MIMEDX GROUP, INC. Form 10-K March 15, 2013

### UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

## FORM 10-K

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

For the fiscal year ended December 31, 2012

o 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 0-52491

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)

30144

(Zip Code)

60 Chastain Center Boulevard, Suite 60 Kennesaw, GA (Address of principal executive offices)

(678) 384-6720

(Registrant's telephone number, including area code)

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

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

Common Stock, par value \$0.001 per share (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 o No þ

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 o No b

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 b No o

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 b No o

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. b

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):

Non-accelerated filer oSmaller reporting CompanyLarge accelerated filer oAccelerated filer þþ(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  $\pounds$  No R

The aggregate market value of Common Stock held by non-affiliates on June 30, 2012, based upon the last sale price of the shares as reported on the OTC Bulletin Board on such date, was approximately \$142,370,000.

There were 93,748,564 shares of Common Stock outstanding as of February 15, 2013.

Documents Incorporated by Reference

Portions of the proxy statement relating to the 2013 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.

### 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 the Company's 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," "believe," "expect," "expectation", "anticipate," "estimate," "intend," "seeks," "pl "continue," "predict," "will," "should," and other words or expressions of similar meaning are intended by us to identify 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; our ability to develop future 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 our two largest distributors; expectations regarding future revenue growth; our ability to procure sufficient quantities of donated placentas for our products and future products; market opportunities for our products and future products; prospects for obtaining additional patents covering our proprietary technology; and our ability to compete effectively.

Our actual results 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 corporatio 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® Group, Inc. is an integrated developer, manufacturer and marketer of patent protected regenerative biomaterial products and allografts processed from human amniotic membrane. "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 include the device technologies HydroFix® and CollaFixTM, and our

tissue technologies, AmnioFix® and EpiFix®.

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 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 ("MiMedx"), the assets of which included licenses to our HydroFix® and CollaFix<sup>™</sup> technology platforms. 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 January 2011, the Company acquired all of the outstanding equity interests in 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. In 2012, these tissue-based products represented approximately 95% of our revenues.

Our Technology and Products

AmnioFix®, EpiFix® and other Tissue -Based Allografts

MiMedx is the leading supplier of allografts processed from amniotic tissue, having supplied over 120,000 allografts to date for application in the Surgical, Orthopedic, Spinal, Wound Care, Ophthalmic, and Dental segments of healthcare. Our tissue-based products include our own brands, AmnioFix® and EpiFix®, as well as products that we supply on a private label or "OEM" basis. The Company continues to research new opportunities for amniotic tissue, and currently has several additional offerings in various stages of conceptualization and development.

Amniotic membrane has long been known to have natural healing characteristics and has been used clinically for over 100 years. The first clinical uses of fresh amnion were for wound care patients and burn victims. There have been over 150 publications on the use of amniotic membrane for uses ranging from wound care to gingival recession and from pterygium repair to reduction of fibrous tissue following spinal surgery. The amniotic membrane has been shown to reduce inflammation, down regulate scar tissue and promote the regeneration of soft tissues.

Amniotic membrane has been shown to lack certain HLA antigens that elicit an immune response. Amniotic Membrane is considered immunoprivileged. Some dehydrated amniotic membranes include the epithelial layer, which studies have shown contributes significant immunosuppressive properties to dehydrated amniotic membrane products.

Natural human amniotic membrane is composed of multiple layers that contain:

• 0	Structural proteins; including: Collagen types IV, V, and VII
	D Elastin
•	Specialized proteins; including:
	Fibrillin
0	Fibronectin
(	Laminins
0	TIMPs 1,2,4, Tissue Inhibitor of Metalloproteinase 1, 2, 4
•	Growth Factors; including:
0	Epidermal Growth Factor (EGF)
0	Transforming Growth Factor Beta (TGF-)

o Fibroblast Growth Factor (FGF) Platelet Derived Growth Factors A & B (PDGF A&B)

As discussed below under the subheading of "Tissue Processing and Recovery," 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.

Also as discussed below under the heading "Government Regulation," we believe that all of our current tissue-based products, as well as those we expect to introduce in the near term, qualify for regulation solely under Section 361 of the Public Health Services Act. This means that AmnioFix® and EpiFix® are regulated differently than the other two MiMedx platform technologies, CollaFixTM and HydroFix®, which are regulated as medical devices for which Food and Drug Administration ("FDA") clearances or approvals are required prior to marketing in the United States. Products that are regulated solely under Section 361 of the Public Health Services Act do not need premarket clearance or approval in the United States, which accelerates our ability to bring new products to market.

### Tissue Processing and Recovery

0

We operate a licensed tissue bank that is registered as an establishment with the FDA. We are an accredited member of the American Association of Tissue Banks ("AATB"). We partner with FDA registered tissue establishments, 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. Our Purion® process produces an allograft that is safe, effective, and minimally manipulated. Our unique processing technique specifically focuses on maintaining the delicate multi-layered structure and collagen matrix of the tissue. The Purion® process does not subject materials to ultra-low temperature conditions during processing or storage. This technique helps maintain graft structure, provides optimal performance and allows the allograft to be stored at room temperature and have a five year shelf life. Additionally, each allograft incorporates specialized visual embossments that assist the surgeon with proper graft placement and orientation.

Our team is dedicated to providing safe, superior allografts that exceed customer expectations. To better satisfy the requirements and expectations of our customers, the Company maintains strict control on quality from the time of procurement. The Company has developed and implemented a Quality Management System in compliance with both FDA and AATB standards. Using this Quality Management System, the Company maintains strict control over each step of the manufacturing process.

#### **EpiFix**®

Our EpiFix® allograft is configured for external use. It is designed to enhance healing of wounds, as well as to reduce inflammation and scarring. Currently, EpiFix® 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).

## AmnioFix®

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

- AmnioFix® is provided in a sheet form. It is configured to enhance non-structural soft tissue healing and to minimize scar tissue formation after primary surgical repair. It is being used currently in spine, general and urology surgeries.
- AmnioFix® Wrap also is supplied in a sheet form and is configured for the same purposes and AmnioFix®, but is optimized for use as a "wrap" for nerves, tendons or ligaments.
- AmnioFix® Injectable is supplied in micronized powder form designed for injection into soft tissue areas. AmnioFix® is designed to reduce inflammation while enhancing healing of soft tissue micro tears. Currently, AmnioFix® is used being used to treat conditions such as tendonitis, plantar fasciitis, lateral epicondylitis, medial epicondylitis, bursitis, strains and sprains.

## Ophthalmic Surgery and Dental

Currently, allografts for ophthalmic surgery and dental and oral maxilla facial 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.

Medical Devices- CollaFix<sup>TM</sup> and HydroFix®

•

## CollaFix<sup>TM</sup>

Our CollaFixTM technology combines an innovative means of creating fibers from soluble collagen and a specialized cross-linking process. MiMedx utilizes two separate cross-linking technologies for various applications. 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.

Embodiments and benefits of products that we believe, based on preliminary studies, could be developed using this licensed technology are:

- Initial tests of cross-linked fibers appear to demonstrate they are stronger than existing collagenous tissue, including healthy tendons and ligaments. These fibers form the fundamental unit from which a variety of devices could be configured as follows:
  - Linear and braided arrays for tendon and ligament repair;
  - Cross-helical arrays forming tubular structures that also can be cut to form flat patches;
    - Woven meshes for general surgical use;

- CollaFixTM biomaterials have been tested and results preliminarily suggest that the materials are biocompatible and biodegradable;
- CollaFixTM Biomaterials coupled with MiMedx proprietary NDGA (nordihydroguaiaretic acid) polymerization can be used to coat synthetic indwelling medical devices to improve their biocompatibility;
- •NDGA treatment of xenograft (animal in origin) and allograft (human in origin) materials could make them more biocompatible and possibly improve functional lifetime; and
  - Cross-linked collagen-based biorivets have the potential to be used for bone fracture fixation.

Our core collagen technology is protected by patents, patent applications and trade secrets. The core patent covers the polymerization chemistry of NDGA as applied to biological materials, bioprostheses, or devices created through its application. It covers chemistries and compounds that have the reactive groups that are responsible for the effectiveness of NDGA, including a variety of organically synthesized NDGA analogs and natural compounds. Multiple medical products potentially could be developed and patented that are all tied to the core patented technology. Our core fiber technology is a closely guarded trade secret.

In January 2012, the Company received the CE certification for its proprietary CollaFixTM Surgical Mesh CD, which is a Class III product in Europe. The certification was issued by the Company's notified body, AMTAC Certification Services, Limited, based in the United Kingdom. The CE marking, also known as "CE Mark," is a mandatory conformity mark on medical devices placed on the market in the European Economic Area (EEA). The CE mark certifies that a product is compliant with the European Council Directive 93/42/EEC concerning medical devices, also known as the Medical Device Directive or MDD. To date, we have not yet received any U.S. clearances or approvals for CollaFixTM.

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.

The Company is required to pay a royalty of 3% on all commercial sales revenue from the sale of products incorporating the licensed technology. The Company is also obligated to pay a \$50,000 minimum annual royalty payment over the life of the license. The license terminates upon the expiration of the patent.

We 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.

## HydroFix®

We license certain patents and patent application rights to a PVA- based hydrogel, which is a water-based biomaterial that can be manufactured with a wide range of mechanical properties, including those that appear to mimic closely the mechanical and physical properties of natural, healthy human tissue. Our licenses allow us to manufacture, market, use and sell medical devices and products incorporating the claimed technology for (i) all neurological and orthopedic uses related to the human spine, (ii) neurological and orthopedic uses (including muscular and skeletal use) related to the rotator cuff, but excluding the product SaluBridge (which is made from Salubria® biomaterial and is currently cleared for use by the FDA) and (iii) for application as a surgical sheet anywhere in the body. Our licenses are exclusive, world-wide and perpetual.

This hydrogel has been used in other orthopedic and general surgery device applications, and it has demonstrated biocompatibility and durability inside the human body. Regulatory agencies both inside and outside the United States have cleared the hydrogel material for use inside the body for several applications.

Protection of veins and arteries is a common issue associated with many types of surgeries. Protection of the aorta, vena cava, iliac vessels and other anatomy is particularly important in anterior spine surgery. The HydroFix® Vaso Shield was designed to help physicians protect vessels during anterior vertebral surgery. The FDA cleared the HydroFix® Vaso Shield as a vessel guard or cover during anterior vertebral surgery, however, the safety and effectiveness of this device for reducing the incidence, severity and extent of post-operative adhesion formation has not been established. During 2011, the Company received two additional 510(k) clearances for its HydroFix® Vaso Shield device; one for an expanded range of sizes and for a higher temperature exposure limit, and the second for additional information to be included in the marketing materials.

We have a similar version of the product for the European market called HydroFix® Anterior Shield. The device, which is classified as a post-surgical adhesion inhibiting barrier (Class IIb), received the CE Mark for only anterior use with no contact with the central nervous system or central circulatory system. Our HydroFix® Spine Shield product is CE marked for applications in contact with the central circulatory system and central nervous system (Class III in Europe). The CE marked HydroFix® Anterior Shield and HydroFix® Spine Shield are not available in the United States.

During 2011, the Company received 510(k) clearance for its HydroFix® Ortho Shield device, which is indicated for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue. The Ortho Shield device is a permanent, protective sheet that minimizes soft tissue attachments to the device providing a protective environment for the repaired tendon to heal. The device is conformable, suturable, and biocompatible, providing surgeons with an easy to use option for tendon protection. The device also provides a smooth inner gliding surface for the tendon to move as part of normal motion.

In 2012, the Company received the CE mark for HydroFix® Crani Shield product. The device is intended to be used as a dura cover to provide a plane of dissection during revision surgery in cranial applications and is classified as a Class III device in Europe. The HydroFix® Crani Shield is not available in the United States.

Because the addressable market for our HydroFix® products is somewhat limited and we do not expect significant expansion in the sales of this product line, we recognized an impairment charge in 2012 and reduced the carrying value of the HydroFix® assets in our consolidated financial statements by \$1,798,495. See Note 2 to Consolidated Financial Statements "Significant Accounting Policies" under the subheading "Impairment of Long-lived Assets."

## Intellectual Property

Our intellectual property includes licensed patents, owned and licensed patent applications and patents pending, proprietary manufacturing processes and trade secrets, brands, trademarks and trade names 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 and own.

## Patents and Patent Applications

On December 6, 2012, the Company announced receipt of its first issued patent "Placental Tissue Grafts" related to tissue grafts derived from the placenta. This patent relates to the AmnioFix® brand grafts.

On February 11, 2013, the Company announced that it had been issued four additional U.S. patents for placental tissue grafts. The patents include "Placental Tissue Grafts," "Improved Placental Tissue Grafts," "Method For Inhibiting Adhesion Formation" and "Method for Treating a Wound Using Improved Placental Tissue Graft." The first three of these patents relate to the AmnioFix® brand grafts and the last of these relates to the EpiFix® brand allografts.

More than twenty-five 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 HydroFix® and CollaFix<sup>™</sup> technologies are protected with 20 issued patents and 49 patent applications.

Of course, the pending patent applications may not result in issued patents and even if they do, the claims may be substantially modified or reduced.

## Trademarks & Trade Names

We also own the following trademarks MiMedx<sup>®</sup>, EpiFix<sup>®</sup>, AmnioFix<sup>®</sup>, HydroFix<sup>®</sup> and Purion<sup>®</sup>. We have filed several intent to use applications as well, including an application for the name "CollaFix<sup>TM</sup>."

## Market Opportunity

The Company is a regenerative biomaterials company with three platform technologies. Our largest addressable market is in chronic wound care consisting of diabetic, venous and pressure ulcers. The Orthopedic, General Surgery, Urology and OB/GYN soft tissue repair markets also represent significant market opportunities.

Each platform technology has competitive advantages that support our projected growth. Amniotic membrane has unique "bio-active" properties that offer benefits that most competitive products cannot offer. MiMedx®'s tissues provide anti-inflammatory, anti-scarring and barrier properties as well as enhanced healing at the surgical or wound site. They can be stored at room temperature, with a five year shelf life and are easy for the physician to handle when treating a patient. Our CollaFixTM platform is the first biological, biodegradable, biomimetic technology that matches a human tendon in strength and stiffness. It also acts as a scaffold for cellular in-growth. Our HydroFix® platform has a micro pore structure that prohibits cellular attachment and has a very low immunogenic response.

The Company is focused primarily on the United States but will pursue other individual markets based upon the specific opportunity. 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.

In the US, the two key areas of focus for the products we market currently are the chronic wound care and surgical markets. There are an estimated 6.5 million patients that have chronic wounds due to compromised health, such as poor circulation or diabetes, and do not heal with traditional wound care therapies. An estimated three million people need some type of restorative sports medicine or spinal treatment. Our tissue technologies have shown marked improvements in healing these patients after short treatment periods. Our tissue platforms help reduce scar tissue formation in a variety of applications, including the estimated two million patients annually undergoing elective aesthetic procedures to reduce the signs of aging or the estimated almost one million patients annually undergoing some type of abdominal surgery where scarring can limit the ability to reproduce, reduce sexual function, or generate post-operative pain.

