achieved all of the requisite conditions for equity classification in accordance with GAAP.

During the months of January and February 2013, all holders of the Notes converted their interest in this obligation to shares of MiMedx common stock. The total amount of debt plus accrued interest that was exchanged was approximately \$5,272,000. In conjunction with this exchange, approximately 5,272,000 shares of the Company's common stock were issued in full satisfaction of this obligation. Included in this total are 532,260 shares representing the CEO's conversion of his Note. This also resulted in the acceleration of amortization of debt discount and total interest expense of approximately \$1,328,000 during the year ended December 31, 2013.

### *Credit Facility*

On October 12, 2015, the Company and its subsidiaries entered into a Credit Agreement (the "Credit Agreement") with certain lenders and Bank of America, N.A., as administrative agent. The Credit Agreement establishes a senior secured revolving credit facility in favor of the Company with a maturity date of October 12, 2018 and an aggregate lender commitment of up to \$50 million. The Credit Agreement also provides for an uncommitted incremental facility of up to \$35 million, which can be exercised as one or more revolving commitment increases or new term loans, all subject to certain customary terms and conditions set forth in the Credit Agreement. Borrowings under the facility will bear interest at LIBOR plus 1.5% to 2.25%. Fees paid in connection with the initiation of the credit facility totaled approximately \$500,000. These deferred financing costs are being amortized to interest expense over the three-year life of the facility. The Credit Agreement contains customary representations, warranties, covenants, and events of default. As of December 31, 2015, there were no outstanding revolving loans under the credit facility.

## 10. Net Income (loss) Per Share

Basic net income (loss) per common share is computed using the weighted-average number of common shares outstanding during the period. Diluted net income per common share is computed using the weighted-average number of common and dilutive common equivalent shares from stock options, warrants and restricted stock using the treasury stock method.

The following table sets forth the computation of basic and diluted net income (loss) per share (in thousands except per share data):

	Year Ended December 31,		
	2015	2014	2013
Net income (loss)	\$ 29,446	\$ 6,220	\$ (4,112)
Denominator for basic earnings per share - weighted average shares	105,929,205	105,793,008	96,285,504
Effect of dilutive securities: Stock options, warrants, and restricted stock (a)	7,699,277	7,502,496	—
Denominator for diluted earnings per share - weighted average shares adjusted for dilutive securities	113,628,482	113,295,504	96,285,504
Income (loss) per common share - basic	0.28	0.06	(0.04)
Income (loss) per common share - diluted	\$ 0.26	\$ 0.05	\$ (0.04)

(a) Securities that are included in the computation of the denominator above, utilizing the treasury stock method for the years ended December 31, 2015 and 2014 are as follows:

Effect of dilutive securities:	2015	2014
Stock Options	7,121,774	7,035,728
Warrants	33,676	226,926
Restricted Stock Awards	543,827	239,842
	<u>7,699,277</u>	<u>7,502,496</u>

Securities for the year ended December 31, 2013 were excluded from the computation of diluted earnings per share because they would have been anti-dilutive.

## 11. Common Stock Placements

### *Public Offering of Common Stock*

In December of 2013, the Company completed a public offering (the "Offering") of 5,750,000 shares of its common stock at \$6.80 per share. Proceeds from the Offering, net of underwriting expenses were \$36,704,000. In addition, the Company incurred approximately \$194,000 in various legal fees for services related to the Offering.

Proceeds from the Offering were used for general corporate purposes, including, but not limited to, research, development and further commercialization of our products, obtaining regulatory approvals, funding of our clinical trials, capital expenditures, working capital and future acquisitions of complementary businesses, technology or products.

## 12. Equity

### *Stock Incentive Plans*

The Company has three share-based compensation plans: the MiMedx Group, Inc. Assumed 2006 Stock Incentive Plan (the "2006 Plan"), the MiMedx Inc. 2007 Assumed Stock Plan (the "Assumed 2007 Plan") and the MiMedx Group Inc. Amended and Restated Assumed 2005 Stock Plan (the "Assumed 2005 Plan") which provide for the granting of qualified incentive and non-qualified stock options, stock appreciation awards and restricted stock awards to employees, directors, consultants and advisors. The awards are subject to a vesting schedule as set forth in each individual agreement. The Company intends to use only the 2006 Plan to make future grants. The number of assumed options under the Assumed 2005 Plan and Assumed 2007 Plan outstanding at December 31, 2015, totaled 70,000. The maximum number of shares of common stock that can be issued under the 2006 Plan total 26,500,000 at December 31, 2015.

Activity with respect to the stock options is summarized as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2015	16,474,227	\$ 3.43		
Granted	75,100	\$ 9.66		
Exercised	(2,220,881)	\$ 2.08		
Unvested options forfeited	(239,322)	\$ 6.66		
Vested options expired	(69,495)	\$ 2.61		
Outstanding at December 31, 2015	14,019,629	\$ 3.62	6.5	\$ 80,740,577
Vested at December 31, 2015	10,951,694	\$ 2.80	6.2	\$ 71,955,234
Vested or expected to vest at December 31, 2015 (a)	13,917,122	\$ 3.60	6.5	\$ 80,496,150

(a) Includes forfeiture adjusted unvested shares.

The intrinsic value of the options exercised during the years ended December 31, 2015, 2014 and 2013 were approximately \$17,181,000, \$10,566,000, and \$8,864,000, respectively.

The intrinsic value of options vested during the years ended December 31, 2015, 2014 and 2013 were approximately \$10,044,000, \$6,615,000, and \$3,351,000, respectively.

Following is a summary of stock options outstanding and exercisable at December 31, 2015:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number outstanding	Weighted-Average Remaining Contractual Term (in years)	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
\$0.50 - \$0.76	441,429	3.4	\$ 0.72	441,429	\$ 0.72
\$0.87 - \$1.35	4,783,304	5.7	1.19	4,783,304	1.19
\$1.40 - \$2.45	1,641,928	5.1	1.93	1,641,928	1.93
\$2.66 - \$3.99	957,454	6.8	3.05	907,452	3.00
\$4.19 - \$6.38	3,552,323	7.4	5.35	2,229,386	5.32
\$6.45 - \$9.78	2,527,525	8.1	7.29	914,703	7.18
\$9.90 - \$10.99	115,666	8.9	10.43	33,492	10.50
	14,019,629	6.5	\$ 3.62	10,951,694	\$ 2.80

A summary of the status of the Company's unvested stock options as of December 31, 2015 is presented below:

<b>Unvested Stock Options</b>	<b>Number of Shares</b>	<b>Weighted- Average Grant Date Fair Value</b>
Unvested at January 1, 2015	7,193,577	\$ 3.08
Granted	75,100	\$ 5.15
Cancelled	(239,322)	\$ 3.79
Vested	(3,961,420)	\$ 2.53
Unvested at December 31, 2015	3,067,935	\$ 3.81

Total unrecognized compensation expense at December 31, 2015, was approximately \$6,241,000 and will be charged to expense through March 2017.

