MIMEDX GROUP, INC. Form 10-K June 27, 2008

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

FORM 10-K

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

For the fiscal year ended March 31, 2008 Commission file number 0-52491 MIMEDX GROUP, INC.

(Exact name of registrant as specified in its charter)

Florida 26-2792552

(State or other jurisdiction of incorporation) (I.R.S. Employer Identification Number)

1234 Airport Road, Suite 105
Destin, Florida
(Address of principal executive offices)

32541

(Zip Code)

(850) 269-0000

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 b

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  $\flat$  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.

Yes o No o

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

Large accelerated filer o Accelerated filer o

Non-accelerated filer o

Smaller reporting company b

(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 o No b

The aggregate market value of Common Stock held by non-affiliates on September 28, 2007, based upon the last sale price of the shares as reported on the OTC Bulletin Board on such date, was approximately \$7,067,163.

There were 37,282,128 shares of Common Stock outstanding as of June 10, 2008.

**Documents Incorporated by Reference** 

Portions of the proxy statement relating to the 2008 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.

# TABLE OF CONTENTS

| <u>PART I</u>  | 2  |
|--|----|
| Item 1. Business   | 2  |
| Item 1A. Risk Factors  | 20 |
| Item 1B. Unresolved Staff Comments   | 32 |
| Item 2. Properties   | 33 |
| Item 3. Legal Proceedings  | 33 |
| Item 4. Submissions of Matters to a Vote of Security Holders   | 33 |
| PART II  | 34 |
| Item 5. Market for Registrant s Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities | 34 |
| Item 6. Selected Financial Data  | 35 |
| Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations                        | 35 |
| Item 7A. Quantitative and Qualitative Disclosures About Market Risk  | 40 |
| Item 8. Financial Statements and Supplementary Data  | 41 |
| Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure                         | 62 |
| Item 9A(T). Controls and Procedures  | 62 |
| Item 9B. Other Information   | 63 |
| PART III   | 64 |
| Item 10. Directors, Executive Officers and Corporate Governance  | 64 |
| Item 11. Executive Compensation  | 64 |
| Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters              | 64 |
| Item 13. Certain Relationships and Related Transactions, and Director Independence                                   | 64 |
| Item 14. Principal Accounting Fees and Services  | 64 |
| PART IV  | 65 |

| tem 15. Exhibits, Financial Statement Schedules   | 65 |
|---|----|
| <u>SIGNATURES</u>   | 66 |
| EXHIBIT INDEX   | 67 |
| Exhibit 10.27 Exhibit 10.57 Exhibit 10.58 Exhibit 10.60 Exhibit 10.61 Exhibit 10.62 Exhibit 10.63 Exhibit 10.64 Exhibit 31.1 Exhibit 31.2 Exhibit 32.1 Exhibit 32.2 |    |
| 1   |    |

#### **PART I**

#### Item 1. Business

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. would. believe. expect. anticipate. estimate. intend. seeks. should, and other words or expressions of similar meaning are intended by us to identify forward-looking will. statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are found at various places throughout this report and in the documents incorporated herein by reference. These statements are based on our current expectations about future events or results and information that is currently available to us, involve assumptions, risks, and uncertainties, and speak only as of the date on which such statements are made.

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.

# Background of MiMedx Group, Inc.

MiMedx Group, Inc. was originally formed as a Utah corporation on July 30, 1985 under the name Leibra, Inc. We later changed domicile, through a merger, to Nevada, and later changed our name to Alynx, Co. We had several additional name changes in connection with various business acquisitions, all of which were discontinued or rescinded. We were an inactive shell corporation for at least the past 10 years, seeking to acquire an interest in a business with long-term growth potential. On March 6, 2007, we (then Alynx, Co.) filed a registration statement with the SEC on Form 10-SB to register our common stock under the Securities Exchange Act of 1934. We have filed periodic reports with the SEC since that time.

As used herein, the terms the Company, we, our and us refer to MiMedx Group, Inc., a Florida corporation (form Alynx, Co., a Nevada corporation), and our consolidated subsidiaries as a combined entity, except where it is clear that the terms mean only MiMedx Group, Inc.

On February 8, 2008, MiMedx Group, Inc., MMX Acquisition Corp., a Florida corporation wholly-owned by Alynx, Co., and MiMedx, Inc., a Florida-based, privately-held, development-stage medical device company (MiMedx), consummated the arrangement set forth in an Agreement and Plan of Merger between the parties (the Merger), whereby (i) MMX Acquisition Corp. merged with and into MiMedx; (ii) MiMedx became a wholly-owned subsidiary of the Company; and (iii) former MiMedx shareholders received approximately 97.25% of the post-merger company s outstanding shares. On March 31, 2008, we merged into a Florida entity, thereby becoming MiMedx Group, Inc. and also effected a reverse split so that each former MiMedx shareholder owned the same number of shares in the Company as such shareholder held in MiMedx prior to the Merger.