In Europe, the Company has similar opportunities to treat large populations of patients with our regenerative biomaterials. We believe there is tremendous opportunity to treat a variety of conditions, including close to seven million chronic wounds and burns, and close to one million tendon or ligament repair/reconstructions.

Market opportunity numbers derived from the following sources:

Wound Repair Regen. 2009 Nov-Dec;17(6):763-71. doi: 10.1111/j.1524-475X.2009.00543.x. Human skin wounds: a major and snowballing threat to public health and the economy. Sen CK, Gordillo GM, Roy S, Kirsner R, Lambert L, Hunt TK, Gottrup F, Gurtner GC, Longaker MT.

2010 Report of the 2009 Statistics, National Clearinghouse of plastic surgery statistics, American Society of Plastic Surgeons

US Orthopedic Foot & Ankle and Hand, Wrist & Elbow Sports Medicine & Soft Tissue Device Market, Millennium Research Report 2011

Worldwide Markets and Emerging Technologies for Tissue Engineering and Regenerative Medicine, 2009, Intellab

## Wound Care

Physicians encounter a variety of wound types on a daily basis, including acute wounds caused by surgical intervention, trauma and burns, as well as chronic wounds that are delayed in closing compared to healing in an otherwise healthy individual. Chronic wounds include diabetic foot ulcers, venous leg ulcers, pressure ulcers, arterial ulcers, and surgical wounds that become infected. The market revenue for biomaterials in wound care is expected to rise at an accelerated compound annual growth rate of 16.5% from 2006-2013 according to the Frost and Sullivan US Interactive Wound Care Markets Report for 2008.

Approximately 6.7 million chronic wounds are treated in the US annually. 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.

The physician's goal when treating traumatic wounds is to heal the wound while allowing the patient to retain natural function in the area of the wound with minimal scaring 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 that complicate or delay the healing cascade.

EpiFix® Dehydrated Human Amniotic Membrane Allograft acts as a tissue regeneration graft that delivers essential wound healing factors, extracellular matrix proteins and inflammatory mediators to help reduce inflammation, enhance healing, and reduce scar tissue formation. EpiFix® is used for the treatment of all types of chronic and acute, partial and full-thickness wounds. EpiFix® is not limited to a specific wound type by the FDA like other technologies and is allowed to be used to heal all types of wounds. EpiFix® is a biologically active tissue allograft that stores at room temperature (0°-38°C) for up to five years. Certain cultured skin substitutes currently on the market require -80°C 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° - 23° Celsius with a ten day shelf-life. These competitors' logistics complications highlight the distinct advantages of EpiFix®.

In addition, our strategic move to supply multiple sizes of grafts (from 2cm2 to 49cm2) minimizes product waste. Both of the two leading competitors' products come in only one size each, 2 inch x 3 inch (38 cm2) and 75 mm disc (42 cm2). Since the majority of diabetic ulcers are less than 6cm2, using one of the competitors' products would result in significant waste.

## Chronic Sports/Work Tissue Injury

AmnioFix® Injectable addresses 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 that 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. We believe AmnioFix® Injectable is the best option for the patient to help to reduce inflammation and scar tissue formation, and enhance healing of micro-tears in soft tissue.

#### Spine Repair and Vessel Protection

Our AmnioFix® technology also is used as a barrier membrane in procedures where scar tissue formation may be problematic. AmnioFix® provides additional benefits including anti-inflammatory materials and growth factors that may help with the soft tissue healing of the area. A reduction of scar tissue is necessary 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 scar attachment to the spinal dura. There are approximately 850,000 spinal surgeries per year(1) and most of them potentially could use AmnioFix® to reduce scarring and inflammation during the primary procedure and may reduce time during reoperations or follow-up surgeries.

Our HydroFix® Vaso Shield sheet is FDA cleared as a vessel protector to protect the major vessels from the anterior spinal column during an anterior spinal procedure. Outside the United States, HydroFix® Spine Shield is CE Marked.

## Marketing and Sales

We have assembled a network of independent sales representatives and stocking distributors to sell our MiMedx-labeled surgical products domestically, and we also have a network of stocking distributors for international distribution.

In 2012, we established a direct sales force for Government accounts and are developing a direct sales force for commercial wound care. While we incurred significant costs due to these initiatives in 2012 and expect to incur significant additional costs in 2013, it is our expectation that this investment in the direct sales network will lead to higher revenue in 2013 and beyond. No assurance can be given that these efforts will be successful.

We continue to pursue private label or "OEM" relationships, which allow us to leverage the sales and distribution resources of our private label customers.

## Reimbursement

In 2012, 40% of our products were purchased for government accounts, which do not depend on reimbursement from third parties. With the exception of government accounts, most medical devices and tissue products are purchased by doctors, hospitals or ambulatory surgery centers that are reimbursed by third-party payers. In the U.S., such payers include governmental programs (e.g., Medicare and Medicaid), private insurance plans, managed care programs and workers' compensation plans. Governmental payment programs have prescribed reimbursement rates for procedures and medical products. Similarly, private third-party payers often have negotiated payment levels for procedures and medical products. In addition, in the United States, an increasing percentage of insured individuals are receiving their medical care through managed care programs, which monitor and may require pre-approval of the services that a member will receive. Accordingly, our growth substantially depends on adequate levels of third-party reimbursement for our products.

In those countries outside the U.S. where our products are approved for sale, we expect that sales volumes and prices of our products will be influenced by the availability of reimbursement from governments or third-party payers. If adequate levels of reimbursement from governments or third-party payers outside of the U.S. are not obtained, international sales of our products will be limited. Outside of the U.S., reimbursement systems vary significantly by country. Many foreign markets have government-managed health care systems that govern reimbursement for medical devices and procedures and often require special consideration for reimbursement for a new product.

Because EpiFix® is a new product, we often need to convince a payer of its safety, efficacy and cost effectiveness before they will reimburse for EpiFix®. As of March 1, 2013, five of the nine Medicare Administrative Contractors have agreed to cover our EpiFix® product for treatment of chronic wounds in the lower extremities. In addition to having to convince private payers as to the efficacy and cost effectiveness of EpiFix®, coverage and reimbursement by private payers also varies according to the patient's benefit coverage with each individual payer. Payment may be based on the contract between the physician provider and the payer, and varies according to each individual contract. Therefore, we do not have reliable data as to how many commercial payers reimburse for EpiFix®, for which indications or at what rate. We are devoting considerable resources to clinical trials to support reimbursement of our products. We also have established a reimbursement support group to facilitate payments to providers as well as to assist in educating payers about the merits of our products.

Our surgical products (AmnioFix® and HydroFix®) generally are bundled as part of a hospital's bill for a diagnosis-related group (DRG). In these cases, we also must convince the hospital that our products are both efficacious and cost-effective.

At this time there can be no assurance that reimbursement policies will provide an acceptable return on our products.

#### **Customer Concentration**

The Company provides products to Government accounts, including the Veteran's Administration, through a distributor relationship. In 2012, sales to this distributor represented 40% of our revenues. The distribution agreement has a term of three years ending in April 2015, and has the potential to be extended for two additional one year terms. This distribution relationship is different than our other distribution relationships in that we have our own sales force selling into those accounts with the distributor handling all the back-office paperwork and contracting matters.

Another of our distributors represented an additional 21% of our total revenues in 2012. Our agreement with this distributor initially had a one year term and has been renewed on an annual basis. The current term expires in November 2013. We expect the agreement to be renewed.

**Government Regulation** 

United States Regulation of Our Products

Human Amniotic Tissue

Our EpiFix® and AmnioFix® products 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 meets 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.

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 does not involve combination with another article, except for water, crystalloids or a sterilizing, preserving or storage agent; and
- It does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function.

12

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. However, the processor of the tissue is required to register with the FDA, comply with regulations regarding labeling, record keeping, donor eligibility, screening and testing, process the tissue in accordance with established Good Tissue Practices, and report any adverse events. MiMedx continues to comply with all applicable regulations, as demonstrated by several FDA and other agency on-site audits.

The American Association of Tissue Banks 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 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. 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.

### Medical Devices

.

Our HydroFix® and CollaFixTM product platforms are medical devices subject to regulation by the FDA, under the Federal Food, Drug, and Cosmetic Act and they are also regulated in the European Economic Area by the Medical Device Directive 93/42/EEC. Similar registration/licensing regulations apply in other countries. These regulations govern, among other things, the following activities:

•	Product design and development;
•	Product testing;
•	Product manufacturing;
•	Product labeling;
•	Product storage;
•	Premarket clearance or approval;
•	Advertising and promotion;
•	Product sales and distribution; and
	Medical device reporting/Vigilance reporting.

Medical Devices are classed 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 deemed Class II, which requires the manufacturer 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 approval.

We believe that the FDA will regulate our next generation products as medical devices, biologics or drugs. However, the FDA may determine that some of our products are combination products comprised of a biologic and medical device component. For a combination product, the FDA must determine which center or centers within the FDA will review the products and under what legal authority the products will be reviewed. While we believe our products would likely be regulated under the medical device authorities even if they are deemed "combination products," there can be no assurances that the FDA will agree. In addition, the review of combination products is often more complex and more time consuming than the review of a product under the jurisdiction of only one center within the FDA.

## 510(k) Clearance Pathway

To obtain 510(k) clearance for our Next Generation products, we must submit a premarket notification demonstrating that the proposed device is substantially equivalent in intended use and in safety and effectiveness to a previously 510(k) cleared device or a device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for submission of PMA applications. The FDA's 510(k) clearance pathway usually takes from three to 12 months, but it can take significantly longer for submissions that include clinical data.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, technological characteristics, performance or labeling requires a new 510(k) clearance or could require a PMA approval. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA approval. The FDA typically inspects the manufacturer's facilities for compliance with 21 CFR Part 820 Quality System Regulation (QSR) which define the requirements for a quality system. A Quality System consists of organizational structure, responsibilities, procedures, processes and resources for implementing controls and monitoring to ensure the quality and integrity of the product.

The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained.

# PMA Approval Pathway

If 510(k) clearance is unavailable for a product it must follow the PMA approval pathway, which requires proof of the safety and effectiveness of the device to the FDA's satisfaction. The PMA approval pathway is much more costly, lengthy and uncertain. It generally takes from one to three years and can take even longer.

A PMA application must provide extensive preclinical and clinical trial data and also information about the device and its components regarding, among other things, device design, manufacturing and labeling. As mentioned above, in conjunction with a PMA review, the FDA typically will inspect the manufacturer's facilities for compliance with QSR requirements.

Upon submission, the FDA determines if the PMA application is sufficiently complete to permit a substantive review, and, if so, the application is accepted for filing. The FDA then commences an in-depth review of the PMA application, which typically takes one to three years, but may take longer. The review time is often significantly extended as a result of the FDA asking for more information or clarification of information already provided. The FDA also may respond with a "not approvable" determination based on deficiencies in the application and require additional clinical trials that are often expensive and time consuming and can delay approval for months or even years. During the review period, an FDA advisory committee may be convened to review the application and recommend to the FDA whether, or upon what conditions, the device should be approved. Although the FDA is not bound by the advisory panel decision, the panel's recommendation is important to the FDA's overall decision making

process.

14

If the FDA's evaluation of the PMA application is favorable, the FDA typically issues an "approvable letter" requiring the applicant's agreement to specific conditions (e.g., changes in labeling) or specific additional information (e.g., submission of final labeling) in order to secure final approval of the PMA application. Once the approvable letter is satisfied, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the manufacturer. The PMA can include post approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval. Even after approval of a PMA, a new PMA or PMA supplement is required in the event of a modification to the device, its labeling or its manufacturing process.

# Clinical Trials

A clinical trial is generally required to support a PMA, Biologic or Drug application and is sometimes required for a premarket notification. Such trials generally require submission of an application for an Investigational Device Exemption, or IDE. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specified number of patients (unless the product is deemed a non-significant risk device eligible for more abbreviated IDE requirements). Clinical trials are subject to extensive monitoring, record keeping and reporting requirements. Clinical trials may begin once the IDE application is approved by the FDA and the appropriate institutional review boards, or IRBs, at the clinical trial sites, and must comply with FDA regulations. T o conduct a clinical trial, we also are required to obtain the patients' informed consent that complies with both FDA requirements and state and federal privacy and human subject protection regulations. We, the FDA or the IRB could suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA approval to market the product in the U.S.

# Post Market

After a device is placed on the market, numerous regulatory requirements apply. These include: the Quality System Regulation, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process; labeling regulations; the FDA's general prohibition against promoting products for unapproved or "off-label" uses; and the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device caused or contributed, or may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur. Class II devices also can have special controls such as performance standards, post market surveillance, patient registries, and FDA guidelines that do not apply to Class I devices.

The manufacturer is subject to inspection and marketing surveillance by the FDA to determine our compliance with regulatory requirements. If the FDA finds that we have failed to comply, it can institute a wide variety of enforcement actions, ranging from a warning letter to more severe sanctions such as:

•Fines, injunctions, and civil penalties;

•Recall or seizure of our products;

•Operating restrictions, partial suspension or total shutdown of production;

•Refusing our requests for 510(k) clearance or PMA approval of new products;

•Withdrawing 510(k) clearance or PMA approvals already granted; and

•Criminal prosecution.

The FDA also has the authority to require repair, replacement or refund of the cost of any medical device that we have manufactured or distributed.

Fraud, Abuse and False Claims

The Company is 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.

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 included 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.

Healthcare fraud and abuse laws are complex, and even minor, inadvertent violations can give rise to claims that the relevant law has been violated. We make payments to physicians and hospitals for a variety of services, such as tissue procurement services, research, serving on our medical advisory board, consulting, and speaking to payers about our products in support of our reimbursement efforts. 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 significant civil or criminal penalties.

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 adopted by the Company in February 2013, MiMedx has incorporated the principles of the AdvaMed Code in its 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. The Company has incorporated these principles into its relationships with healthcare professionals under its consulting agreements, payment of travel and lodging expenses, research and educational grant procedures and sponsorship of third-party conferences. In addition, the Company has conducted training sessions on these principles. However, the Company cannot provide any assurance that regulatory or enforcement authorities will view these arrangements as being in compliance with applicable laws or that one or more of its employees or agents will not disregard the rules established by the Company.

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."

#### International

International sales of the Company's products are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ. In addition, the export of certain MiMedx Group products that have not yet been cleared or approved for domestic distribution may be subject to FDA export restrictions. There can be no assurance that we will receive on a timely basis, if at all, any foreign government or United States export approvals necessary for the marketing of our products abroad.

The primary regulatory environment in Europe is that of the European Union, which consists of twenty-seven countries, encompassing most of the major countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. The European Union has adopted numerous directives and standards regulating design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear a CE Mark and can be commercially distributed throughout Europe. For tissue products, the Company must submit for approval and clearance with each individual country, supporting the compliance of the product with the country's directives and/or standards. Once approved, the tissue product can be distributed within that particular country. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third party assessment by a "Notified Body." This third party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's product. A successful assessment by a Notified Body resident in one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Economic Area EEA.