The fair value of the options granted was estimated on the date of grant using the Black-Scholes-Merton option-pricing model that uses assumptions for expected volatility, expected dividends, expected term, and the risk-free interest rate. Expected volatilities are based on historical volatility of peer companies and other factors estimated over the expected term of the options. The term of employee options granted is derived using the "simplified method" which computes expected term as the midpoint between the weighted average time to vesting and the contractual maturity. The simplified method was used due to the Company's lack of sufficient historical data to provide a reasonable basis upon which to estimate the expected term due to the limited period of time its equity shares have been publicly traded. The term for non-employee options is generally based upon the contractual term of the option. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the period of the expected term or contractual term as described.

The assumptions used in calculating the fair value of options using the Black-Scholes-Merton option-pricing model are set forth in the following table:

	Year ended December 31,		
	2015	2014	2013
Expected volatility	54.35 - 58.14%	58.14 - 64.50%	61.41 - 64.77%
Expected life (in years)	6	6	6
Expected dividend yield	—	—	—
Risk-free interest rate	1.51 - 1.68%	1.64 - 1.96%	0.85 - 1.88%

The weighted-average grant date fair value for options granted during the years ended December 31, 2015, 2014 and 2013 were approximately \$5.15, \$4.18 and \$3.08, respectively.

#### ***Restricted Stock Awards***

Following is summary information for restricted stock awards for the year ended December 31, 2015. Shares vest over a one to three year period. As of December 31, 2015, there was approximately \$16,606,000 of total unrecognized stock-based compensation related to time-based, non-vested restricted stock. That expense is expected to be recognized on a straight-line basis over a weighted-average period of 2.1 years.

Additionally, during the twelve months ended December 31, 2015, 5,172 shares of common stock valued at approximately \$57,000 were issued under the 2006 Plan to a consultant in return for services performed.

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested at January 1, 2015	1,228,898	\$ 7.16
Granted	1,974,259	\$ 9.80
Vested	(517,883)	\$ 6.90
Forfeited	(72,007)	\$ 9.77
Unvested at December 31, 2015	2,613,267	\$ 9.14

For the years ended December 31, 2015, 2014, and 2013 the Company recognized stock-based compensation as follows (in thousands):

	Year Ended December 31,		
	2015	2014	2013
Cost of sales	\$ 352	\$ 322	\$ 279
Research and development	790	660	417
Selling, general and administrative	15,754	10,471	5,314
	\$ 16,896	\$ 11,453	\$ 6,010

### *Warrants*

On November 18, 2015, 42,400 common stock warrants representing the balance remaining from those granted in connection with equity share purchases by investors as an additional incentive for providing long - term equity capital to the Company and as additional compensation to consultants and advisors were exercised at an exercise price of \$1.09. The warrants were granted at negotiated prices in connection with the equity share purchases and at the market price of the common stock in other instances. The warrants were issued for terms of five years.

### **Treasury Stock**

On May 12, 2014, our Board of Directors authorized the repurchase of up to \$10 million of our common stock from time to time, through December 31, 2014. The Board subsequently extended the program until December 31, 2016. In December 2014, the Board increased the authorization to \$20 million and further increased the authorization in 2015 to \$60 million. The timing and amount of repurchases will depend upon the Company's stock price, economic and market conditions, regulatory requirements, and other corporate considerations. The Company may initiate, suspend or discontinue purchases under the stock repurchase program at any time.

For the year ended December 31, 2015, the Company purchased approximately 4,610,000 shares of its common stock for an aggregate purchase price of approximately \$40,143,000 exclusive of commissions of approximately \$136,000. As of December 31, 2015, the Company had approximately \$14,274,000 remaining under the repurchase program.

### **13. 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,	
	2015	2014
<b>Deferred tax assets and liabilities:</b>		
Accruals and prepaids	\$ 4,606	\$ 3,563
Intangible assets	146	619
Property and equipment	(1,396)	(770)
R&D and other tax credits	3,293	2,086
Stock compensation	7,063	4,163
Charitable contributions	—	1
Federal and state basis difference	145	114
Net operating loss	1,763	6,382
Net deferred tax assets	<u>\$ 15,620</u>	<u>\$ 16,158</u>
Valuation allowance	<u>(782)</u>	<u>(16,158)</u>
	<u>\$ 14,838</u>	<u>\$ —</u>

The reconciliation of the Federal statutory income tax rate of 34% to the effective rate is as follows:

	December 31,	
	2015	2014
Federal statutory rate	34.00 %	34.00 %
State taxes, net of federal benefit	3.33 %	9.58 %
Non deductible compensation	0.63 %	5.59 %
Meals & entertainment	2.27 %	5.55 %
Stock based compensation - ISO	6.39 %	21.73 %
Other	(4.58)%	(5.92)%
Valuation allowance	(63.33)%	(58.73)%
	<u>(21.29)%</u>	<u>11.80 %</u>

Current and deferred income tax expense (benefit) is as follows (in thousands):

	December 31, 2015	December 31, 2014
<b>Current:</b>		
Federal	\$ 8,452	\$ —
State	1,218	832
Total current	<u>9,670</u>	<u>832</u>
<b>Deferred:</b>		
Federal	(13,070)	—
State	(1,768)	—
Total deferred	<u>(14,838)</u>	<u>—</u>
Total expense	<u>\$ (5,168)</u>	<u>\$ 832</u>

Income taxes are based on estimates of the annual effective tax rate and evaluations of possible future events and transactions and may be subject to subsequent refinement or revision.

Certain items of income and expense are not reported in tax returns and financial statements in the same year. The tax effect of such temporary differences is reported as deferred income taxes. 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 likely.

As of December 31, 2015, our deferred tax assets were primarily the result of accrued liabilities, equity compensation, and tax credit and net operating loss carryforwards. A valuation allowance of approximately \$782,000 and \$16,158,000 was recorded against our gross deferred tax asset balance as of December 31, 2015, and December 31, 2014, respectively. For the year ended December 31, 2015, we recorded a net valuation allowance release of \$15,376,000 on the basis of management's reassessment of the amount of its deferred tax assets that are more likely than not to be realized.

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. As of December 31, 2015, in part because in the current year we achieved three years of cumulative pretax income in the U.S. federal tax jurisdiction, management determined that there is sufficient positive evidence to conclude that it is more likely than not that additional deferred taxes are realizable. It therefore reduced the valuation allowance accordingly.