#### Overview

Our business is now the business conducted by our subsidiaries, MiMedx and SpineMedica, LLC (SpineMedica). MiMedx is currently developing products primarily for use by musculoskeletal specialists in surgical and non-surgical application. In February and March of 2007, MiMedx raised approximately \$14 million in a private placement. In July 2007, MiMedx acquired SpineMedica Corp., which is focused on developing medical devices to treat spinal disorders. In late 2007, MiMedx raised approximately \$3.9 million in a private placement.

2

#### **Recent Events**

On February 20, 2008, we appointed Brian J. Splan, former President of the Healthcare Division of Smith & Nephew, Inc., President of MiMedx.

On March 31, 2008, we entered into an exclusive world-wide license with SaluMedica, LLC for a poly-vinyl alcohol (PVA) based hydrogel biomaterial for applications as a surgical sheet. The license covers both internal and external applications. Initially, SpineMedica plans to focus on developing the hydrogel surgical sheet technology for a spine surgery vessel guard used for anterior spinal surgeries. Additionally, we believe there is potential for this technology to be used in the prevention of scarring and as an anti-adhesive or in tissue repair. In exchange for the exclusive, worldwide, perpetual license to develop, manufacture, and sell the surgical sheet technology for application anywhere in the body, we issued SaluMedica, LLC 400,000 shares of restricted Common Stock. In addition, SaluMedica, LLC is eligible to receive up to an aggregate additional 600,000 shares of restricted Common Stock if certain sales and revenue milestones are achieved not later than June 30, 2013.

On April 29, 2008, Ronald G. Wallace, former President of UPS International, was appointed to our Board of Directors and to the Audit and Compensation Committees of our Board.

On April 8, 2008, our Board of Directors streamlined and clarified our corporate and executive officer reporting structure, so that MiMedx Group, Inc. has only four executive officers, as follows: Steve Gorlin, Chairman of the Board, Thomas W. D. Alonzo, Chief Executive Officer, John C. Thomas, Jr., Chief Financial Officer, and Matthew J. Miller, Executive Vice President; and all other executive officers are officers of our operating subsidiary, MiMedx (with the exception of the officers of R. Lewis Bennett and Rebeccah Brown, Ph.D., who are officers of SpineMedica, as previously disclosed). In accordance with the Board s directive, in June of 2008, the employment agreements of the four officers listed above were assigned to and assumed by MiMedx Group, Inc. and the employment agreement of Brian J. Splan was assigned to and assumed by MiMedx.

#### **Our Strategy**

Our business strategy is to identify, acquire and commercialize innovative new medical products and technologies, focused initially for the musculoskeletal market, as well as novel medical instrumentation and surgical techniques. We have organized an advisory panel of leading physicians in our primary fields of interest for new products and technology as well as guidance and advice with ongoing product development programs. We plan to utilize our experienced management team to commercialize these medical technologies by advancing them through the proper regulatory approval processes, arranging for reliable and cost-effective manufacturing, and to ultimately either sell the product lines to others or market the products in Europe, the United States, and Asia.

We have already started implementing our business strategy through our acquisition of several products and services, and SpineMedica. We intend to build on this effort by continuing to search for and utilize complementary technology that we believe can enhance our products currently under development, add to our product line, and move us to profitability.

# **Products and Services Under Development**

We currently operate in one business segment, musculoskeletal products, which will include the design, manufacture and marketing of four major market categories: soft-tissue reconstructive products, fixation devices, spinal products and joint reconstruction products including tendons and ligaments of the hand and upper and lower extremity joint markets, and procedure-specific instrumentation required to implant our reconstructive systems. Fixation devices may include internal, bone-to-bone fixation devices that do not address the spine. Spinal products may include artificial spinal discs to treat cervical pain and degeneration as well as lumbar indications, facet arthroplasty, intervertebral spacers, spinous process spacers, and other spinal systems and implants, as well as orthobiologics. Other product categories may include arthroscopy products, general surgical implants and instruments, operating room supplies and other surgical products and implants.

# MiMedx Products and Services

MiMedx s core technology is a unique cross-linking process that utilizes nordihydroguaiaretic acid (NDGA), a naturally occurring compound. Initial bench testing shows that collagen cross-linked with NDGA produces a very strong, biocompatible, and durable material which could possibly be used to treat a number of orthopedic and general soft-tissue trauma and disease disorders.