## Export of Uncleared or Unapproved Devices

Export of devices eligible for the 510(k) clearance process, but not yet cleared to market, is permitted without FDA approval, provided that certain requirements are met. Unapproved devices subject to the PMA process can be exported to any country without FDA approval provided that, among other things, they are not contrary to the laws of the country to which they are intended for import, they are manufactured in substantial compliance with the Quality System Regulations, and they have been granted valid marketing authorization by any member country of the European Union, Australia, Canada, Israel, Japan, New Zealand, Switzerland or South Africa. If these conditions are not met, FDA approval must be obtained, among other things, by demonstrating to the FDA that the product is approved for import into the country to which it is to be exported and, in some cases, by providing safety data for the device. There can be no assurance that the FDA will grant export approval when necessary or that countries to which the device is to be exported will approve the device for import. Our failure to obtain necessary FDA export authorization and/or import approval could have a material adverse effect on our business, financial condition and results of operation.

## Manufacturing

MiMedx Group performs all tissue processing in Kennesaw, Ga. The Company expanded production capacity from one (1) to three (3) processing lines in the second quarter of 2012. The Company also performs research and early stage product and process development activities in its Kennesaw, Georgia, location.

We are subject to the FDA's quality system regulations, state regulations, and regulations promulgated by the European Union. We are FDA registered, CE marked and ISO certified. 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.

# Suppliers

We have identified reliable sources and suppliers of collagen, source materials of NDGA, which we believe will provide a product in compliance with FDA guidelines. We engage in the manufacture of our own hydrogel products and accessibility to critical raw materials for the PVA-based biomaterial products is not inhibited by supply or market constraints.

We have a comprehensive network of hospitals who participate in our placenta donation program. We have a dedicated staff that works at these hospitals, collecting donated placentas from mothers who undergo Caesarian section births and consent to donation. In addition, we have entered into agreements with certain third party companies who also collect placenta donations in other hospitals. We believe that we will be able to procure an adequate supply of tissue to meet anticipated demand.

## Research and Development

Our research and development group has extensive experience in developing products related to our field of interest, and works with our Medical Advisory Board 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 "Management's Discussion and Analysis of Financial Condition and Results of Operations" at Item 7 below for information regarding expenditures for research and development in each of the last two fiscal years.

## **Environmental Matters**

The Company's tissue preservation activities generate some chemical and biomedical wastes, consisting primarily of diluted alcohols and acids, 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 the Company are placed in appropriately constructed and labeled containers and are segregated from other wastes generated by the Company. The Company contracts with third parties for transport, treatment, and disposal of waste. The Company strives to remain compliant with applicable laws and regulations promulgated by the Resource Conservation and Recovery Act, the U. S. Environmental Protection agency and the Georgia Department of Natural Resources, Environmental Protection/division.

#### Employees

As of December 31, 2012, we had 166 employees, of whom 159 are full-time and 7 are part-time employees. We consider our relationships with our employees to be satisfactory. None of our employees is covered by a collective bargaining agreement.

#### Litigation

None outside the ordinary course of business.

### Available Information

Our website address is 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 U.S. Securities and Exchange Commission ("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 Corporate Governance and Nominating 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

We have limited operating experience and a history of net losses, and we may never achieve or maintain profitability.

We have a limited operating history and have focused primarily on research and development, clinical trials, product engineering, expanding our manufacturing capabilities, and building a sales force to market our EpiFix® and AmnioFix® products. We have incurred significant net losses over the last few years, including net losses of approximately \$7.7 million in 2012, \$10.2 million in 2011, and \$11.4 million in 2010. At December 31, 2012, we had an accumulated deficit of approximately \$69.7 million. We will continue to incur significant expenses for the foreseeable future as we expand our sales and marketing, research and development, and clinical activities. We may never generate sufficient revenues to achieve or sustain profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability. Our business and prospects must be evaluated in light of the expenses, delays, uncertainties and complications typically encountered by businesses in our stage of development, many of which may be beyond our control. These include, but are not limited to, lack of sufficient capital, unanticipated problems, delays or expenses relating to product development, governmental approvals, and licensing and marketing activities, competition, technological changes and uncertain market acceptance. In addition, if we are unable to manage growth effectively, our operating results could be materially and adversely affected. We may not be able to successfully address any or all of these risks, and the failure to adequately do so could cause our business, results of operations, and financial condition to suffer.

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;
  - •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.

As a result of our limited operating history, limited resources, and the nature of the markets in which we compete, it is extremely difficult for us to forecast accurately. 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, the Company 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 field and face competition from large, well-established, tissue processors, 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.

Many of our products have short regulatory timeframes and our competitors may be able to develop competitive products that are as or more effective than our products or that render our products and technologies less competitive or obsolete.

Many of our competitors have competitive advantages over us, including some or all of the following:

•Significantly greater name recognition;

•Established relations with surgeons, hospitals, other healthcare providers and third party payers;

•Large and established sales and distribution networks in the United States and/or in international markets;

- •Greater experience in obtaining and maintaining regulatory approvals and/or clearances from the United States Food and Drug Administration and other regulatory agencies;
- •Greater financial, managerial and other resources for product research and development, sales and marketing efforts and protecting and enforcing intellectual property rights.

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.

Our EpiFix® and AmnioFix® products are dependent on the availability of sufficient quantities of placental 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 placental tissue from human donors. The availability of donated placental 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.

Our EpiFix® and AmnioFix® products 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 EpiFix® and AmnioFix® 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 qualified personnel or the loss of services of our key personnel may have a material and adverse effect on our business, operations and results of operations.

We are dependent on our relationships with distributors and independent sales representatives to generate revenue.

We derive material revenues through our relationships with distributors and independent sales representatives. If such relationships were terminated for any reason, it could materially and adversely affect our ability to generate revenues and profits. The Company intends to obtain the assistance of additional distributors and independent sales representatives to continue its sales growth. We may not be able to find additional distributors and independent sales representatives who will agree to market and/or distribute our 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 are investing significant capital in expanding our sales force, and there can be no assurance that these efforts will result in significant increases in sales.

We are engaged in a major initiative to build and further expand our sales and marketing capabilities. As a result, we are investing in a direct sales force to allow us to reach new customers. The incurrence of these expenses impacts our operating results, and there can be no assurance that we will be successful in significantly expanding the sales of our products.

A significant portion of our revenues come from a limited number of accounts .

Three customers accounted for approximately 68% of revenues for the year ended December 31, 2012. We provide products to Government accounts, including the Veteran's Administration, through a distributor that has a Federal Supply Schedule Contract that recently was extended through January 2018. These sales represented 40% of our revenue in 2012. Our agreement with the distributor has an initial term of three years ending in April 2015. The agreement has the potential of being extended for two additional one year terms. We believe the risk related to that concentration of revenue from a single distributor is mitigated by the fact that our own sales force calls on and has a personal relationship with the individual Veteran's Administration facilities that represent most of that revenue. Therefore, we believe we eventually could regain much of the Veteran's Administration business, even if our relationship with our distributor were terminated. Nevertheless, if our agreement with our distributor were terminated prematurely or if the distributor were for any reason unable to service the Government market, there could be a disruption of our Government accounts business that could materially and adversely affect our business, revenues and results of operations.

Another of our distributors represented 21% of total revenue in 2012. While we believe our relationship with this distributor is good, if this relationship were terminated for any reason, including non-renewal of our contract upon expiration of the current term in May 2013, our business, revenues and results of operations could suffer.

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

Our results of operations are dependent upon the continued operation of our manufacturing and 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. 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 becoming profitable.

We will need to expand our organization, and we may be unable to manage rapid growth effectively.

Our failure to manage growth effectively could have a material and adverse effect on our business, results of operations and financial condition. 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.

Additional financing may be necessary for implementation of our growth strategy.

We may require additional debt and/or equity financing to pursue our growth strategy. Given our limited operating history and history of net losses, there can be no assurance that we will be successful in obtaining additional financing. Lack of additional funding could force us to curtail substantially our growth plans or cease operations. Furthermore, our issuance of any additional securities would dilute the ownership of existing shareholders and may substantially reduce the price of our common stock. Furthermore, debt financing, if available, will require the payment of interest and may involve restrictive covenants that could impose limitations upon our operating flexibility. Our failure to successfully obtain additional future funding may jeopardize our ability to expand our business and operations.

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. 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, 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 due to product defects, which could significantly increase our costs, damage our reputation and disrupt our business.

The manufacturing, marketing and processing of our tissue products and medical devices involves an inherent risk that our products may be defective or that our 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 manufactured or processed by another manufacturer, 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.

We may not be successful in commercializing all of our technologies for our medical device products, such as HydroFix® and CollaFix<sup>TM</sup>.

We have had only limited sales of our HydroFix® products. We have invested substantial time and resources in developing various additional products using our HydroFix® and CollaFixTM technologies. Further commercialization of these technologies 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.

Our international business and prospects could be adversely impacted by risks inherent in international markets.

Sales to customers outside the United States subject us to inherent risks in the economic, political, legal and business environments in the foreign countries in which we do business, including the following:

•Fluctuations in currency exchange rates;

•Regulatory, product approval and reimbursement requirements;

•Tariffs and other trade barriers;

•Greater difficulty in accounts receivable collection and longer collection periods;

•Difficulties and costs of managing foreign distributors;

•Reduced protection for intellectual property rights in some countries;

- •Burdens of complying with a wide variety of foreign laws;
  - •The impact of recessions in economies outside the U.S.;
    - •Political and economic instability; and
      - •U.S. Export regulatory restrictions.

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 would 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 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 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.

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

We have obtained licenses from third parties for patents and patent application rights related to our HydroFix® and CollaFix<sup>TM</sup> 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 companies. We may also hire additional employees who are currently employed at other medical device 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 NDGA License Agreement for our CollaFix<sup>TM</sup> 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, it would have a negative impact on our business.

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

Reclassification of our EpiFix® and AmnioFix® products could 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

Our EpiFix® and AmnioFix® products 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.

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 does not involve combination with another article, except for water, crystalloids or a sterilizing, preserving or storage agent; and
- It does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function.

We believe that our EpiFix® and AmnioFix® products are properly classified as 361 HCT/Ps and not as medical devices, biologics or drugs. However, there can be no assurance that the FDA would agree that this regulatory classification applies to these products 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. Additionally, 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.

Obtaining and maintaining the necessary regulatory approvals for our medical device products are expensive and time-consuming and may impede our ability to exploit our HydroFix® and CollaFix<sup>TM</sup> technologies.

The process of obtaining regulatory clearances or approvals to market a 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. The FDA's 510(k) clearance process generally takes three months to twelve months from submission, depending on whether a Special or traditional 510(k) premarket notification has been submitted, but can take significantly longer. An application for premarket approval, or PMA, must be submitted to the FDA if the device cannot be cleared through the 510(k) clearance process and is not exempt from premarket review by the FDA. The PMA process almost always requires one or more clinical trials and can take one to three years from the date of filing, or longer. In some cases, the FDA has indicated that it will require clinical data as part of the 510(k) process.

There is no certainty that any of our contemplated additional medical device products will be cleared by the FDA by means of either a 510(k) notice or a PMA application. Even if the FDA permits us to use the 510(k) clearance process, we cannot assure you that the FDA will not require either supporting data from laboratory tests or studies that

we have not conducted, or substantial supporting clinical data. If we are unable to use the 510(k) clearance process for any of our products, are required to provide clinical data or laboratory data that we do not possess to support our 510(k) premarket notifications for any of these products, or otherwise experience delays in obtaining or fail to obtain regulatory clearances, the commercialization of such product will be delayed or prevented, which will adversely affect our ability to generate revenue. It also may result in the loss of potential competitive advantages that we might otherwise attain by bringing our products to market earlier than our competitors. Any of these contingencies could adversely affect our business.

Our business is subject to continuing regulatory compliance by the FDA and other authorities, which is costly and or 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'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-event reporting, and inspection and enforcement.

Medical device products 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, FDA could take enforcement action, including 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, consent decrees and civil penalties;

•Customer notifications for repair, replacement, refunds;

•Recall, detention or seizure of our products;

•Operating restrictions or partial suspension or total shutdown of production;

•Refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products;

•Withdrawing 510(k) clearances or PMA approvals that have already been granted;

•Refusal to grant export approval for our products; or

It is likely that the FDA's regulation of our medical device products 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 the Company.

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 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 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. 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.

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 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 formed a Medical Advisory Board consisting of an aggregate of over 14 physicians and scientists to assist us with scientific research and development and to help us evaluate technologies. We have also entered into consulting agreements and product development agreements with physicians, including some who may order our products after our products are introduced to market. In addition, some of these physicians own our stock, which they purchased in arms' length transactions on terms identical to those offered to non-physicians, or received stock options from us as consideration for consulting services performed by them. We also may engage additional physicians on a consulting basis and have entered into clinical trial agreements with physicians. 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. Because our strategy relies on the involvement of physicians who consult with us on the design of our products, we could be materially impacted if regulatory or enforcement agencies or courts interpret our financial relationships with our physician advisors 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 our physician advisors. 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 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.

The implementation of the reporting and disclosure obligations of the Physician Payment Sunshine Act provisions of the Health Care Reform Law could adversely affect our business.

The Patient Protection and Affordable Care Act also includes new reporting and disclosure requirements, commonly referred to as the "Sunshine Act", for manufacturers of drugs, biological, medical devices and medical supplies with regard to payments or other transfers of value made to certain physicians and teaching hospitals. Implementation had been delayed pending the issuance of applicable rules by the Centers for Medicare and Medicaid Services ("CMS"). On February 1, 2013, CMS released the final rule to implement the Sunshine Act. The final rule provides that data collection activities begin on August 1, 2013, and first disclosure reports are due by March 31, 2014 for the period August 1, 2013 through December 31, 2013.

The final rule implementing the Physician Payment Sunshine Act is complex, ambiguous, and broad in scope, and we are in the process of analyzing its application to our businesses. It is difficult to predict how the new requirements may impact existing relationships among manufacturers, distributors, physicians, and teaching hospitals and the costs of compliance with these new requirements if we determine that they apply to us.

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. Over the past two fiscal years, the closing price of our common stock, as reported by the OTC Bulletin Board, has fluctuated from a low of \$0.76 to a high of \$3.85. 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 regulation;

•Additions or departures of key personnel;

•Our investments in research and development or other corporate resources;

•Announcements of technological innovations or new commercial products or services 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 distribution channels; and

•The ability of our vendors to effectively and timely deliver necessary materials and product components.

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. Accordingly, our operating results for any particular quarter may not be indicative of results for future periods and should not be relied upon as an indication of our future performance. 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, particularly on the OTC Bulletin Board where our stock is quoted. This volatility is often not related to the operating performance of companies listed thereon and will probably continue in the foreseeable future.

The concentrated common stock ownership by certain of our executive officers and directors will limit your ability to influence corporate matters.