At December 31, 2015, and December 31, 2014, the Company had income tax net operating loss ("NOL") carryforwards for federal and state purposes of \$579,000 and \$27,552,000, respectively. If not utilized, the federal and state tax loss carryforwards will expire between 2026 and 2031. The Company has recorded a deferred tax asset for both federal and state NOL carryforwards of approximately \$197,000 and approximately \$1,566,000, respectively. A valuation allowance remains recorded against the deferred tax asset for certain federal net operating loss carryovers in the amount of \$197,000 due to limitations provided by Internal Revenue Code Section 382 and certain state net operating loss carryovers in the amount of \$585,000 not expected to be utilized prior to expiration.

The Company's net operating losses and tax credits are subject to annual limitations due to ownership change limitations provided by Internal Revenue Code Section 382. The Company has performed an analysis and determined that the limitation exceeds the utilization of NOLs in the current year and does not anticipate much limitation going forward.

As a result of certain realization requirements of ASC 718, Compensation - Stock Compensation, the table of deferred tax assets and liabilities shown above does not include certain deferred tax assets as of December 31, 2015, and December 31, 2014, that arose directly from (or the use of which was postponed by) tax deductions related to equity compensation that are greater than the compensation recognized for financial reporting. During 2015, deferred tax assets in the amount of \$7,757,000 were realized resulting in an increase to equity in the same amount. The Company has approximately \$1,661,000 of remaining deferred tax assets that will result in an increase to equity, if and when these deferred tax assets are ultimately realized. The Company uses ASC 740 ordering when determining when excess tax benefits have been realized.

The following is a tabular reconciliation of the total amounts of unrecognized tax benefits (in thousands):

	December 31, 2015	December 31, 2014
Unrecognized tax benefits - January 1	\$ —	\$ —
Gross increases - tax positions in current period	170	—
Unrecognized tax benefits - December 31	<u>\$ 170</u>	<u>\$ —</u>

Included in the balance of unrecognized tax benefits as of December 31, 2015 and December 31, 2014, are \$170,000 and \$0, respectively, of tax benefits that, if recognized, would affect the effective tax rate. Also included in the balance of unrecognized tax benefits as of December 31, 2015 and December 31, 2014, are \$170,000 and \$0, respectively, of tax benefits that, if recognized, would result in adjustments to other tax accounts, primarily deferred taxes. This amount is recorded in Other Liabilities in the accompanying consolidated balance sheets.

The Company recognizes interest accrued related to unrecognized tax benefits and penalties as income tax expense. Related to the unrecognized tax benefits noted above, the Company accrued no penalties or interest during 2015, and, in total, as of December 31, 2015 has not recognized any liabilities for penalties or interest. During 2014, we also did not accrue any penalties or interest and, in total, as of December 31, 2014, had not recognized any liability for penalties or interest.

The Company is subject to taxation in the US and various state jurisdictions. As of December 31, 2015, the Company's tax years for 2012, 2013, 2014 and 2015 are subject to examination by the tax authorities. As of December 31, 2015, the Company is generally no longer subject to US federal, state, or local examinations by tax authorities for years before 2012.

#### 14. Supplemental Disclosure of Cash Flow and Non-Cash Investing and Financing Activities

Selected cash payments, receipts, and noncash activities are as follows (in thousands):

	Years Ended December 31,		
	2015	2014	2013
Cash paid for interest	\$ 86	\$ 48	\$ 36
Income taxes paid	2,293	384	61
Purchases of equipment financed through capital leases	—	—	355
Retirement of fixed assets	319	—	—
Deferred financing costs	504	—	27
APIC related tax adjustments	7,757	—	—
Stock issuance in connection with Earn-Out Liability of 1,174,915 shares	—	—	5,792
Stock issuance in exchange for convertible debt of 5,272,004 shares	—	—	5,272
Stock issuance of 16,493 and 15,958 shares in exchange for services performed in 2015 and 2014, respectively	164	117	—
Tenant improvement incentive	—	—	997
Legal fees paid for public offering	—	—	102
Legal fees related to public offering included in accounts payable	—	—	30
Legal fees related to public offering included in accrued expenses	—	—	62



## 15. 401k Plan

The Company has a 401(k) plan (the "Plan") covering employees who have attained 21 years of age and have completed three months of service. Under the Plan, participants may defer up to 100% of their eligible wages to a maximum of \$18,000 per year (annual limit for 2015). Employees age 50 or over in 2015 may make additional pre-tax contributions up to \$6,000 above and beyond normal plan and legal limits. Annually, the Company may elect to match employee contributions up to 6% of the employee's compensation. Additionally, the Company may elect to make a discretionary contribution to the Plan. The Company did not provide matching contributions for the years ended December 31, 2015, 2014 and 2013.

## 16. Commitments and Contingencies

### *Contractual Arrangements*

In addition to the capital leases noted under Property and Equipment above, the Company has entered into operating lease agreements for facility space and equipment. These leases expire over the next five years and generally contain renewal options. The Company anticipates that most of these leases will be renewed or replaced upon expiration. The Company also has commitments for meeting space and to various charitable organizations.

The estimated annual payments are as follows (in thousands):

	Year ended December 31,	
2016	\$	2,818
2017		2,340
2018		1,766
2019		1,763
2020		352
	\$	<u>9,039</u>

Rent expense for the years ended December 31, 2015, 2014 and 2013, was approximately \$1,317,000, \$1,130,000 and \$1,000,000, respectively and is allocated among cost of sales, research and development, and selling, general and administrative expenses.

### *Letters of Credit*

As a condition of the leases for the Company's facilities we are obligated under standby letters of credit in the amount of approximately \$235,000. These obligations are reduced at various times over the lives of the leases.

### *FDA Untitled Letter, Draft Guidance and Related Litigation*

#### FDA Untitled Letter and Draft Guidance

On August 28, 2013, the FDA issued an Untitled Letter alleging that the Company's micronized allografts do not meet the criteria for regulation solely under Section 361 of the Public Health Service Act and that, as a result, MiMedx would need a biologics license to lawfully market those micronized products. Since the issuance of the Untitled Letter, the Company has been in discussions with the FDA to communicate its disagreement with the FDA's assertion that the Company's allografts are more than minimally manipulated. To date, the FDA has not changed its position that the Company's micronized products are not eligible for marketing solely under Section 361 of the Public Health Service Act, but discussions are continuing. The Company continues to market its micronized products but is also pursuing the Biologics License Application ("BLA") process for certain of its micronized products.

On December 22, 2014, the FDA issued for comment "Draft Guidance for Industry and FDA Staff: Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products." Essentially the Minimal Manipulation draft guidance takes the same position with respect to micronized amniotic tissue that it took in the Untitled Letter to MiMedx 16 months earlier. The Company submitted comments asserting that the Minimal Manipulation draft guidance represents agency action that goes far beyond the FDA's statutory authority, is inconsistent with existing HCT/P regulations and the FDA's prior positions, and is internally inconsistent and scientifically unsound.