As of December 31, 2012, our directors and executive officers together beneficially owned approximately 16% of our outstanding common stock. This group has significant influence over our management and affairs and overall matters requiring shareholder approval, including the election of directors and significant corporate transactions, such as a merger or sale of our company or our assets, for the foreseeable future. This concentrated control will limit the ability of other shareholders to influence corporate matters and, as a result, we may take actions that some of its shareholders do not view as beneficial. In addition, such concentrated control could discourage others from initiating changes of control. As a result, the market price of our shares could be adversely affected.

The exercise of warrants or options or conversion of notes may depress our stock price and may result in dilution to our common stockholders.

There are a significant number of outstanding options to purchase our stock, as well as outstanding warrants and notes that are convertible into our common stock. If the market price of our common stock rises above the exercise price of outstanding warrants and options or the conversion price of the outstanding notes, holders of those securities may be likely to exercise their warrants and options or convert their notes and sell the common stock acquired upon exercise or conversion of such securities, as applicable, in the open market. Sales of a substantial number of shares of our common stock in the public market by holders of warrants, options, or notes may depress the prevailing market price for our common stock and could impair our ability to raise capital through the future sale of our equity securities. Additionally, if the holders of outstanding options, warrants, or notes exercise those options or warrants or convert those notes, as applicable, our common stockholders will incur dilution in their relative percentage ownership.

As of December 31, 2012, warrants to purchase 3,129,168 shares of our common stock at a weighted average exercise price of \$1.04 per share were outstanding and exercisable; options to purchase 13,614,135 shares of common stock were outstanding, at a weighted average exercise price of \$1.42 per share, which 5,236,597 were exercisable at a weighted average exercise price of \$1.05 per share; the senior secured promissory notes were convertible into 5,313,527 shares of common stock at a weighted average conversion price of \$1.00 per share; and the short term

earnout liability was convertible into an estimated 1,508,419 shares of common stock at a weighted average conversion price of \$3.84 per share. There is also potential further dilution in the future from the long term portion of the earnout liability and from the unvested portion of the contingent warrants.

Our common stock is and likely will remain subject to the SEC's "Penny Stock" rules, which may make its shares more difficult to sell.

Because the price of our common stock is currently and may remain less than \$5.00 per share, it is expected to be classified as a "penny stock." The SEC rules regarding penny stocks may have the effect of reducing trading activity in our shares, making it more difficult for investors to sell. Under these rules, broker-dealers who recommend such securities to persons other than institutional accredited investors must:

•Make a special written suitability determination for the purchaser;

•Receive the purchaser's written agreement to a transaction prior to sale;

- •Provide the purchaser with risk disclosure documents which identify certain risks associated with investing in "penny stocks" and which describe the market for these "penny stocks" as well as a purchaser's legal remedies;
- •Obtain a signed and dated acknowledgment from the purchaser demonstrating that the purchaser has received the required risk disclosure document before a transaction in a "penny stock" can be completed; and
- •Give bid and offer quotations and broker and salesperson compensation information to the customer orally or in writing before or with the confirmation.

These rules make it more difficult for broker-dealers to effectuate customer transactions and trading activity in our securities and may result in a lower trading volume of our common stock and lower trading prices.

Our common stock may be thinly traded.

At times the public market for our common stock has been minimal. We cannot be certain more of a public market for our common stock will continue to develop, or if developed, that it will be sustained. Our common stock will likely be thinly traded compared to larger more widely known companies. We cannot predict the extent to which an active public market for our common stock will develop or be sustained at any time in the future. If we are unable to develop or sustain a market for our common stock, investors may be unable to sell the common stock they own, and may lose the entire value of their investment.

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, two 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. It may remain difficult for a company such as ours, with a smaller market capitalization, to attract independent financial analysts that will cover our common stock. 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.

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 any future debt or credit facility we may obtain may preclude us from paying any 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.

Shareholders may experience significant dilution if future equity offerings are used to fund operations or acquire complementary businesses.

If future operations or acquisitions are financed through the issuance of equity securities, shareholders could experience significant dilution. In addition, securities issued in connection with future financing activities or potential acquisitions may have rights and preferences senior to the rights and preferences of our common stock.

We may become involved in securities class action litigation that could divert management's attention and harm its business.

The stock market in general and the stocks of medical device companies in particular have experienced extreme price and volume fluctuations. These fluctuations have often been unrelated or disproportionate to the operating performance of the companies involved. If these fluctuations occur in the future, the market price of our shares could fall regardless of its operating performance. In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has been brought against that company. If the market price or volume of our shares suffers extreme fluctuations, then we may become involved in this type of litigation which would be expensive and divert management's attention and resources from managing the business.

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 replace or remove current management

Our Articles of Incorporation and Bylaws contain provisions that could delay or prevent a change of control of our company or its Board of Directors that shareholders might consider favorable. Some of these provisions include:

•Authorizing the issuance of preferred stock which 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.

Item 1B.	Unresolved Staff Comments			
None.				
Item 2.	Properties			
Our corporate headquarters are located in Kennesaw, Georgia where we lease approximately 20,300 square feet of office, laboratory and manufacturing space. We lease approximately 21,200 square feet nearby, which primarily consists of laboratory, manufacturing and warehouse space. On January 31, 2013, the Company signed a lease agreement under which the Company will lease approximately 79,854 square feet of office, laboratory, and warehouse space which will become the Company's new corporate headquarters. The Company expects to occupy the new facility and vacate its current headquarters building in May 2013.				
Item 3.	Legal Proceedings			
None outside the ordinary course of business.				
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. The following table sets forth the high and low bid prices on the OTC Bulletin Board for our common stock, based on information provided from OTC Bulletin Board. These quotations reflect inter-dealer prices, without retail mark-up, mark-down, or commission and may not necessarily represent actual transactions.

Year ended December 31, 2012	High	Low
First Quarter	\$ 1.40	\$ 1.10
Second Quarter	2.20	1.03
Third Quarter	2.99	1.97
Fourth Quarter	3.85	2.59
Year ended December 31, 2011	High	Low
Year ended December 31, 2011 First Quarter	High \$ 1.42	Low \$ 1.04
	U	
First Quarter	\$ 1.42	\$ 1.04

Based upon information supplied from our transfer agent, there were approximately 805 shareholders of record of our common stock as of February 15, 2013.

We have not paid any cash dividends on our common stock since our formation and do not intend to do so in the future.

To facilitate trading in the Company's shares, the Board is considering applying for a listing on a national exchange. If the Board does determine to pursue listing on a national exchange, the Company may consider implementing a reverse split of its common stock.

Unregistered Sales of Equity Securities and Use of Proceeds

In the fourth quarter os 2012, the Company issued 532,260 unregistered shares of common stock in connection with the conversion by Mr. Petit, our Chairman and Chief Executive Officer, of his Convertible Senior Secured Promissory Note.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not repurchase any shares of our common stock in 2012.

Item 6.

Selected Financial Data

Not applicable.

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

You should read the following discussion and analysis of financial condition and results of operations, together with the financial statements and the related notes appearing at the end of this report. Some of the information contained in this discussion and analysis or set forth elsewhere in this report, including information with respect to our plans and related financing, 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 the Company's 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 Group, Inc. and subsidiaries ("MiMedx" or the "Company") is an integrated developer, manufacturer and marketer of patent protected regenerative biomaterial products and allografts processed from human amniotic membrane. "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 include the device technologies HydroFix® and CollaFixTM, and our tissue technologies, AmnioFix® and EpiFix®. Our tissue technologies, processed from the human amniotic membrane, utilize our proprietary Purion® process that was developed by our wholly-owned subsidiary, Surgical Biologics LLC, to produce a safe, effective and minimally manipulated implant. Surgical Biologics is the leading supplier of amniotic tissue, having supplied over 120,000 implants to date to distributors and OEMs for application in the Surgical, Ophthalmic, Orthopedics, Spine, Wound Care and Dental sectors of healthcare.

Our focus is on soft tissue repair. Our largest addressable market is in wound care consisting of diabetic, venous & pressure ulcers. The Orthopedic, General Surgery, Urology & OBIGYN soft tissue repair market represent significant growth opportunities.

Our distribution model is currently comprised of direct sales, an evolving network of third party sales agents and stocking distributors managed by regional sales managers marketing MiMedx branded products. We have several OEM relationships targeting several niche markets. We also market our products internationally through stocking distributors.

We have organized an advisory panel of leading physicians to provide insight into our primary fields of interest for new products and technology, as well as guidance and advice with respect to ongoing product development programs.

Our core focus is on our EpiFix® and AmnioFix® platforms. We are continuing to evaluate our HydroFix® and CollaFixTM products to determine how to exploit this technology.

With the acquisition of Surgical Biologics we have added technologies that do not require a 510(K) or PMA clearance as both the EpiFix® and AmnioFix® platforms are regulated by Section 361 of the Public Health Services Act due to the fact that the products are not more than minimally manipulated and are for homologous use only. Our near-term focus for these products is on working with the private payers and Medicare to assure adequate and timely reimbursement. On January 1, 2012, our CMS C-Code went into effect which allows for Medicare reimbursement in Ambulatory Surgery Centers and Hospital Outpatient Centers for EpiFix®. Additionally, we added the permanent position of Chief Medical Officer to lead the efforts related to reimbursement. We filled the position with a doctor who served for many years as Medical Director for a major private payer and has extensive experience working with Medicare. This individual is also responsible for managing our clinical trials.

## 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. Accordingly, these are the policies we believe are the most critical to aid in fully understanding and evaluating our consolidated financial condition and results of operations.

Goodwill and Impairment of Long-Lived Assets

Goodwill represents the excess of the purchase price over the fair value of net assets acquired. No goodwill impairment has been recognized during 2012 or 2011.

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Because our 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. The Impairment was reported as a separate line item in the Consolidated Statement of Operations and included Loss From Operations.

Judgment and complexity related to goodwill and impairment of long-lived assets involve consideration of:

- Significant underperformance relative to expected historical or projected future operating results,
  - Significant negative industry or economic trends,
  - Significant decline in the Company's stock price for a sustained period, or
  - Significant decline in the Company's market capitalization relative to net book value.

#### Fair Value Measurements

The Company records certain financial instruments at fair value, including: cash equivalents and contingent consideration. 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, 2012 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 applying 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; 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. 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.

## 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. The Company uses projected volatility rates, which are based upon historical volatility rates, trended into future years. Because the Company's employee 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 option, the existing models do not necessarily provide a reliable single measure of the fair value of the Company's options.

Debt Instruments with Detachable Warrants and Beneficial Conversion Features

According to ASC470 "Debt" Instruments with Detachable Warrants, proceeds from the sale of convertible debt instruments with stock purchase warrants (detachable call options) shall be allocated to the two elements based upon the relative fair values of the debt instrument without the warrants and of the warrants themselves at the time of issuance. The Black-Scholes-Merton pricing model, consistent with the provisions of ASC 470, was used to determine the fair value of each warrant granted. The portion of the proceeds so allocated to the warrants is accounted for as paid-in capital. The remainder of the proceeds is allocated to the debt instrument is recognized separately at issuance by allocating a portion of the proceeds equal to the intrinsic value of that feature to additional paid-in capital.

## **Contingent Consideration**

The Agreement and Plan of Merger between the Company and the former owners of Surgical Biologics ("the Merger") dated January 5, 2011 involved the potential for the payment of future contingent consideration in MiMedx common stock. The contingent consideration was originally recorded at the estimated fair value of the contingent milestone payment on the acquisition date. Payment of the additional consideration was contingent on the acquired company reaching sixty percent (60%) of the excess of the amniotic tissue based gross revenues in calendar year 2011 over gross revenues in calendar year 2010 minus any FDA approval costs. The payment was made as the aggregate number of shares of MiMedx common stock per a specified formula in the Agreement and Plan of Merger. At December 31, 2011 the fair value of the contingent consideration tied to 2011 revenue was calculated to be approximately \$3,185,000 and resulted in the issuance of approximately 2,632,576 shares of MiMedx common stock in April 2012. In addition the Company shall deliver to the former owners of Surgical Biologics an aggregate number of shares of the Company equal to thirty percent (30%) of the Gross Revenues in calendar year 2012 over the Gross Revenues in calendar year 2011 minus any FDA approval costs. The fair value of the contingent milestone consideration was remeasured at the estimated fair value as of December 31, 2012 with the change in fair value recognized as income or expense within Other Income (Expense) in the consolidated statements of earnings. At December 31, 2012, the fair value of the contingent consideration tied to 2012 revenue was calculated to be approximately \$5,792,000 and the liability adjusted and recorded as a non-current liability in the consolidated balance sheet and is due to be paid in MiMedx common stock not more than 30 days following the filing of our Form 10-K.

Recently Adopted Accounting Pronouncements

In January 2012 the Company adopted Accounting Standards Update ("ASU") 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs, which clarifies some existing concepts and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. The adoption of ASU 2011-04 did not have a material effect on the Company's financial condition, profitability, and/or cash flows.

In January 2012 the Company adopted ASU 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income. The amendments to the Codification in this ASU will require companies to present the components of net income and other comprehensive income either as one continuous statement or as two consecutive statements. It eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity. The standard does not change the items which must be reported in other comprehensive income, how such items are measured or when they must be reclassified to net income. This standard is effective for interim and annual periods beginning after December 15, 2011. Because this ASU impacts presentation only, it had no effect on our financial condition, results of operations or cash flows.

In January 2012 the Company adopted ASU 2011-08, Intangibles-Goodwill and Other (Topic 350): Testing Goodwill for Impairment, which gives entities testing goodwill for impairment the option of performing a qualitative assessment before calculating the fair value of a reporting unit in step 1 of the goodwill impairment test. The adoption of ASU 2011-08 did not have a material effect on the Company's financial condition, profitability, and cash flows.

In July 2012, the FASB issued ASU No. 2012-02, which amends the guidance in ASC 350-30 on testing indefinite-lived intangible assets, other than goodwill, for impairment. Under the revised guidance, companies testing an indefinite-lived intangible asset for impairment have the option of performing a qualitative assessment before calculating the fair value of the asset (i.e. step 1 of the impairment test). If companies determine, on the basis of qualitative factors, that the fair value of the indefinite-lived intangible asset is more likely than not less than the carrying amount, the two-step impairment test would be required. This update is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012, with early adoption permitted. The Company adopted the revised guidance, and it did not have a material impact on the Company's Consolidated Financial Statements.

Results of Operations for the year ended December 31, 2012, compared to the year ended December 31, 2011

#### Revenue

Total revenue increased from approximately \$7,760,000 in 2011 to \$27,054,000 in 2012. The increase in revenue as compared to the prior year is due primarily to increased sales of our amniotic membrane tissue products, EpiFix® and AmnioFix®. The Company experienced an approximate increase of \$8,508,000 or 189% in demand in the Surgical and Sports Medicine market which is predominantly sold through independent sales agents and distributors. This growth over the prior year was driven by the launch of AmnioFix® injectable as well as additional surgical applications such as prostatectomy surgery where the anti-scarring properties of the tissue were deemed to be beneficial. The growth in Wound Care market revenue of approximately \$10,239,000 or 870% as compared to the prior year was driven by the addition of a direct sales force starting in the third quarter and continuing into the fourth quarter focusing on Government accounts. The sales executives hired have extensive experience in the wound care sector and maintain direct relationships with the physicians. Sales to government accounts are sold through a distributor who handles all of the contracting matters including invoicing and collection. This distributor is also a service disabled veteran owned small business. The Other markets category which includes our Ophthalmic and Dental tissue based products which are sold on an OEM basis as well as our HydroFix® medical device product sold through distributors increased approximately \$546,000 or 26% as compared to prior year.

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

Cost of products sold as a percentage of revenue improved to 19.2% from 43.3% as compared to prior year. The improvement was due primarily to the increase in direct sales revenue, improved product mix and higher production rates that absorb a greater percentage of fixed manufacturing costs. During the year the Company increased its clean room capacity from one line to three lines, added 32 tissue processors to fully staff the new production lines and tripled the number of tissue recovery technicians. The expansion of production capacity was driven by increased demand for processed tissue. The new hires were given extensive training resulting in increasing daily processing rates over the course of the year. Personnel costs represent approximately \$3,087,000 or 42.2% of total manufacturing, quality assurance and recovery spending for the year ended December 31, 2012.

Beginning in 2012, the Company decided to allocate both depreciation expense and share-based compensation to each functional area. These expenses were reclassified in the prior year to maintain comparability. The amount of depreciation expense in cost of products sold was approximately \$156,000 and \$105,000, and the amount of share-based compensation in cost of products sold was \$98,000 for the years ended December 31, 2012 and 2011, respectively.

## Research and Development Expenses

Our research and development expenses ("R&D expenses") decreased approximately \$92,000 or 3.1% to \$2,885,000 during the year ended December 31, 2012, compared to approximately \$2,976,000 in the prior year. The decrease is primarily related to the closure of our Tampa research facility in mid-2011, along with decreased spending on animal studies for our CollaFix<sup>™</sup> and HydroFix® products. Approximately \$783,000, or 27.1%, of R&D expenses for the year ended December 31, 2012 were attributable to personnel costs, compared to approximately \$1,186,000 or 39.8% for the year ended December 31, 2012 and 2011, respectively. This decrease of approximately \$94,000 is a result of lower costs in animal studies related to our CollaFix<sup>™</sup> and HydroFix® products. It is expected that expenses related to clinical studies will increase in subsequent quarters driven by new market opportunities and our reimbursement efforts. Spending on legal costs related to patent filings tripled to \$611,000 for the year ended December 31, 2012. The increase was driven by the Company's focus on building a strong

patent portfolio related to our EpiFix® and AmnioFix® platforms. Additionally, as described above in Cost of Products Sold, beginning in 2012, we decided to allocate both depreciation expense and share-based compensation expense to the appropriate functional areas, and have reclassified prior year amounts to maintain comparability. During the years ended December 31, 2012 and 2011, we recorded approximately \$120,000 and \$119,000 for depreciation expense, respectively, and approximately \$289,000 and \$255,000 for share-based compensation expense, respectively, to research and development.

Our research and development expenses consist primarily of internal personnel costs, fees paid to external consultants, and supplies and instruments used in our laboratories. During the current year, the Company filed 3 international patent applications for the amniotic tissue technology and 1 international patent application for the collagen technology. The Company also filed 11 US patent applications, including 6 non-provisional applications for the amnion technology, 4 provisional applications for the amnion technology and 1 non-provisional application for the collagen technology. Additionally, during the current year the Company was granted 1 US patent for the amnion technology, 3 US patents for the hydrogel technology, 1 US patent for the collagen technology, and 2 European patents for the collagen technology. We expect overall R&D spending to increase as we continue to invest in our patent portfolio as well as scientific and clinical studies related to our amnion technology.

#### Selling, General and Administrative Expenses

Selling, General and Administrative expenses for the year ended December 31, 2012, increased approximately \$9,789,000 or 87.5% to \$20,971,000 compared to \$11,181,000 for the year ended December 31, 2011. The increase was driven by costs associated with building our direct sales organization for government accounts and commercial accounts for wound care, building a customer service and sales training organization as well as increased commissions due to higher sales volume paid to both company personnel as well as third party representatives and distributors. Total headcount increased by 57 full and part time associates from 23 at the beginning of the year to 80 as of December 31, 2012. Also contributing to the increase was higher 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 marketing costs including trade shows, increased share based compensation expense and a provision for anticipated costs associated with its 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. Personnel costs excluding sales commissions and bonuses represent approximately \$6,288,000 or 30.0% of total Selling, General and Administrative expenses for the year ended December 31, 2012, compared to approximately \$3,144,000 or 28.1% in the year ended December 31, 2011. Sales commissions to both MiMedx personnel as well as third party representatives and distributors totaled \$3,884,000 or 18.5% of total Selling, General and Administrative expenses for the year ended to \$547,000 or 4.9% in the prior year. The increase was driven by higher sales volume and the move to a direct sales model for wound care.

Historically, the Company has reported depreciation and share-based compensation expense as part of Selling, General and Administrative expense. The Company decided to report these expenses in each functional area in order to more accurately present all of the costs attributable to each functional area. During the years ended December 31, 2012 and 2011, we recorded a total of approximately \$465,000 and \$447,000 in depreciation expense allocated to each functional area per the table below. The overall \$19,000 increase in depreciation was attributable to the purchase of additional production and office equipment and leasehold build-out to support our revenue growth and additional staff. We depreciate our assets on a straight-line basis, principally over five to seven years.

The following table shows the allocation of depreciation for the years ended December 31, 2012 and 2011, to operating departments:

	Year Ended	l Deceml	cember 31,		
Depreciation expense included in:	2012		2011		
Cost of products sold	\$ 155,987	\$	104,950		
Research and development	120,260		118,565		
Selling, general and administrative	189,120		222,987		
	\$ 465,367	\$	446,502		

Share-based compensation for the years ended December 31, 2012 and 2011, was approximately \$2,539,000 and \$1,659,000, respectively, an increase of approximately \$880,000 or 53.0%. Increased employee stock option grants reflecting management's philosophy of aligning employee compensation with investor objectives and the increase in the market price of MiMedx common stock was the primary reason for the increase in expense. The following table shows the allocation of share-based compensation for the years ended December 31, 2012 and 2011, to operating departments:

	Year Ended	Ended December 31,		
Share-based compensation included in:	2012		2011	
Cost of products sold	\$ 97,970	\$	98,366	
Research and development	289,341		254,997	
Selling, general and administrative	2,151,410		1,305,720	
	\$ 2,538,721	\$	1,659,083	

We recorded approximately \$1,380,000 and \$1,336,000 in amortization expense related to intangible assets in the years ending December 31, 2012 and 2011, respectively. The increase of approximately \$45,000 is the result of additional amortization recognized in the current year related to our development costs of our AmnioFix® injectable product that we began selling in early 2012. We amortize our intangible assets over a period of three to fourteen 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 at least annually our goodwill 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 \$2,307,000 during the year ended December 31, 2012, compared with approximately \$433,000 of financing and net interest expense during the year ended December 31, 2011. The increase of approximately \$1,874,000 is primarily due to interest related to our Convertible Senior Secured Promissory Notes, which were issued during the last quarter of 2011. The following table summarizes the interest charges for the yearsended December 31, 2012 and 2011.

	Year Ended December 31,									
	2012 2011									
	Amortization			1	Amortization					
	of		Interest		of		Interest			
	Debt	Accrued	Expense,		Debt	Accrued	Expense,			
	Discount	Interest	net	Total	Discount	Interest	net	Total		
Convertible Line of Credit with Related										
Party	\$561,202	\$60,904	\$ —	\$622,106	\$33,254	\$42,726	\$ —	\$75,980		
Convertible Debt related to										
acquisition	170,509	21,078	—	191,587	266,991	49,315	—	316,306		
Convertible Senior SecuredPromiss	ory									
Notes	961,941	500,000		1,461,941	14,907	7,732		22,639		
Deferred financing related to Senior Secured Promissory										
Notes	20,449	_		20,449		_		_		
Other		_	10,910	10,910			18,045	18,045		
	\$1,714,101	\$581,982	\$ 10,910	\$2,306,993	\$315,152	\$99,773	\$ 18,045	\$432,970		

**Contractual Commitments** 

The table below sets forth our known contractual obligations as of December 31, 2012:

			less than			More than
<b>Contractual Obligations</b>		TOTAL	1 year	1-3 years	3-5 years	5 years
Convertible senior secured	l					
promissory notes (a)	\$	5,313,645	\$ 5,313,645			
Capital lease obligation		87,041	22,510	60,135	4,395	
Operating lease						
obligations		482,886	350,696	132,190		
Royalty payments		600,000	50,000	150,000	150,000	250,000
	\$	6,483,572	\$ 5,736,851	\$ 342,325	\$ 154,395	\$ 250,000

(a) In January and February of 2013 all note holders elected to convert their notes including the Company's Chairman and CEO, resulting in the issuance of 5,271,963 shares of common stock which represents the face value of their respective notes plus accrued but unpaid interest. The Company's Chairman and CEO received 532,260 shares of common stock upon conversion of his note.

**Off-Balance Sheet Arrangements** 

We have no off-balance sheet arrangements.

Liquidity and Capital Resources

Revenue continues to increase quarter over quarter while management maintains tight controls over spending. As of December 31, 2012, the Company had approximately \$6,754,000 of cash and cash equivalents. The Company reported total current assets of approximately \$18,089,000 at December 31, 2012 and total current liabilities of approximately \$5,071,000 at December 31, 2012. The resulting current ratio for the period improved to 3.6 as compared to 3.0 as of December 31, 2011 when current liabilities are adjusted for approximately \$2,425,000 of the current portion of long term debt convertible into MiMedx common stock. Management believes that its anticipated cash from operating and financing activities and existing cash and cash equivalents will enable the Company to meet its operational liquidity needs and fund its planned investing activities for the next year. For our long-term capital requirements, the company may seek additional debt and/or equity financing.

#### Discussion of Cash Flows

Net cash used in operations during the year ended December 31, 2012, decreased approximately \$3,280,000 to \$3,385,000 compared to \$6,665,000 used in operating activities for the year ended December 31, 2011, primarily attributable to our increased sales activity and improved gross margins.

Net cash used in investing activities during the year ended December 31, 2012, decreased approximately \$120,000 to \$583,000 compared to \$703,000 used in investing activities for the year ended December 31, 2011. 2012 activity included higher equipment purchases of approximately \$97,000, while 2011 activity included approximately \$466,000 related to the Surgical Biologics acquisition offset by a grant from the state of Georgia of \$250,000.

Net cash flows from financing activities during the year ended December 31, 2012 decreased approximately \$3,529,000 to \$6,610,000 as compared to \$10,139,000 during the year ended December 31, 2011. Cash flows from financing activities during the current year include approximately \$6,001,000 received from the exercise of warrants, \$1,052,000 received from the exercise of stock options, \$427,000 in payments related to the acquisition of Surgical Biologics, and \$16,000 in payments on an equipment lease.

Due to the material amount of non-cash related items included in the Company results of operations, the Company has developed an Adjusted EBITDA metric which provides management with a clearer view of operational use of cash (see the table below). The Adjusted EBITDA for 2012 was approximately \$2,394,000 which is an improvement of approximately \$8,708,000 as compared to the prior year. This improvement was the result of increased revenue and improved gross margins.

We use various numerical measures in investor conference calls, investor meetings and other forums which are or may be considered "Non-GAAP financial measures" under Regulation G. We have provided below for your reference, supplemental financial disclosure for these measures, including the most directly comparable GAAP measure and an associated reconciliation. The following table provides reconciliation of reported Net Loss on a GAAP basis to Adjusted EBITDA defined as Earnings before Interest, Taxes, Depreciation, Amortization and Share-Based Compensation:

	Year Ended December 31,				
	2012		2011		
Net Loss (Per GAAP)	\$ (7,662,376)	\$	(10,193,986)		
Add back: Financing expense associated with beneficial					
conversion of note payable issued in conjunction with acquisition	170,509		266,991		
Financing expense associated with beneficial conversion of Line of Credit with Related Party	561,202		33,254		
Financing expense associated with beneficial conversion of Senior Secured Promissory Notes	982,390		14,907		
Other interest expense, net	592,891		117,818		
Depreciation Expense	465,367		446,502		
Amortization Expense	1,380,241		1,335,908		
Employee Share Based Compensation	2,075,680		1,307,869		
Other Share Based Compensation	463,041		351,214		
Impairment of Intangible Assets	1,798,495		-		
Fair Value Adjustment of Earn-out Liability	1,567,050		5,803		
Income (Loss) Before Interest, Taxes, Depreciation, Amortization and Share Based Compensation	\$ 2,394,490	\$	(6,313,720)		

#### 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

Not applicable.

Item 8.

Financial Statements and Supplementary Data

Index to Financial Statements

Report of Independent Registered Public Accounting Firm	49
Consolidated Balance Sheets - As of December 31, 2012 and December 2011	51
Consolidated Statements of Operations – For the years ended December 31, 2012 and 2011	52
Consolidated Statements of Stockholders' Equity - For the Years ended December 31, 2012 and 2011	53
Consolidated Statements of Cash Flows – For the years ended December 31, 2012 and 2011	55
Notes to Consolidated Financial Statements	57

#### Index to Financial Statements

#### 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 as of December 31, 2012 and 2011, and the related consolidated statements of income, comprehensive income, stockholders' equity, and cash flows for the years then ended. These financial statements 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 of America). 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, 2012 and 2011, and the consolidated results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States of America), MiMedx Group, Inc.'s internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 15, 2013 expressed an unqualified opinion.

/s/ Cherry Bekaert LLP

Atlanta, Georgia

March 15, 2013

#### Index to Financial Statements

#### 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, 2012, based on criteria established in Internal Control—Integrated Framework 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. 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 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, 2012, based on criteria established in Internal Control—Integrated Framework 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 of America), the consolidated balance sheets and the related consolidated statements of income, comprehensive income, stockholders' equity, and cash flows of MiMedx Group, Inc., and our report dated March 15, 2013 expressed an unqualified opinion.