On October 28, 2015, the FDA issued for comment, "Draft Guidance for Industry and FDA Staff: Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products." The Company submitted comments on this Homologous Use

draft guidance. The FDA has also indicated that it will hold a public hearing on a date in 2016 to be determined to obtain input on the Homologous Use draft guidance and the previously released Minimal Manipulation draft guidance, as well as other recently issued guidance documents on HCT/Ps. The Company has requested, and has been granted an opportunity to speak at this hearing.

If the FDA does allow the Company to continue to market a micronized form of its sheet allografts without a biologics license either prior to or after finalization of the draft guidance documents, it may impose conditions, such as labeling restrictions and compliance with cGMP. Although the Company is preparing for these requirements in connection with its pursuit of a BLA for certain of its micronized products, earlier compliance with these conditions would require significant additional time and cost investments by the Company. It is also possible that the FDA will not allow the Company to market any form of a micronized product without a biologics license even prior to finalization of the draft guidance documents and could even require the Company to recall its micronized products. Revenues from micronized products comprised approximately 12% of the Company's revenues in 2015.

#### Related Litigation

Following the publication of the Untitled Letter from the FDA regarding the Company's micronized products in September 2013, the trading price of the Company's stock declined and several putative shareholder class action lawsuits were filed against the Company and certain of its executive officers asserting violations of the Securities Exchange Act of 1934. The cases were consolidated in the United States District Court for the Northern District of Georgia. On November 17, 2015, the parties entered into a stipulation of settlement to settle the consolidated case in its entirety. The stipulation of settlement was filed with the Court on November 18, 2015. On November 19, 2015, the Court preliminarily approved the settlement and has set the final settlement hearing for April 5, 2016.

#### ***OIG Subpoena***

In the fourth quarter of 2014, the Company received a subpoena from the Office of Inspector General, U.S. Department of Health and Human Services, or OIG, in connection with a civil investigation into matters primarily related to the Company's sales and marketing activities. In March 2015, the Company received notice from the Department of Justice that it declined at that time to intervene in the qui tam action that gave rise to the issuance of the subpoena. The qui tam plaintiff had 120 days from the date of the Department of Justice's notice to proceed with the case. The 120 day period passed without initiation of the lawsuit. The plaintiff, who is an executive at the Company's competitor Organogenesis, Inc., voluntarily dismissed the lawsuit in July 2015. This dismissal was approved by the Court on October 6, 2015.

#### ***Patent Litigation***

MiMedx continues to diligently enforce its intellectual property against several entities. Currently, there are three actions pending, as described below:

#### The Liventa Action

First, there is an action pending against several entities in the in the United States District Court for the Northern District of Georgia, i.e., "the Liventa Action". On April 22, 2014, the Company filed a patent infringement lawsuit against Liventa Bioscience, Inc. ("Liventa"), Medline Industries, Inc. ("Medline") and Musculoskeletal Transplant Foundation, Inc. ("MTF") for permanent injunctive relief and unspecified damages. In addition to the allegations of infringement of MiMedx's patents, the lawsuit asserts that Liventa and Medline knowingly and willfully made false and misleading representations about their respective products to providers, patients, and in some cases, prospective investors. The Liventa Action was filed in the United States District Court for the Northern District of Georgia.

MiMedx asserts that Liventa (formerly known as AFCCell Medical, Inc.), Medline and MTF infringed and continue to infringe certain of the Company's patents relating to the MiMedx dehydrated human amnion/chorion membrane ("dHACM") allografts. MTF is the tissue processor while Liventa and Medline are the distributors of the allegedly infringing products. On May 30, 2014, defendants filed answers to the Complaint, denying the allegations in the Complaint. They also raised affirmative defenses of non-infringement, invalidity, laches and estoppel. MTF and Medline also filed counterclaims seeking declaratory judgments of non-infringement and invalidity.

On June 30, 2014, fact discovery began and the parties have engaged in extensive fact discovery.

MiMedx served Infringement Contentions on August 29, 2014, and Defendants served Invalidity Contentions and Responses to Infringement Contentions on September 29, 2014. After a protracted series of meet and confers, MiMedx required Defendants to supplement their invalidity contentions in view of parallel Inter Partes Review ("IPR")(see further discussion, *infra*) proceedings. MTF complied on June 26, 2015.

In September 2015, the Defendants filed a renewed Motion to Stay in light of the Patent Trial and Appeal Board's ("PTAB") decisions to institute IPRs on the '437 and '687 Patents, seeking a partial stay of the litigation as to the '437, '687, and '494 Patents (i.e., the '437 Patent family). MiMedx opposed the Motion to Stay with respect to the '494 Patent and once again successfully defeated Defendants' motion to stay.

Claim Construction proceedings began in October 2014. The parties submitted proposed constructions for key terms for the '701, '092, '437, '687, '207, and '494 Patents. Briefing was completed in March 2015.

On December 22, 2015, a Markman Hearing was held before Special Master Sumner C. Rosenberg. Over thirty disputed claim terms were at issue. One week later, on December 30, 2015, the Special Master issued its Report and Recommendation. Except for one term, the Special Master's Report essentially adopted MiMedx's proposed constructions. The parties are awaiting a final Court decision pending their respective objections.

#### The Bone Bank Action

On May 16, 2014, the Company also filed a patent infringement lawsuit against Transplant Technology, Inc. d/b/a Bone Bank Allografts ("Bone Bank") and Texas Human Biologics, Ltd. ("Biologics") for permanent injunctive relief and unspecified damages (the "Bone Bank Action"). The Bone Bank Action was filed in the United States District Court for the Western District of Texas. This lawsuit similarly asserts that Bone Bank and Biologics infringed certain of the Company's patents through the manufacturing and sale of their placental-derived tissue graft products. On July 10, 2014, defendants filed an answer to the Complaint, denying the allegations in the Complaint. They also raised affirmative defenses of non-infringement and invalidity and filed counterclaims seeking declaratory judgments of non-infringement and invalidity. The Bone Bank Action is in an advanced stage. The parties have (i) substantially completed document production; (ii) taken several fact depositions (both party and non-party); and (iii) completed claim construction briefing. The Markman hearing in this case was held on October 2, 2015. Except for one term, the Court adopted MiMedx's proposed construction of the disputed terms. The parties have submitted a proposed scheduling order to the Court and are awaiting the Court's order in this regard. Meanwhile, the parties continue with fact discovery in view of recent depositions.

#### The NuTech Action

Finally, on March 2, 2015, the Company filed a patent infringement lawsuit against NuTech Medical, Inc. ("NuTech") and DCI Donor Services, Inc. ("DCI") for permanent injunctive relief and unspecified damages. This lawsuit was filed in the United States District Court for the Northern District of Alabama. The lawsuit alleges that NuTech and DCI have infringed and continue to infringe the Company's patents through the manufacture, use, sale, and/or offering of their tissue graft product. The lawsuit also asserts that NuTech knowingly and willfully made false and misleading representations about its products to customers and/or prospective customers.