/s/ Cherry Bekaert LLP

Atlanta, Georgia

March 15, 2013

# MIMEDX GROUP, INC. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS

# ASSETS

	December 31,		
	2012	2011	
Current assets:			
Cash and cash equivalents	\$6,754,485	\$4,112,326	
Accounts receivable, net	7,653,561	1,891,919	
Inventory, net	3,022,784	712,602	
Prepaid expenses and other current assets	657,961	164,664	
Total current assets	18,088,791	6,881,511	
Property and equipment, net of accumulated depreciation of \$2,279,840 and			
\$1,814,473, respectively	1,071,625	869,411	
Goodwill	4,040,443	4,040,443	
Intangible assets, net of accumulated amortization of \$4,848,756 and \$3,468,515,			
respectively	11,911,749	15,090,485	
Deposits and other long term assets	70,000	214,342	
Total assets	\$35,182,608	\$27,096,192	
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable	\$1,251,684	\$1,517,449	
Accrued expenses	3,743,934	783,189	
Other current liabilities	75,154	6,620	
Current portion of line of credit with related party	-	1,295,980	
Current portion of long term convertible debt related to acquisition	-	1,128,806	
Total current liabilities	5,070,772	4,732,044	
Earn-out liability payable in MiMedx common stock	5,792,330	7,410,503	
Convertible Senior Secured Promissory Notes	4,012,442	2,744,587	
Other liabilities	299,762	312,493	
Total liabilities	15,175,306	15,199,627	
Commitments and contingency (Notes 14 and 15)			
Stockholders' equity:			
Preferred stock; \$.001 par value; 5,000,000 shares authorized and 0 shares issued and			
outstanding	-	-	
Common stock; \$.001 par value; 130,000,000 shares authorized; 88,423,169 issued			
and 88,373,169 outstanding for 2012 and 74,306,895 issued and 74,256,895			
outstanding for 2011	88,423	74,307	
Additional paid-in capital	89,627,601	73,868,604	
Treasury stock (50,000 shares at cost)	(25,000)	(25,000)	
Accumulated deficit	(69,683,722)	(62,021,346)	

Total stockholders' equity	20,007,302	11,896,565
Total liabilities and stockholders' equity	\$35,182,608	\$27,096,192

# See notes to consolidated financial statements

# MIMEDX GROUP, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,			
	2012 2011			
REVENUES:				
Net sales	\$27,053,773 \$7,760,446			
OPERATING COSTS AND EXPENSES:				
Cost of products sold	5,188,378 3,357,909			
Research and development expenses	2,884,546 2,976,313			
Selling, general and administrative expenses	20,970,687 11,181,437			
Impairment of intangible assets	1,798,495 -			
Fair value adjustment of earn-out liability	1,567,050 5,803			
LOSS FROM OPERATIONS	(5,355,383) (9,761,016)			
OTHER INCOME (EXPENSE), net				
Amortization of debt discount	(1,714,101) (315,152)			
Interest expense, net	(592,892) (117,818)			
LOSS BEFORE INCOME TAXES	(7,662,376) $(10,193,986)$			
Income taxes				
NET LOSS	\$(7,662,376) \$(10,193,986)			
Net loss per common share				
Basic and diluted	\$(0.09) \$(0.14)			
Shares used in computing net loss per common share				
Basic and diluted	81,646,295 72,450,337			

See notes to consolidated financial statements

# MIMEDX GROUP, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY FOR THE YEARS ENDED DECEMBER 31, 2012 AND 2011

	Prefe Sto Seri A Sha	ck les		Common Stock nt Shares	Amount	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total
Balances, December 31, 2010	-	\$	-	64,381,910	\$64,382	\$57,888,506	\$(25,000)	\$(51,827,360)	\$6,100,52
Employee share-based compensation expense	-		_	-	-	1,307,869	-	-	1,307,86
Other share-based compensation expense	se -		-	-	-	351,214	-	-	351,214
Exercise of stock options	-		-	490,000	490	295,263	-	-	295,753
Sale of common stock and warrants (ne of \$47,733 of offering costs)	et -		-	3,778,321	3,779	3,726,808	-	-	3,730,58
Shares issued in conjunction with conversion of convertible debt	-		_	406,664	406	406,257	-	-	406,663
Shares issued in conjunction with acquisition of Surgical Biologics, LLC	-		_	5,250,000	5,250	7,082,250	-	-	7,087,50
Beneficial conversion feature recognize on convertible debt	ed -		_	-	-	2,715,552	-	-	2,715,55
Warrants issued in conjunction with convertible promissory notes	-		-	-	-	14,885	-	-	14,885
Discount on beneficial conversion feature recognized on line of credit with related party			_	-	-	80,000	-	-	80,000
Net loss	-		-	-	-	-	-	(10,193,986)	(10,193,
Balances, December 31, 2011	-	\$	-	74,306,895	\$74,307	\$73,868,604	\$(25,000)	\$(62,021,346)	\$11,896,5
Continued on next page									

Continued on next page

See notes to consolidated financial statements.

# MIMEDX GROUP, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY FOR THE YEARS ENDED DECEMBER 31, 2012 AND 2011

(	Conver Prefer Stoc Serie A Shat	red k es	Common Stock nt Shares	Amount	Additional Paid-in Capital	Treasury Stock	Accumulated Deficit	Total
Balances, December 31, 2011		\$-	74,306,895				\$(62,021,346)	
Employee share-based compensation expense	-	-	-	-	2,075,680	-	-	2,075,6
Other share-based compensation expense	se -	-	-	-	463,041	-	-	463,041
Exercise of stock options	-	-	843,863	844	1,051,824	-	-	1,052,6
Exercise of warrants	-	-	7,959,767	7,960	5,993,103	-	-	6,001,0
Repurchase warrants	-	-	-	-	(568	) -	-	(568
Cashless exercise of warrants	-	-	216,085	216	(216	) -	-	-
Common stock issued for accrued direc fees	tor -	-	167,086	167	184,486	-	-	184,653
Common stock issued for earn-out liability	-	-	2,632,576	2,632	3,182,591	-	-	3,185,2
Discount on beneficial conversion featu	ıre -	-	-	-	514,456	-	-	514,456
Common stock issued for acquisition no	ote -	-	893,267	893	892,374	-	-	893,267
Conversion of line of credit with relate party	d		1,403,630	1,404	1,402,226			1,403,6
Net loss	-	-	-	-	-	-	(7,662,376)	(7,662,3
Balances, December 31, 2012	-	\$-	88,423,169	\$88,423	\$89,627,601	\$(25,000)	\$(69,683,722)	\$20,007,

See notes to consolidated financial statements.

# MIMEDX GROUP, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended 2 2012	December 31, 2011
Cash flows from operating activities:		
Net loss	\$(7,662,376)	\$(10,193,986)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Depreciation	465,367	446,502
Amortization of intangible assets	1,380,241	1,335,908
Impairment of intangible assets	1,798,495	-
Amortization of debt discount and deferred financing costs	1,714,101	315,152
Employee share-based compensation expense	2,075,680	1,307,869
Other share-based compensation expense	463,041	351,214
Change in fair value of earn-out liability	1,567,050	5,803
Increase (decrease) in cash resulting from changes in (net of effects of acquisition):		
Accounts receivable	(5,761,642)	(1,208,456)
Inventory	(2,310,182)	(253,942)
Prepaid expenses and other current assets	(466,060)	(70,980)
Other assets	96,657	(80,375)
Accounts payable	(81,112)	929,039
Accrued expenses	2,960,744	327,212
Accrued interest	387,896	107,886
Other liabilities	(12,731)	16,383
Net cash flows from operating activities	(3,384,831)	(6,664,771)
Cash flows from investing activities:		
Purchases of equipment	(582,931)	(486,091)
Proceeds from grant	-	250,000
Cash paid for acquisition, net of cash acquired of \$33,583	-	(466,417)
Net cash flows from investing activities	(582,931)	(702,508)
Cash flows from financing activities:		
Proceeds from exercise of warrants	6,001,063	-
Proceeds from exercise of stock options	1,052,668	295,753
Repayment of convertible debt related to acquisition	(427,126)	-
Repayment of equipment lease	(16,116)	-
Repurchase of warrants	(568)	-
Proceeds from Senior Secured Promissory Notes	-	5,000,000
Proceeds from Line of Credit with related party	-	1,300,000
Repayment of Line of Credit	-	(99,000)
Repayment of Note Payable	-	(88,657)
Proceeds from sale of common stock and warrants and common stock with registration		(
rights, net	-	3,730,587
Net cash flows from financing activities	6,609,921	10,138,683
	,,	, ,
Net change in cash	2,642,159	2,771,404
	_,,,,	-,,
Cash, beginning of period	4,112,326	1,340,922

Cash, end of period

\$6,754,485 \$4,112,326

continued on next page See notes to consolidated financial statements

\*

\*

\*

#### MIMEDX GROUP, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years End	led December 31,
	2012	2011
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$13,322	\$15,456
Cash paid for income taxes	\$-	\$-

Supplemental disclosure of non-cash financing activity:

During the year ended December 31, 2012:

- the Company issued 167,086 shares of stock valued at \$184,653 for accrued Director's fees
  - the Company issued 216,085 shares of stock for cashless exercise of warrants
- \* the Company recognized a beneficial conversion feature valued at \$514,456 related to the vested contingent warrants on the line of credit with related party
- \*the Company issued 2,632,576 shares of stock valued at \$3,185,223 for payment of the 2011 Earn-out liability related to its acquisition of Surgical Biologics
  - the Company acquired equipment under a capital lease in the amount of \$84,650
- \*the Company issued 893,267 shares of stock valued at \$893,267 for payment of the Convertible Secured Promissory Notes related to the acquisition of Surgical Biologics
- \*The Company issued 1,403,630 shares of stock valued at \$1,403,630 for payment of the Line of Credit with related party

During the year ended December 31, 2011:

- \* the Company converted its outstanding convertible debt and accrued interest to equity by issuing 406,664 shares of common stock
- \*the Company issued 5,250,000 shares of stock valued at \$7,087,500 and issued convertible secured promissory notes for \$1,250,000 in conjunction with its acquisition of Surgical Biologics
- \* the Company recognized a beneficial conversion feature valued at \$437,500 related to the convertible debt issued with regard to its acquisition of Surgical Biologics, LLC
- \* the Company recognized a beneficial conversion feature valued at \$80,000 related to the convertible debt issued with regard the Note Payable to related party
- \* the Company recognized a beneficial conversion feature valued at \$2,278,052 related to the convertible debt issued with regard to the Senior Secured Promissory Notes
- \*the Company issued warrants valued at \$14,885 for placement fees associated with the Senior Secured Promissory Notes

See notes to consolidated financial statements

#### Index to Financial Statements

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS FOR THE FISCAL YEARS ENDED DECEMBER 31, 2012 AND 2011

#### 1.

#### Nature of Business

MiMedx Group, Inc. ("MiMedx," "The Company," "we," or "us") operates in one business segment, Regenerative Biomaterials, which includes the design, manufacture, and marketing of products and tissue processing services for the Wound Care, Orthopedics, Spine, Ophthalmic and Dental market categories. Our biomaterial platform technologies include the device technologies HydroFix® and CollaFixTM, and our tissue technologies, AmnioFix® and EpiFix®.

The Company is focused primarily on the United States but will pursue other individual markets based upon the specific opportunity. 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 amounts of revenue and expenses 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., SpineMedica, LLC., and Surgical Biologics, LLC. All significant inter-company balances and transactions have been eliminated

#### Reclassifications

Certain amounts in the prior year financial statements have been reclassified to conform to the current year financial statement presentation.

Historically, the Company has reported depreciation and share-based compensation expense as part of Selling, General and Administrative expense. The Company decided to report these expenses in each functional area in order to more accurately present all of the costs attributable to each functional area. During the years ended December 31, 2012 and 2011, we recorded a total of approximately \$465,000 and \$447,000 in depreciation expense allocated to each functional area per the table below. The overall \$19,000 increase in depreciation was attributable to the purchase of additional production and office equipment and leasehold build-out to support our revenue growth and additional staff. We depreciate our assets on a straight-line basis, principally over five to seven years.

The following table shows the allocation of depreciation for the years ended December 31, 2012 and 2011, to operating departments:

	Year Ended	ber 31,	
Depreciation expense included in:	2012		2011
Cost of products sold	\$ 155,987	\$	104,950
Research and development	120,260		118,565
Selling, general and administrative	189,120		222,987
	\$ 465,367	\$	446,502

Share-based compensation for the years ended December 31, 2012 and 2011, was approximately \$2,539,000 and \$1,659,000, respectively, an increase of approximately \$880,000 or 53.0%. Increased employee stock option grants reflecting management's philosophy of aligning employee compensation with investor objectives and the increase in the market price of MiMedx common stock was the primary reason for the increase in expense. The following table shows the allocation of share-based compensation for the years ended December 31, 2012 and 2011, to operating departments:

	Year Ended D	Decemt	per 31,
Share-based compensation included in:	2012		2011
Cost of products sold	\$ 97,970	\$	98,366
Research and development	289,341		254,997
Selling, General and administrative	2,151,410		1,305,720
	\$ 2,538,721	\$	1,659,083

#### 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 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 by 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 and temporarily provides unlimited coverage for certain qualifying and participating non-interest bearing transaction accounts. The temporary unlimited coverage expired on December 31, 2012, at which time the amounts insured by the FDIC returned to \$250,000. As of January 1, 2013, the Company had cash and cash equivalents of approximately \$6,254,000 in excess of these insured amounts.

The Company's principal market concentration of risk is related to its limited distribution channels. Three customers accounted for approximately 68% of revenues for the year ended December 31, 2012, including one customer who represented 40% and another customer which represented 21% of total revenue. Two customers accounted for approximately 37% of the revenues for the year ended December 31, 2011, including one customer who represented 19% and another customer which represented 18% of total revenue. The Company's accounts receivable are derived from customers primarily located in the United States of America. As of December 31, 2012 two customers accounted for 78% of total accounts receivable, 53% and 25% respectively compared to December 31, 2011 when two

customers accounted for 43% of total accounts receivable, 33% and 10%, respectively.

#### Cash and Cash Equivalents

Cash and cash equivalents include all highly liquid investments 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, customer's current creditworthiness, customer concentration, age of accounts receivable balance and general economic conditions that may affect the customer's ability to pay. As of December 31, 2012, and 2011, the Company has \$49,400 and \$19,500, respectively, in the allowance for doubtful accounts. Actual customer collections could differ from estimates. The approximate provision during the year ended December 31, 2012 was \$56,900, with charge-offs of approximately \$27,000 as compared to the approximate provision during the year ended December 31, 2011 of \$57,900 with charge-offs of approximately \$60,000.

#### 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. Within WIP labor and overhead costs are absorbed through the various production processes upon work order closes in our ERP (Enterprise Resource Planning) system. 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. For goodwill, the Company performs a two-step impairment test. 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.

#### Index to Financial Statements

The Company estimates the fair value of indefinite-lived purchased intangible assets using a market approach. The Company recognizes an impairment loss when the estimated fair value of the indefinite-lived purchased intangible assets is less than the carrying value. 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. Recoverability of these intangible assets is assessed based on the undiscounted future cash flows expected to result from the use of the asset. If the undiscounted future cash flows are less than the carrying value, the purchased intangible assets with finite lives are considered to be impaired. The amount of the impairment loss, if any, is measured as the difference between the carrying amount of these assets and the fair value based on a discounted cash flow approach or, when available and appropriate, to comparable market values. The Company amortizes purchased intangible assets with finite lives using the straight-line method over the estimated economic lives of the assets. Intangible assets with finite useful lives are amortized into Selling, General and Administrative Expenses in the consolidated statement of operations using the straight-line method over various periods depending upon the specific asset.

#### Impairment of Goodwill

We tested for impairment of the Intangible Assets related to the Licenses for SaluMedica LLC, Spine Repair and Polyvinyl Alcohol Cryogel as of September 30, 2012 using an undiscounted cash flow methodology. The impairment was the result of the HydroFix® product line experiencing slower than projected growth in each of its markets. Our test indicated that the carrying value of the 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. The impairment was reported as a separate line item in the Consolidated Statement of Operations and included in the Loss From Operations.

# Property and Equipment

Property and equipment are recorded at cost and depreciated on a straight-line basis over their estimated useful lives, principally five 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.

# 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.

# Deferred 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. To retain the grant monies the Company must add a certain number of full time positions and spend a certain amount on capital and operations expenditures by December 31, 2014. The Company recorded the grant monies received as Deferred Grant Income which is included in the Other Liabilities section of the balance sheet per ASC 450-30 Gain Contingencies where an existing condition, situation, or set of circumstances involving uncertainty as to possible gain will ultimately be resolved when one or more future events occur or fail to occur. A contingency that might result in a gain should not be reflected in the financial statements because to do so might be to recognize the gain before its realization. As part of the transaction, the Company sold and is leasing back \$250,000 of the assets from the State for \$100 payable at the time the performance standards are achieved or at the termination date of the lease whichever is earlier. Once the Company has met the headcount and expenditure goals of the project the Company shall notify the State and pay the fixed rent amount of \$100 at which time ownership of the equipment will transfer back to the Company. The Company also entered into a Performance and Accountability Agreement with the State of Georgia which defines the performance standard that if the Company fails to reach by no later than December 31, 2014, the Company shall repay a portion of the Grant amount.

Debt Instruments with Detachable Warrants and Beneficial Conversion Features

According to ASC-470 Debt Instruments with Detachable Warrants, proceeds from the sale of convertible debt instruments with stock purchase warrants (detachable call options) shall be allocated to the two elements based upon the relative fair values of the debt instrument without the warrants and of the warrants themselves at the time of issuance. The portion of the proceeds so allocated to the warrants shall be accounted for as paid-in capital. The remainder of the proceeds shall be allocated to the debt instrument portion of the transaction. Also, the embedded beneficial conversion feature present in the convertible instrument shall be recognized separately at issuance by allocating a portion of the proceeds equal to the intrinsic value of that feature to additional paid-in capital.

# **Revenue Recognition**

The Company sells its products primarily through a combination of independent stocking distributors and 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 utilized 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

Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective income tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that included the enactment date. Valuation allowances are recorded for deferred tax assets when the recoverability of such assets is not deemed more likely than not.

#### Uncertain Tax Positions

Tax positions are evaluated in a two-step process. The Company first determines whether it is more likely than not that a tax position will be sustained upon examination. If a tax position meets the more-likely-than-not recognition threshold it is then measured to determine the amount of benefit to recognize in the financial statements. The tax position is measured as the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement. The Company classifies gross interest and penalties and unrecognized tax benefits that are not expected to result in payment or receipt of cash within one year as non-current liabilities in the Consolidated Balance Sheets.

#### Share-based Compensation

The Company follows the provisions of ASC topic 718 "Compensation — Stock compensation" which requires the use of the fair-value based method to determine compensation for all arrangements under which employees and others receive shares of stock or equity instruments (options and warrants). All awards are amortized on a straight-line basis over their vesting terms.

#### Fair Value of Financial Instruments

The carrying value of accounts payable and accrued expenses approximate their fair value due to the short-term nature of these liabilities. The fair value of our convertible debt approximates \$4,012,000 which represents the face value less the unamortized discount of any beneficial conversion feature plus accrued but unpaid interest at December 31, 2012, as compared to the fair value of our short term and long term convertible debt of approximately \$5,169,000 which represented the face value less the unamortized discount of any beneficial conversion feature plus accrued but unpaid interest at December 31, 2011. As of December 31, 2012, and December 31, 2011, the fair value of warrants issued in conjunction with placement fees was approximately \$20,500 and \$15,000, respectively, which represents the face value less the unamortized discount of any beneficial conversion feature.

#### Fair Value Measurements

The Company records certain financial instruments at fair value, including: cash equivalents and contingent consideration. 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, 2012 the Company has not chosen to make any such elections. Fair value financial instruments are recorded in accordance with the fair value measurement framework.

#### Index to Financial Statements

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 applying 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:

- Λεφελ 1: Θυοτεδ πριχες (υναδφυστεδ) ιν αχτιφε μαρκετς τηατ αρε αχχεσσιβλε ατ της μεασυρεμεντ δατε φορ ιδεντιχαλ ασσετς ορ λιαβιλιτιες;
- Λεφελ 2: Θυοτεδ πριχες in active markets for similar assets or liabilities or observable πριχες that are based on inputs not quoted on active markets, but corroborated by market data; and
  Λεφελ 3: Ynobservable inputs or valuation technides that are used when little or no market data
- ισ ασαιλαβλε.

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. 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.

#### Net loss Per Share

Basic net loss per common share is computed using the weighted-average number of common shares outstanding during the period.

For all periods presented, diluted net loss per share is the same as basic net loss per share, as the inclusion of equivalent shares from outstanding common stock options, warrants, and convertible debt would be anti-dilutive.

The following table sets forth the computation of basic and diluted net loss per share for the fiscal years ended December 31, 2012 and 2011:

	Year ended December 31,				
		2012		2011	
Net loss	\$	(7,662,376)	\$	(10,193,986)	
Denominator for basic earnings per share - weighted					
average shares		81,646,295		72,450,337	
Effect of dilutive securities: Stock options and					
warrants outstanding and convertible debt (a)		—			
Denominator for diluted earnings per share -					
weighted average shares adjusted for dilutive					
securities		81,646,295		72,450,337	
Loss per common share - basic and diluted	\$	(0.09)	\$	(0.14)	

(a) Securities outstanding that were excluded from the computation, prior to the use of the treasury stock method, because they would have been anti-dilutive are as follows:

	December 31, 2012	December 31, 2011
Outstanding Stock Options	13,614,135	10,333,583
Outstanding Warrants	3,129,168	9,388,817
Convertible Debt, promissory notes	5,313,645	5,007,732
Convertible Line of Credit with Related Party	-	1,342,726
Convertible Debt, Acquisition	-	1,299,315
	22,056,948	27,372,173

The table above excludes all securities with contingencies including the earnout liability and contingent warrants.

#### Recently Adopted Accounting Pronouncements

In January 2012 the Company adopted Accounting Standards Update ("ASU") 2011-04, Fair Value Measurement (Topic 820): Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs, which clarifies some existing concepts and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. The adoption of ASU 2011-04 did not have a material effect on the Company's financial condition, profitability, and cash flows.

In January 2012 the Company adopted ASU 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income. The amendments to the Codification in this ASU will require companies to present the components of net income and other comprehensive income either as one continuous statement or as two consecutive statements. It eliminates the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity. The standard does not change the items which must be reported in other comprehensive income, how such items are measured or when they must be reclassified to net income. This standard is effective for interim and annual periods beginning after December 15, 2011. Because this ASU impacts presentation only, it had no effect on our financial condition, results of operations or cash flows.

In January 2012 the Company adopted ASU 2011-08, Intangibles-Goodwill and Other (Topic 350): Testing Goodwill for Impairment, which gives entities testing goodwill for impairment the option of performing a qualitative assessment before calculating the fair value of a reporting unit in step 1 of the goodwill impairment test. The adoption of ASU 2011-08 did not have a material effect on the Company's financial condition, profitability, and cash flows.

#### Index to Financial Statements

In July 2012, the FASB issued ASU No. 2012-02, which amends the guidance in ASC 350-30 on testing indefinite-lived intangible assets, other than goodwill, for impairment. Under the revised guidance, companies testing an indefinite-lived intangible asset for impairment have the option of performing a qualitative assessment before calculating the fair value of the asset (i.e. step 1 of the impairment test). If companies determine, on the basis of qualitative factors, that the fair value of the indefinite-lived intangible asset is more likely than not less than the carrying amount, the two-step impairment test would be required. This update is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012, with early adoption permitted. The Company adopted the revised guidance, and it did not have a material impact on the Company's Consolidated Financial Statements.

#### Recently Issued Accounting Pronouncements Not Yet Adopted

Disclosures about offsetting assets and liabilities – In December 2011, the FASB issued accounting guidance on disclosures about offsetting assets and liabilities. The guidance requires entities to disclose both gross and net information about instruments and transactions that are offset in the statement of financial position, as well as instruments and transactions that are subject to an enforceable master netting arrangement or similar agreement. In January 2013, the FASB issued guidance clarifying the scope of the disclosures to apply only to derivatives, including bifurcated embedded derivatives, repurchase and reverse repurchase agreements, and securities lending and securities borrowing transactions. This guidance is effective January 1, 2013, with retrospective application required. We do not expect the adoption to have a material impact on our financial statements.

Reporting of amounts reclassified out of accumulated other comprehensive income – In February 2013, the FASB issued accounting guidance on the reporting of reclassifications out of accumulated other comprehensive income. The guidance requires an entity to present, either on the face of the statement where net income is presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income if the amount is reclassified to net income in its entirety in the same reporting period. For other amounts not required to be reclassified in their entirety to net income in the same reporting period, a cross reference to other disclosures that provide additional detail about the reclassification amounts is required. This guidance is effective January 1, 2013. We do not expect the adoption to have a material impact on our financial statements.

#### 3.

# Liquidity and Management's Plans

As of December 31, 2012, the Company had approximately \$6,754,000 of cash and cash equivalents. The Company reported total current assets of approximately \$18,089,000 and current liabilities of approximately \$5,071,000. The Company believes that its anticipated cash from operating and financing activities and existing cash and cash equivalents will enable the Company to meet its operational liquidity needs, fund its planned investing activities and pay its debt when due for the next year.

#### Index to Financial Statements

4.

Acquisition of Surgical Biologics, LLC

On December 21, 2010, we entered into an Agreement and Plan of Merger ("the Merger Agreement") with Membrane Products Holdings, LLC and OnRamp Capital Investments, LLC, the owners of Surgical Biologics, LLC ("Surgical Biologics"), a privately held company headquartered in Kennesaw, Georgia. This transaction closed on January 5, 2011 and as a result we acquired all of the outstanding shares of Surgical Biologics in exchange for \$500,000 cash, a total of \$1,250,000 in 4% Convertible Secured Promissory Notes, and \$7,087,500 in stock, represented by 5,250,000 shares of our common stock (525,000 of which were held in escrow for the purpose of securing the indemnification obligations outlined in the Merger Agreement). Contingent consideration shall be payable in a formula determined by sales for the years 2011 and 2012. The significant unobservable inputs used in the fair value measurement of contingent consideration related to the acquisitions are annualized revenue forecasts developed by the Company's management and the probability of achievement of those revenue forecasts. The contingent consideration was initially valued at \$7,404,700 and is shown in the schedule below as fair value of earn-out (level 3 input under the valuation hierarchy). We completed the acquisition of Surgical Biologics in an effort to extend our biomaterials product lines. As of December 31, 2011, the Company evaluated the contingent liability based on operating results for the year, and adjusted the earn-out liability to \$7,410,503. On April 30, 2012, the Company issued 2,632,576 shares of its Common Stock valued at \$3,185,223 in payment of the 2011 earn-out. As of December 31, 2012, the Company evaluated the 2012 contingent liability based on operating results for the year ended December 31, 2012, and adjusted the 2012 earn-out liability to \$5,792,330.

#### Accrued Earn - Out Acquisition Consideration

	2012	2011
Beginning balance at January 1,	\$ 7,410,503 \$	-
Valuation at acquisition date		7,404,700
Remeasurement adjustments	1,567,050	5,803
Common stock issued on earn - out	(3,185,223)	-
Ending balance at December 31,	\$ 5,792,330 \$	7,410,503

In total, the 4% Convertible Promissory Notes were convertible into up to 1,250,000 shares of the Company's common stock at \$1.00 per share (a) at any time upon the election of the holder of the Convertible Notes; or (b) at the election of the Company, at any such time as the closing price per share of the Company's common stock (as reported by the OTCBB or on any national securities exchange on which the Company's shares may be listed, as the case may be) closes at no less than \$1.75 per share for not less than 20 consecutive trading days in any period prior to the maturity date. The 4% Convertible Promissory Notes matured in eighteen (18) months and earned interest at 4% per annum on the outstanding principal amount payable in cash on the maturity date or convertible into shares of common stock of the Company as provided for above. The 4% Convertible Promissory Notes were secured by a security interest in the Intellectual Property, including the Patents and know-how and trade secrets related thereto, owned by, or exclusively licensed to, Surgical Biologics, LLC. In July, 2012, the Company settled the Convertible Promissory Notes by paying approximately \$177,000 in cash and issuing 893,267 shares of MiMedx common stock.

The Company has evaluated the contingent consideration for accounting purposes under GAAP and has determined that the contingent consideration is within the scope of ASC 480 Distinguishing Liabilities from Equity whereby a financial instrument other than an outstanding share, that embodies a conditional obligation that the issuer may settle by issuing a variable number of its equity shares, shall be classified as a liability if, at inception, the monetary value of the obligation is based solely or predominantly on variations in something other than the fair value of the issuer's equity shares.

The actual purchase price was based on cash paid, the fair value of our stock on the date of the Surgical Biologics acquisition, and direct costs associated with the combination. The actual purchase price was allocated as follows:

Value of 5,250,000 shares issued at \$1.35 per share	\$ 7,087,500
Cash paid at closing	350,000
Cash retained for working capital	150,000
Assumed Debt	182,777
Convertible Secured Promissory Note	1,250,000
Fair value of earn-out	7,404,700
Total fair value of purchase price	\$ 16,424,977
Assets purchased:	
Tangible assets:	
Debt-free working capital	\$ 671,880
Other assets, net	385
Property, plant and equipment	72,866
	745,131
Intangible assets:	
Customer relationships	3,520,000
Supplier relationships	241,000
Patents and know-how	5,530,000
Trade names and trademarks	1,008,000
In-process research and development – liquid	2,160,000
In-process research and development – other	25,000
Licenses and permits	13,000
	12,497,000
Goodwill	3,182,846
Total Assets Purchased	\$ 16,424,977

Working capital and other assets were composed of the following:

\$ 33,583
2,738
181,087
340,000
347,106
(196,101)
(36,533)
671,880
(62,590)
(21,187)
(99,000)
\$ 489,103
\$ 16,582
(16,197)
\$ 385
\$

The combination was accounted for as a purchase business combination as defined by ASC Topic 805 – Business Combinations. The allocation of the purchase price to the assets acquired and liabilities assumed was based on an independent valuation report obtained by us.

The values assigned to intangible assets are subject to amortization. The intangible assets were assigned the following lives for amortization purposes:

	Estimated useful
Intangible asset:	life (in years)
Customer relationships	14
Supplier relationships	14
Patents and know-how	14
Trade names and trademarks	indefinite
In-process research and development – liquid	indefinite(a)
In-process research and development – other	indefinite
Licenses and permits	3

(a)AmnioFix® injectable was launched in 2012 with amortization recorded over its expected useful life.

Goodwill consists of the excess of the purchase price paid over the identifiable net assets and liabilities acquired at fair value. Goodwill was determined using the residual method based on an independent appraisal of the assets and liabilities acquired in the transaction. Goodwill is tested for impairment as defined by ASC Topic 350 – Intangibles – Goodwill and Other.