On April 17, 2015, NuTech filed a motion to dismiss the case purportedly for lack of patentable subject matter, which the Company opposed. NuTech also filed a motion to stay the case pending disposition of the motion to dismiss, which MiMedx also opposed, and on which the Court declined to rule. Hearing on the motion to dismiss occurred on August 20, 2015. On November 24, 2015, the court ruled on NuTech's Motion to Dismiss, granting in part, and denying in part. MiMedx still has claims against NuTech for infringement of the '494 and '687 patents, as well as violations of the Lanham Act; these claims shall proceed.

On December 30, 2015, the parties submitted a Joint Rule 26(f) Report of Parties' Planning Meeting and Proposed Case Management Order to the Court. In the Report, the parties requested that the Court stay the proceedings with respect to the '687 patent pending the completion of the inter partes review on that patent.

On January 8, 2016, MiMedx served its infringement contentions. Discovery has recently begun.

#### Pending IPRs

In addition to defending the claims in the pending district court litigations, defendants in the Liventa and Bone Bank cases have challenged certain of the Company's patents in several IPR proceedings to avoid the high burden of proof of proving

invalidity by "clear and convincing evidence" in the district court litigations. An inter partes review (or "IPR") is a request for a specialized group within the United States Patent and Trademark Office to review the validity of a plaintiff's patent claims. The defendants in the Bone Bank Action have challenged the validity of the Company's 8,597,687 and 8,709,494 patents (the "'687" and "'494" patents, respectively); while the defendants in the Liventa Action have challenged the validity of the Company's 8,372,437 and 8,323,701 patents (the "'437" and "'701" patents, respectively).

On June 29, 2015, the Patent Trial and Appeals Board ("PTAB") denied defendants' request for institution of an IPR with respect to the '494 patent on all seven challenged grounds. On August 18, 2015, the PTAB also denied defendants' request for institution of an IPR with respect to the '701 patent on all six challenged grounds. That is, the PTAB decided in each case that the defendants failed to establish a reasonable likelihood that defendants would prevail in showing any of the challenged claims of the '494 or the '701 patent were unpatentable.

On July 10, 2015 the PTAB issued an opinion allowing a review of the '687 patent to proceed, although on only two of the five challenged grounds. The PTAB also adopted MiMedx's construction of the claims which will govern the Board's review of the '687 patent. On August 18, 2015, the PTAB issued an opinion allowing a review of the '437 patent to proceed, although only on one of the seven challenged grounds. Briefing and expert discovery is ongoing.

Following the PTAB decisions, the defendants in the Bone Bank Action moved to stay the district court litigation, despite the Court's previous denial of such a stay, pending the outcome of the '687 patent inter partes review. The parties agreed to stay the case with respect to the '687 patent only and the Court denied Bone Bank's motion to stay the litigation with respect to the '494 patent. The Company has also successfully defeated an attempt by defendants in the Liventa Action to stay that litigation -- also pending the outcome of the IPR of the patents at issue in that case.

17. Quarterly Financial Data (Unaudited) (in thousands except per share data)

			First Quarter	Second Quarter	Third Quarter	Fourth Quarter
NET SALES	2015	\$	40,767	\$ 45,679	\$ 49,015	\$ 51,835
	2014		19,559	25,573	33,518	39,573
	2013		11,556	13,515	16,116	17,994
GROSS MARGIN	2015	\$	35,619	\$ 40,590	\$ 44,036	\$ 46,849
	2014		16,582	22,833	30,170	35,973
	2013		9,651	11,316	14,002	14,883
NET INCOME (LOSS)	2015	\$	4,087	\$ 5,430	\$ 6,551	\$ 13,378
	2014		(922)	(390)	3,700	3,832
	2013		(1,620)	(757)	(307)	(1,427)
NET INCOME (LOSS) PER COMMON SHARE - BASIC	2015	\$	0.04	\$ 0.05	\$ 0.06	\$ 0.13
	2014		(0.01)	—	0.03	0.04
	2013		(0.02)	(0.01)	—	(0.01)
NET INCOME (LOSS) PER COMMON SHARE - DILUTED	2015	\$	0.04	\$ 0.05	\$ 0.06	\$ 0.11
	2014		(0.01)	—	0.03	0.03
	2013		(0.02)	(0.01)	—	(0.01)

## 18. Subsequent Events

On January 13, 2016, the Company completed the acquisition of Stability Inc., d/b/a Stability Biologics, a provider of human tissue products to surgeons, facilities, and distributors serving the surgical, spine, and orthopedic sectors of the healthcare industry. The acquisition of Stability was effected by the merger of Stability Inc. into a newly created wholly owned subsidiary of the Company. The new subsidiary was the surviving company in the merger and was subsequently renamed Stability Biologics, LLC ("Stability"). The Company paid \$10 million at the closing, comprised of 60% cash and 40% in shares of common stock of MiMedx Group, Inc., assumed approximately \$800,000 in debt, and eliminated a \$2.4 million receivable related to Company products sold to Stability prior to the acquisition. The Company will also pay future contingent consideration through a two-year earn out arrangement based on the 2016 and 2017 performance of Stability's business. The Company expects the earn out will be the larger portion of the overall consideration for the transaction. The earn out will also be paid in the form of 60% cash and 40% in shares of stock of MiMedx Group, Inc.

### Schedule II Valuation and Qualifying Accounts

#### MIMEDX GROUP, INC. AND SUBSIDIARIES SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS

Years ended December 31, 2015, 2014 and 2013 (in thousands)

	Balance at Beginning of Year	Additions charged to Expense or Revenue	Deductions and write-offs	Balance at End of Year
For the Year ended December 31, 2015				
Allowance for doubtful accounts	\$ 1,750	\$ 1,698	\$ (178)	\$ 3,270
Allowance for product returns	841	3,257	(2,836)	1,262
Allowance for obsolescence	527	540	(670)	397
For the Year ended December 31, 2014				
Allowance for doubtful accounts	\$ 407	\$ 1,357	\$ (14)	\$ 1,750
Allowance for product returns	215	2,215	(1,589)	841
Allowance for obsolescence	322	405	(200)	527
For the Year ended December 31, 2013				
Allowance for doubtful accounts	\$ 49	\$ 391	\$ (33)	\$ 407
Allowance for product returns	89	917	(791)	215
Allowance for obsolescence	159	213	(50)	322

## **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

### **Item 9A. Controls and Procedures**

#### **Disclosure Controls and Procedures**

We maintain “disclosure controls and procedures” within the meaning of Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by the Company in the reports filed under the Exchange Act, such as this Annual Report on Form 10-K, is recorded, processed, summarized and reported within the time periods specified in the U.S. Securities and Exchange Commission’s rules and forms. Our disclosure controls and procedures include controls and procedures designed to provide reasonable assurance that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and no evaluation of controls and procedures can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) of the Exchange Act, prior to filing this Annual Report on Form 10-K, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K. Based on their evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this Annual Report on Form 10-K.