#### 5.

#### Inventories

Inventories consisted of the following items as of December 31, 2012 and 2011:

	December 31,			
		2012		2011
Raw materials	\$	233,747	\$	95,288
Work in process		1,598,537		308,763
Finished goods		1,349,121		361,007
Inventory, gross		3,181,405		765,058
Reserve for obsolescence		(158,621)		(52,456)
Inventory, net	\$	3,022,784	\$	712,602

#### 6.

#### Property and Equipment

Property and equipment consist of the following as of December 31, 2012 and 2011:

	December 31,				
		2012		2011	
Leasehold improvements	\$	1,022,230	\$	925,086	
Lab and clean room equipment		1,887,645		1,463,144	
Furniture and equipment		431,563		295,654	
Construction in Progress		10,027		-	
Property, Equipment, gross		3,351,465		2,683,884	
Less accumulated depreciation		(2,279,840)		(1,814,473)	
Property, Equipment, net	\$	1,071,625	\$	869,411	

The table above includes reclassifications of production equipment previously included in the furniture and office equipment category.

7.

#### Intangible Assets and Royalty Agreement

Intangible assets activity is summarized as follows:

	December 31. Average Amortization Lives	Gross	Impairment Adjustment	Accumulated Amortization		December 31 Gross Carrying Value	, 2011 Accumulate Amortizatic
License-Shriners Hsp for							
Children & USF Research							
(a)	10 years	\$996,000	\$ <u> </u>	\$(587,633)	\$408,367	\$996,000	\$(488,033
License - SaluMedica LLC							
Spine Repair (b)	10 years	2,399,000	(851,676)	(1,547,324)		2,399,000	(1,313,573
License - Polyvinyl							
Alcohol Cryogel (c)	10 years	2,667,000	(946,819)	(1,223,561)	496,620	2,667,000	(998,932
Customer Relationships (d)	14 years	3,520,000		(502,857)	3,017,143	3,520,000	(251,429
Supplier Relationships (d)	14 years	241,000		(34,429)	206,571	241,000	(17,215
Patents & Know-How (d)	14 years	5,530,000		(790,000)	4,740,000	5,530,000	(395,000
Micronized Processing							
Know-How (d)	14 years	2,160,000		(154,286)	2,005,714	2,160,000	
Licenses/Permits (d)	3 years	13,000		(8,667)	4,333	13,000	(4,333
		17,526,000	(1,798,495)	(4,848,756)	10,878,749	17,526,000	(3,468,51
Trade Names/Trademarks							
(d)	indefinite	1,008,000			1,008,000	1,008,000	
In-process Research &							
Development-Other (d)	indefinite	25,000			25,000	25,000	
•		\$18,559,000	\$(1,798,495)	\$(4,848,756)		\$18,559,000	\$(3,468,515
			,	,			

(a) On January 29, 2007, the Company acquired a license from Shriners Hospitals for Children and University of South Florida Research Foundation, Inc. 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.

(b) License from SaluMedica, LLC (SaluMedica) for the use of certain developed technologies related to spine repair. This license was acquired through the acquisition of SpineMedica Corp.

(c) On March 31, 2008, the Company entered into a license agreement for the use of certain developed technologies related to surgical sheets made of polyvinyl alcohol cryogel. The agreement also provides for the issuance of an additional 600,000 shares upon the Company meeting certain milestones related to future sales. On December 31, 2009 the Company completed the sale of its first commercial product and met its first milestone under this agreement. As a result the Company issued 100,000 shares of common stock to the licensor valued at \$71,000. At December 31, 2012 or 2011, there are no additional amounts accrued for this obligation due to its contingent nature.

(d) On January 5, 2011, the Company acquired Surgical Biologics, LLC. As a result, the Company recorded intangible assets for customer and supplier relationships, patents and know-how, licenses/permits, trade names and

trademarks and in-process research and development.

Expected future amortization of intangible assets is as follows:

	Estimated		
	А	mortization	
Year ending December 31,		Expense	
2013	\$	1,050,380	
2014		1,046,047	
2015		1,022,651	
2016		976,998	
2017		886,927	
Thereafter		5,895,746	
	\$	10,878,749	

#### 8.

# Accrued Expenses

Accrued Expenses consist of the following as of December 31, 2012 and December 31, 2011:

	December 31,			
		2012		2011
Accrued Personnel Related Costs	\$	1,761,760	\$	311,849
Accrued Commissions		1,469,925		112,905
Other Accrued Expenses		512,249		358,435
Total Accrued Expenses	\$	3,743,934	\$	783,189

9.

#### Long-Term Debt

The following table summarizes our long-term debt:

	Decemt 2012	ber 31, 2011
\$5M Convertible Senior Secured Promissory Notes including interest at 5% per annum payable quarterly through December 31, 2013, and an additional one time 5% interest charge payable on January 15, 2013 if not repaid by December 31, 2012, collateralized by a first priority lien shared equally with holder of the Convertible Line of Credit with Related Party in all of the patents and intellectual property owned by the Company subordinated to the Convertible Debt related to acquisition for Surgical Biologics intellectual property until repaid. (a)	\$5,313,645	\$5,007,732
Convertible Line of Credit with Related Party with 5% interest; principal and interest payable in full December 31, 2012 collateralized by a first priority lien shared equally with holders of Convertible Senior Secured Promissory Notes in all patents and intellectual property of the Company subordinated to the Convertible debt related to the acquisition for Surgical Biologics intellectual property until repaid. (b)	_	1,342,726
Convertible debt related to acquisition with 4% interest; principal and interest payable in full on July 5, 2012, collateralized by a first priority lien in all the intellectual property owned by Surgical Biologics immediately after the closing. (c)	-	1,299,315
Total debt	\$5,313,645	\$7,649,773
Less unamortized debt discount	(1,301,203)	(2,480,400)
Less current portion	-	(2,424,786)
Long-term portion	\$4,012,442	\$2,744,587

(a) Investors received First Contingent Warrants (25% of amount invested) and Second Contingent Warrants (25% of amount invested) at an exercise price of \$.01 per share. In March 2012 a total of 1,250,000 First Contingent Warrants were vested. In July 2012, a total of 1,250,000 Second Contingent Warrants were voided due to the Company share price trading at or above \$1.75 for ten consecutive trading days. The additional interest resulting from the beneficial conversion feature, inclusive of the First Contingent Warrants, totaled \$2,278,052 which has been recorded as a debt discount that has been and will continue to be charged to interest expense using the effective interest rate over the life of the note.

(b) The same terms offered to the Senior Secured Promissory note with regard to Contingent Warrants applied to the Convertible Line of Credit. In March 2012 a total of 325,000 First Contingent Warrants vested. In July 2012, a total of 325,000 Second Contingent Warrants were voided. The additional interest related to the beneficial conversion feature totaled \$594,456 and was recorded as a debt discount and charged to interest expense using the effective interest rate over the life of the note. On December 7, 2012, the Chairman and CEO elected to convert his note and accrued interest resulting in the issuance of 1,403,630 shares of MiMedx common stock.

(c) Additional financing expense of \$437,500 was recorded for the beneficial conversion feature of the convertible notes over the term of the note. In July, 2012, the Company settled the Convertible Promissory Notes by paying

approximately \$177,000 in cash and issuing 893,267 shares of MiMedx common stock.

Convertible Line of Credit with related party

On March 31, 2011, the Company and its Chairman of the Board and CEO ("the Lender") entered into a Subscription Agreement for a 5% Convertible Senior Secured Promissory Note ("Subscription Agreement") and, in connection therewith, agreed to issue a 5% Convertible Senior Secured Promissory Note ("Note") in the amount borrowed by the Company. At the option of the Lender, the Note was convertible into the number of shares of common stock of the Company equal to the quotient of the outstanding principal amount and accrued interest of the Note as of the date of such election divided by \$1.00 per share.

#### 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 is 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.

As of December 31, 2012 the Company had not repaid the Notes in full and as a result requires the Company to pay each lender an additional interest payment in the amount of five percent (5%) of the aggregate outstanding principal amount of such lender's Notes as of December 31, 2012. The additional interest was accrued on a monthly basis during the year.

In conjunction with the sale of the Convertible Senior Secured Promissory 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. The warrants expire in five years. 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 are recorded as deferred financing costs and are being amortized over the term of the Senior 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.

In January and February of 2013 all note holders elected to convert their notes including the Company's Chairman and CEO, resulting in the issuance of 5,271,963 shares of common stock which represents the face value of their respective notes plus accrued but unpaid interest. The Company's Chairman and CEO received 532,260 shares of common stock upon conversion of his note. This will also result in the acceleration of amortization of debt discount of \$1,301,000 in the same period.

#### **10.Common Stock Placements**

#### October 2010 Private Placement

In October 2010, the Company commenced a private placement to sell common stock and warrants. For the year ended December 31, 2011, the Company sold 3,778,321 shares of Common Stock and issued 1,889,161 warrants and received cash proceeds of \$3,730,587 net of \$47,733 in offering costs. Under the terms of the offering, for each share purchased, the investor received one 5-year warrant to purchase the common stock of the Company at an exercise price of \$1.50 per share. The terms of the warrant, (the "Callable Warrant") are that for every two shares of common stock purchased, the holder is issued a 5-year warrant to purchase one share of the Company's Common Stock at an exercise price of \$1.50 per share. The Callable Warrant was callable by the Company at any time after the issuance if the closing sale price of the Stock exceeds \$1.75 for fifteen (15) or more consecutive trading days. Upon written notice, the Company may redeem the Callable Warrant at a price of \$0.01 per share. In July 2012, the Company decided to exercise its right to call approximately 3,345,000 warrants. The Company raised approximately \$4,900,000 and issued approximately 3,289,000 shares of MiMedx common stock including a total of 503,332 Callable Warrants exercised by the Company's Chairman and CEO. The balance of 56,750 warrants were repurchased at \$0.01 per share.

Additionally, under the terms of the offering the Company issued a First Contingent Warrant ("First Contingent Warrant") and a Second Contingent Warrant ("Second Contingent Warrant") to Purchase Common Stock. These warrants vested assuming certain revenue targets were not achieved and could be voided if the closing trading price of the Company's stock achieved a certain level for a specified number of consecutive trading days. The First Contingent Warrant vested during the second quarter of 2012 resulting in the issuance of approximately 1,673,000 warrants including approximately 252,000 to the Company's Chairman and CEO, at an exercise price of \$0.01 per share. On July 3, 2012, 1,672,742 Second Contingent Warrants were voided which represented the tenth consecutive trading day of the closing trading price of the Company stock being at least \$1.75. As of December 31, 2012 approximately 1,609,000 First Contingent Warrants have been exercised.

11.

Equity

#### Stock Incentive Plan

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, 2012 and December 31, 2011 totaled 375,000. The maximum number of shares of common stock which can be issued under the 2006 Plan is 16,500,000 at December 31, 2012 and 12,500,000 at December 31, 2011, with an increase of 4,000,000 shares in May 2012.

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, 2011	8,257,650	\$1.20		
Granted	3,918,500	\$1.17		
Exercised	(490,000)	\$0.60		
Unvested options forfeited	(217,252)	\$1.10		
Vested options expired	(1,135,315)	\$1.70		
Outstanding at December 31, 2011	10,333,583	\$1.17	7.1	\$1,457,218
Vested or expected to vest at December 31, 2011	10,283,583	\$1.17	5.7	\$1,395,223
Outstanding at January 1, 2012	10,333,583	\$1.17		
Granted	5,307,500	\$1.90		
Exercised	(843,862)	\$1.25		
Unvested options forfeited	(387,171)	\$1.17		
Vested options expired	(795,915)	\$1.55		
Outstanding at December 31, 2012	13,614,135	\$1.42	8.0	\$32,924,881
Vested or expected to vest at December 31, 2012	13,367,278	\$1.41	7.9	\$32,490,930

The intrinsic value of options exercised during the year ended December 31, 2012, was approximately \$718,978 and was \$258,000 for the year ended December 31, 2011.

The following is a summary of stock options outstanding for years ended December 31, 2012 and 2011, respectively:

	2012 Options Outstanding Weighted- Average			Options Exercisable	
		Remaining	Weighted-		Weighted-
	NT	Contractual	Average	NI	Average
Danga of Everaina Driana	Number	Term	Exercise Price	Number Exercisable	Exercise Price
Range of Exercise Prices \$0.50 - \$0.76	outstanding 2,372,500	(in years) 5.3	\$ 0.66	2,372,500	\$ 0.66
\$0.87 - \$1.35	7,048,668	8.6	\$ 1.15	1,674,638	\$ 1.15
\$1.40 - \$2.18	1,958,467	6.8	\$ 1.68	1,189,459	\$ 1.68
\$2.29 - \$3.47	2,177,000	9.7	\$ 1.08	1,109,439	¢
\$3.49 - \$3.85	57,500	10.0	\$ -	-	¢
φ5.49 - φ5.85	13,614,135	8.0	\$ 1.42	- 5,236,597	\$ - \$ 1.05
	15,014,155	8.0	φ 1.42	5,250,597	\$ 1.03
		2011			
	0	ptions Outstanding		Options Ex	ercisable

	Options Outstanding		Options Exercisable		
		Weighted-			
		Average			
		Remaining	Weighted-		Weighted-
		Contractual	Average		Average
	Number	Term	Exercise	Number	Exercise
Range of Exercise Prices	outstanding	(in years)	Price	Exercisable	Price
\$0.50	587,250	2.9	\$ 0.50	513,268	\$ 0.50
\$0.65 - \$1.00	2,967,500	5.7	\$ 0.79	2,730,224	\$ 0.79
\$1.04 - \$1.80	6,228,833	8.8	\$ 1.30	2,207,005	\$ 1.45
\$2.40	550,000	0.7	\$ 2.40	550,000	\$ 2.40
	10,333,583	7.1	\$ 1.17	6,000,497	\$ 1.16

A summary of the status of the Company's unvested stock options as of December 31, 2012 and December 31, 2011 is presented below:

	Number of	Weighted- Average Grant Date	
Unvested Stock Options	Shares	Fair Value	
Unvested at January 1, 2012	4,333,086	\$ 0.72	
Granted	5,307,500	\$ 1.90	
Cancelled/expired	(387,171)	\$ 1.17	
Vested	(875,877)	\$ 1.05	
Unvested at December 31, 2012	8,377,538	\$ 0.96	
	Number of	Weighted- Average Grant Date	
Unvested Stock Options	Number of Shares	Average	
Unvested Stock Options Unvested at January 1, 2011		Average Grant Date	
•	Shares	Average Grant Date Fair Value	
Unvested at January 1, 2011	Shares 2,679,787	Average Grant Date Fair Value \$ 0.87 \$ 0.63	
Unvested at January 1, 2011 Granted	Shares 2,679,787 3,918,500	Average Grant Date Fair Value \$ 0.87 \$ 0.63 ) \$ 0.59	

Total unrecognized compensation expense at December 31, 2012, was approximately \$6,151,000 and will be charged to expense through December 2015.

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 average of the sum of the vesting term plus the contract term. 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 publically 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 Dece	Year ended December 31,	
	2012	2011	
Expected volatility			