#### **Management’s Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2015. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) in Internal Control-Integrated Framework (2013). Our management has concluded that, as of December 31, 2015, our internal control over financial reporting is effective based on these criteria.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of the effectiveness of internal controls over financial reporting to future periods are subject to the risk that the controls may become inadequate.

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any changes in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Cherry Bekaert LLP, an independent registered accounting firm, as auditors of our financial statements have issued an attestation report on the effectiveness of the Company’s and its subsidiaries’ internal control over financial reporting as of December 31, 2015. Cherry Bekaert LLP’s report is included in this report.

### **Item 9B. Other Information**

None.

## 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 2016 Annual Meeting of Shareholders under the captions "Executive Officers," "Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance," or similar captions which are incorporated herein by reference.

We have adopted our "Code of Business Conduct and Ethics" and a copy is posted on our website at [www.mimedx.com](http://www.mimedx.com). In the event that we amend any of the provisions of this Code of Business Conduct and Ethics that require disclosure under applicable law, SEC rules or listing standards, we intend to disclose such amendment on our website.

Any waiver of the Code of Business Conduct and Ethics for any executive officer or director must be approved by the Board and will be disclosed on a Form 8-K filed with the SEC, along with the reasons for the waiver.

### **Item 11. Executive Compensation**

Information required by this Item will be contained in our definitive proxy statement relating to our 2016 Annual Meeting of Shareholders under the caption "Executive Compensation," or similar caption which is incorporated herein by reference.

### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters**

Information required by this Item will be contained in our definitive proxy statement relating to our 2016 Annual Meeting of Shareholders under the captions "Stock Ownership," "Executive Compensation," 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 2016 Annual Meeting of Shareholders under the captions "Certain Relationships and Related Party Transactions," and "Election of Directors" 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 2016 Annual Meeting of Shareholders under the captions "Ratification of Appointment of Independent Registered Public Accounting Firm" and "Election of Directors," or similar captions which are incorporated herein by reference.



**PART IV**

**Item 15. Exhibits, Financial Statement Schedules**

(a) Documents filed as part of this report:

- (1) Financial Statements
- (2) 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, 2015, 2014 and 2013

- (3) Exhibits

See Item 15(b) below. Each management contract or compensation plan has been identified.

(b) Exhibits

<b>Exhibit Number</b>	<b>Description</b>
2.1##	Agreement and Plan of Merger is entered into as of the 22nd day of December, 2010 by and among MiMedx Group, Inc., MP Holdings Acquisition Sub, LLC, ORCI Acquisition Sub, LLC, Membrane Products Holdings, LLC, Onramp Capital Investments, LLC, each of the OnRamp Members (as defined therein); John R. Daniel, in his capacity as the representative of the Members and Surgical Biologics, LLC (Incorporated by reference to Exhibit 2.2 filed with Registrant's Form 10-K filed on March 31, 2011)
2.2##	Agreement and Plan of Merger dated January 10, 2016, by and among MiMedx Group, Inc., Titan Acquisition Sub I, Inc., Titan Acquisition Sub II, LLC, Stability Inc., certain stockholders of Stability Inc. and Brian Martin as representative of the Stability stockholders (Incorporated by reference to Exhibit 2.1 filed with Registrant's Form 8-K filed on January 13, 2016)
3.1	Articles of Incorporation of MiMedx Group, Inc. as filed with the Secretary of the State of Florida on March 31, 2008 (Incorporated by reference to Exhibit 3.1 filed with Registrant's Form 10-Q on August 8, 2013)
3.2	Articles of Amendment to Articles of Incorporation as filed with the Secretary of the State of Florida on May 14, 2010 (Incorporated by reference to Exhibit 3.2 filed with Registrant's Form 10-Q on August 8, 2013)
3.3	Articles of Amendment to Articles of Incorporation as filed with the Secretary of the State of Florida on August 8, 2012 (Incorporated by reference to Exhibit 3.3 filed with Registrant's Form 10-Q on August 8, 2013)
3.4	Articles of Amendment to Articles of Incorporation as filed with the Secretary of the State of Florida on November 8, 2012 (Incorporated by reference to Exhibit 3.4 filed with Registrant's Form 10-Q on August 8, 2013)
3.5	Articles of Amendment to Articles of Incorporation as filed with the Secretary of the State of Florida on May 15, 2015 (Incorporated by reference to Exhibit 3.5 to the Company's 10-Q filed on August 7, 2015)
3.6	Bylaws of MiMedx Group, Inc. (Incorporated by reference to Exhibit 3.2 filed with Registrant's Form 8-K filed on April 2, 2008)
3.7	Amendment to the Bylaws of MiMedx Group, Inc. adopted by the Board of Directors on May 11, 2010, (Incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K filed on May 14, 2010)
10.1*	MiMedx Group, Inc. 2006 Assumed Stock Incentive Plan, as amended and restated effective February 25, 2014 (Incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed on March 3, 2014)
10.2*	Form of Restricted Stock Agreement for Non-employee Directors (Incorporated by reference to Exhibit 10.66 to the Registrant's Form 10-Q filed on August 8, 2013)
10.3*	Form of Restricted Stock Agreement under the MiMedx Group, Inc. 2006 Assumed Stock Incentive Plan (Incorporated by reference to Exhibit 10.3 to the Registrant's Form 10-K filed on March 4, 2014)
10.4*	Form of Incentive Award Agreement under the MiMedx Group, Inc. 2006 Assumed Stock Incentive Plan (Incorporated by reference to Exhibit 10.4 to the Registrant's Form 10-K filed on March 4, 2014)

10.5*	Form of Nonqualified Incentive Award Agreement under the MiMedx Group, Inc. 2006 Assumed Stock Incentive Plan (Incorporated by reference to Exhibit 10.5 to the Registrant's Form 10-K filed on March 4, 2014)
10.6*	MiMedx, Inc. 2005 Assumed Stock Plan, formerly the SpineMedica Corp. 2005 Employee, Director and Consultant Stock Plan (Incorporated by reference to Exhibit 10.4 filed with the Registrant's Form 8-K filed February 8, 2008)
10.7*	Declaration of Amendment to MiMedx, Inc. 2005 Assumed Stock Plan (Incorporated by reference to Exhibit 10.6 filed with the Registrant's Form 8-K filed February 8, 2008)
10.8*	Form of Incentive Award Agreement under the MiMedx, Inc. Assumed 2005 Stock Plan (formerly the SpineMedica Corp. 2005 Employee, Director and Consultant Stock Plan), including a list of officers and directors receiving options thereunder (Incorporated by reference to Exhibit 10.7 filed with the Registrant's Form 8-K filed February 8, 2008)
10.9*	Form of Nonqualified Incentive Award Agreement under the MiMedx, Inc. Assumed 2005 Stock Plan (formerly the SpineMedica Corp. 2005 Employee, Director and Consultant Stock Plan) (Incorporated by reference to Exhibit 10.8 filed with the Registrant's Form 8-K filed February 8, 2008)
10.10*	MiMedx, Inc. Assumed 2007 Stock Plan (formerly the SpineMedica Corp. 2007 Stock Incentive Plan) (Incorporated by reference to Exhibit 10.9 filed with the Registrant's Form 8-K filed February 8, 2008)
10.11*	Declaration of Amendment to MiMedx, Inc. Assumed 2007 Stock Plan (formerly the SpineMedica Corp. 2007 Stock Incentive Plan) (Incorporated by reference to Exhibit 10.10 filed with the Registrant's Form 8-K filed February 8, 2008)
10.12*	Form of Incentive Award Agreement under the MiMedx, Inc. Assumed 2007 Stock Plan (formerly the SpineMedica Corp. 2007 Stock Incentive Plan) (Incorporated by reference to Exhibit 10.11 filed with the Registrant's Form 8-K filed February 8, 2008)
10.13*	Form of Nonqualified Incentive Award Agreement under the MiMedx, Inc. Assumed 2007 Stock Plan (formerly the SpineMedica Corp. 2007 Stock Incentive Plan) (Incorporated by reference to Exhibit 10.12 filed with the Registrant's Form 8-K filed February 8, 2008)
10.14*	Form of Indemnification Agreement (Incorporated by reference to Exhibit 10.65 filed with the Registrant's Form 8-K filed July 15, 2008)
10.15*	MiMedx Group, Inc. Amended and Restated Assumed 2005 Stock Plan (Incorporated by reference to Exhibit 10.4 filed with the Registrant's Form S-8 filed August 29, 2008)
10.16*	Form of Incentive Stock Option Award Agreement under MiMedx Group, Inc. Amended and Restated Assumed 2005 Stock Plan (Incorporated by reference to Exhibit 10.68 filed with the Registrant's Form 8 -K filed September 4, 2008)
10.17*	Form of Nonqualified Stock Option Award Agreement under MiMedx Group, Inc. Amended and Restated Assumed 2005 Stock Plan (Incorporated by reference to Exhibit 10.69 filed with the Registrant's Form 8 -K filed September 4, 2008)
10.30	Form of MiMedx, Inc. Employee Proprietary Information and Inventions Assignment Agreement (Incorporated by reference to Exhibit 10.13 filed with the Registrant's Form 8-K filed February 8, 2008)

10.31	Technology License Agreement between MiMedx, Inc., Shriners Hospitals for Children, and University of South Florida Research Foundation dated January 29, 2007 (Incorporated by reference to Exhibit 10.12 filed with the Registrant's Form 8-K filed February 8, 2008)
10.35	Warrant to Purchase Common Stock dated September 22, 2009 (Incorporated by reference to Exhibit 10.3 filed with Registrant's Form 8-K filed September 28, 2009)
10.36	Form of Warrant to Purchase Common Stock (Incorporated by reference to Exhibit 10.4 filed with Registrant's Form 8-K filed January 7, 2010)
10.37	Form of Subscription Agreement 5% Convertible Promissory Note (Incorporated by reference to Exhibit 10.1 filed with Registrant's Form 8-K filed October 25, 2010)
10.38	Form of 5% Convertible Promissory Note (Incorporated by reference to Exhibit 10.2 filed with Registrant's Form 8-K filed October 25, 2010)
10.39	Form of Warrant to Purchase Common Stock (Incorporated by reference to Exhibit 10.3 filed with Registrant's Form 8-K filed October 25, 2010)
10.40	Revolving Secured Line of Credit Agreement dated March 31, 2011 (Incorporated by reference to Exhibit 10.89 filed with Registrant's Form 10-K filed March 31, 2011)
10.41	Amendment dated January 2, 2012, to Revolving Secured Line of Credit Agreement (Incorporated by reference to Exhibit 10.6 filed with Registrant's Form 8-K filed January 3, 2012)
10.42	Form of Subscription Agreement 5% Convertible Senior Secured Promissory Note (Incorporated by reference to Exhibit 10.1 of Registrant's Form 8-K filed January 3, 2012)
10.43	Form of 5% Convertible Senior Secured Promissory Note (Incorporated by reference to Exhibit 10.2 filed with Registrant's Form 8-K filed January 3, 2012)
10.44	Form of Warrant to Purchase Common Stock (Incorporated by reference to Exhibit 10.3 filed with Registrant's Form 8-K filed January 3, 2012)

10.45	Form of Warrant to Purchase Common Stock (Incorporated by reference to Exhibit 10.4 filed with Registrant's Form 8-K filed January 3, 2012)
10.46	Form of Warrant to Purchase Common (Incorporated by reference to Exhibit 10.5 filed with Registrant's Form 8-K filed January 3, 2012)
10.47	Form of Amended and Restated Security and Intercreditor Agreement (Incorporated by reference to Exhibit 10.6 filed with Registrant's Form 8-K filed January 3, 2012)
10.48	Form of Registration Rights Agreement (Incorporated by reference to Exhibit 10.7 filed with Registrant's Form 8-K filed January 3, 2012)
10.49*	Change of Control Agreement Severance Compensation and Restrictive Covenant Agreement dated November 11, 2011, between MiMedx Group, Inc. and Parker H. Petit (Incorporated by reference to Exhibit 10.91 filed with Registrant's Form 10-Q filed on November 14, 2011)
10.50*	Change of Control Agreement Severance Compensation and Restrictive Covenant Agreement dated November 11, 2011, between MiMedx Group, Inc. and with William C. Taylor (Incorporated by reference to Exhibit 10.92 filed with Registrant's Form 10-Q filed on November 14, 2011)
10.51*	First Amendment to Change in Control Severance Compensation and Restrictive Covenant Agreement dated May 9, 2013 by and between MiMedx Group, Inc., and William C. Taylor (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on May 15, 2013)
10.52*	Change of Control Agreement Severance Compensation and Restrictive Covenant Agreement dated November 11, 2011, between MiMedx Group, Inc., and Michael J. Senken (Incorporated by reference to Exhibit 10.93 filed with Registrant's Form 10-Q filed on November 14, 2011)
10.53*	First Amendment to Change in Control Severance Compensation and Restrictive Covenant Agreement dated May 9, 2013 by and between MiMedx Group, Inc., and Michael J. Senken (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on May 15, 2013)
10.54*	2013 Management Incentive Plan and 2013 Operating Incentive Plan (Incorporated by reference to Exhibit 10.1 filed with Registrant's Form 8-K filed March 12, 2013)
10.55*	2014 Management Incentive Plan and 2014 Operating Incentive Plan (Incorporated by reference to Exhibit 10.2 filed with Registrant's Form 8-K filed March 3, 2014)
10.56*	2015 Management Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q filed on May 1, 2015)
10.60**	Product Distribution Agreement by and between AvKARE, Inc. and MiMedx Group, Inc. dated April 19, 2012 (Incorporated by reference to Exhibit 10.56 to the Registrant's Form 10-K filed March 15, 2013)
10.61	First Amendment to Product Distribution Agreement amending that certain Product Distribution Agreement that was effective April 19, 2012 (Incorporated by reference to Exhibit 10.56 filed with the Registrant's Form 10-Q filed on November 8, 2013)
10.62**	Second Amendment to Product Distribution Agreement between MiMedx Group, Inc. and AvKARE, Inc. (Incorporated by reference to Exhibit 10.58 filed with the Registrant's Form 10-Q filed on November 8, 2013)
10.63**	Third Amendment to Product Distribution Agreement dated April 17, 2015 between MiMedx Group, Inc. and AvKARE, Inc. (Incorporated by reference to Exhibit 10.2 to the Company's 10-Q filed on August 7, 2015)
10.64	Loan Agreement between MiMedx Group, Inc., and Bank of America N.A. dated May 17, 2013 (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on May 23, 2013)
10.65	Security Agreement dated May 17, 2013, executed by MiMedx Group, Inc. in favor of Bank of America and Bank of America Corporation and its subsidiaries and affiliates (Incorporated by reference to Exhibit 10.4 to the Registrant's Form 10-Q filed on August 8, 2013)
10.66	Lease by and between Hub Properties of GA, LLC and MiMedx Group, Inc., effective May 1, 2013 (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q filed May 10, 2013)
10.67	Credit Agreement dated October 12, 2015, among MiMedx Group, Inc., the Guarantors identified therein, Bank of America, N.A., and the other Lenders party thereto (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on October 13, 2015)
10.68	First Amendment to the Credit Agreement dated October 12, 2015, by and among MiMedx Group, Inc., the Guarantors identified therein, Bank of America, N.A. and the other Lenders party thereto (Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on January 13, 2016)
10.69	Security and Pledge Agreement dated October 12, 2015, among MiMedx Group, Inc., the Guarantors identified therein and Bank of America, N.A., as administrative agent (Incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K filed on October 13, 2015)

21.1#	Subsidiaries of MiMedx Group, Inc.
23.1#	Consent of Independent Registered Public Accounting Firm
31.1#	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Acts of 2002
31.2#	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Acts of 2002
32.1#	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2#	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
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
	XBRL Taxonomy Extension Label Linkbase Document
101.LAB#	
101.PRE#	XBRL Taxonomy Extension Presentation Linkbase Document

**Notes**

- \* Indicates a management contract or compensatory plan or arrangement
- # Filed herewith
- \*\* Certain confidential material appearing in this document, marked by [\*\*\*\*\*], has been omitted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment under rule 24b-2 promulgated under the Securities Exchange Act of 1934, as amended.
- ## Certain exhibits and schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K, but a copy will be furnished supplementally to the Securities and Exchange Commission upon request)

**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.

February 29, 2016

MIMEDX GROUP, INC.

By: /s/ Michael J. Senken  
Michael J. Senken  
Chief Financial Officer

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.

<u>Signature / Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/: Parker H. Petit</u> Parker H. Petit	Chief Executive Officer and Chairman (principal executive officer)	February 29, 2016
<u>/s/: Michael J. Senken</u> Michael J. Senken	Chief Financial Officer (principal financial and accounting officer)	February 29, 2016
<u>/s/: Joseph G. Bleser</u> Joseph G. Bleser	Director	February 29, 2016
<u>/s/: J. Terry Dewberry</u> J. Terry Dewberry	Director	February 29, 2016
<u>/s/: Charles Evans</u> Charles Evans	Director	February 29, 2016
<u>/s/: Bruce Hack</u> Bruce Hack	Director	February 29, 2016
<u>/s/: Charles E. Koob</u> Charles E. Koob	Director	February 29, 2016
<u>/s/: Larry W. Papasan</u> Larry W. Papasan	Director	February 29, 2016
<u>/s/: William C. Taylor</u> William C. Taylor	Director	February 29, 2016
<u>/s/: Neil Yeston</u> Neil Yeston	Director	February 29, 2016

MiMedx Group, Inc.  
List of Subsidiaries

<b>Company</b>	<b>Jurisdiction of Organization</b>
MiMedx, Inc.	Florida
MiMedx Processing Services, LLC	Florida
MiMedx Tissue Services, LLC	Georgia
Stability Biologics, LLC	Georgia



**Consent of Independent Registered Public Accounting Firm**

We hereby consent to the incorporation by reference in the Registration Statements (Form S-8 Nos. 333-153255, 333-183991, 333-189784 and 333-199841 and Form S-3 No. 333-189785) of our reports dated February 29, 2016, included in this Annual Report on Form 10-K of MiMedx Group, Inc. and Subsidiaries (the Company) relating to the consolidated balance sheets of the Company as of December 31, 2015 and 2014, and the related consolidated statements of operations, stockholders' equity, and cash flows and the related consolidated financial statement schedule for each of the three years in the period ended December 31, 2015, and the effectiveness of internal control over financial reporting for the Company as of December 31, 2015.

/s/ Cherry Bekaert LLP

Atlanta, Georgia

February 29, 2016

## Section 302 Certification

I, Parker H. Petit, certify that:

1. I have reviewed this annual report on Form 10-K of MiMedx Group, Inc.;
2. Based on my knowledge, this annual 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 annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual 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 the 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 annual 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 annual report based on such evaluation, and
  - (d) disclosed in this annual 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 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 function):
  - (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 29, 2016

/s/: Parker H. Petit

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Parker H. Petit

Chief Executive Officer

(principal executive officer)

## Section 302 Certification

I, Michael J. Senken, certify that:

1. I have reviewed this annual report on Form 10-K of MiMedx Group, Inc.;
2. Based on my knowledge, this annual 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 annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual 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 the 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 annual 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 annual report based on such evaluation, and
  - (d) disclosed in this annual 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 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 function):
  - (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 29, 2016

/s/ Michael J. Senken

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Michael J. Senken

Chief Financial Officer

(principal financial officer)

Section 906 Certification

The undersigned Parker H. Petit, 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 year ending December 31, 2015 (the “Report”). The undersigned hereby certifies, to the best of 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 29, 2016

/s/: Parker H. Petit

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Parker H. Petit

Chief Executive Officer

(principal executive officer)

Section 906 Certification

The undersigned Michael J. Senken, 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 year ending December 31, 2015 (the “Report”). The undersigned hereby certifies, to the best of 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 29, 2016

/s/ Michael J. Senken

Michael J. Senken

Chief Financial Officer

(principal financial officer)