#### **Table of Contents**

The core technology is licensed to us and is embodied in two patents. It 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 could potentially be developed and patented that are all tied to the core patented technology.

We believe NDGA cross-linking has advantages over other cross-linking agents. Initial biocompatibility tests conducted showed NDGA cross-linked biomaterials have a high degree of biocompatibility. Furthermore, tests have shown NDGA biocompatibilizes certain materials that may otherwise create a foreign body response. NDGA is a biological compound, and therefore biomaterials cross-linked with NDGA are composed entirely of biological components. NDGA is commercially available from numerous sources, and we have identified several qualified suppliers in the U.S.

Characteristics and benefits of products that we believe could possibly be developed using this licensed technology are:

Initial tests of fibers cross-linked with NDGA 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 arrays of fibers for tendons

Fiber braids for ligament bioprostheses

Woven meshes for general surgical use;

NDGA-treated biomaterials have been tested and results preliminarily suggest that the materials are biocompatible and biodegradable;

Biocompatibilization (making a material biocompatible that may otherwise not be) of in-dwelling medical devices by coating with NDGA polymerized collagen;

NDGA treatment of xenograft (animal in origin) and allograft (human in origin) materials could make them more biocompatible and possibly improve functional lifetime; and

NDGA-treated collagen-based biorivets have the potential to be used for bone repair.

MiMedx s efforts presently focus on development of the potential products identified and designing a manufacturing process for those products. We are planning to initially pursue linear arrays and braided constructs for tendon repair as the first products to enter clinical development.

We may license rights to others for unique applications and indications that we do not intend to exploit.

#### SpineMedica Products and Services

As much as \$100 billion is spent annually to treat back pain, which leads national healthcare expenditures and is projected to increase as the baby boomers age. According to iData Research Inc., U.S. Markets for Spinal Implants & Biomaterials, the total United States spinal implants and biomaterials market in 2006 approached \$5 billion, approximately a 15% increase over 2005.

SpineMedica is currently developing two products in addition to the surgical sheet discussed under Recent Events above: a cervical total disc replacement and a posterior interbody fusion device for this market. SpineMedica owns specific rights to a PVA and water-based biomaterial that can be manufactured with a wide range of mechanical properties, including those that appear to closely mimic the mechanical and physical properties of natural, healthy human tissue. We believe the intervertebral disc space and the normal mobility of the spine can be preserved using a biomimetic material like this specific hydrogel. This hydrogel, in a form called Salubria®, has been used in other medical device applications and we believe it has demonstrated biocompatibility and durability inside the human body. In the United States, the FDA has cleared the material for use next to nerves and in the European Union and Canada it has been cleared for use next to nerves and to replace worn-out and lesioned cartilage in the knee.

According to SaluMedica, LLC, our licensor, the material has been tested to withstand 10 million cycles of high stress and shear using standard industry materials-testing methods. In addition, a first generation prototype of the total disc replacement ( TDR ) has been implanted in sheep, demonstrating ease of implantation and acceptable osteoconductive fixation and biocompatibility.

We have developed a strategic plan that anticipates the first human implantation of a hydrogel arthroplasty product in the lumbar spine in 2009, as an interbody device. However, this pilot study may not be completed or may not have favorable results. The cervical artificial disc development program is still in the initial bench testing stage of development and is not anticipated to be ready for human implantation until 2010.

4

SpineMedica has recently begun developing a third product for the spine, a vessel guard made of the hydrogel material. This vessel guard, which is anticipated to be a 510(k) device with the FDA, would be designed to reduce the risk of potential vessel damage during a spinal revision surgery. We also plan to pursue a CE Mark in Europe for this vessel guard. If successful, the strategic plan for this device anticipates introduction into the market in 2009.

#### **Market Opportunity**

Since 2001, 78% of the orthopedic implants approved by the FDA have incorporated new or unique biomaterials, according to industry analyst Robin Young, *Orthopedics This Week*. Biomaterials have developed into a number of new technologies that can offer a high level of biocompatibility and overcome certain disadvantages associated with traditional treatment modalities, such as synthetic prostheses. Biomaterials are natural or synthetic (when consolidated with natural materials) products used for many indications, such as tissue engineering and stimulating the repair processes innate to the human body.

Orthopedics is one of the largest medical sectors utilizing biomaterials. The development of advanced generation products has prompted many orthopedic companies whose foundations lie in traditional therapies to focus on biomaterials due to physician and patient demand. We believe that new biomaterial products will continue to replace existing products.

The main orthopedic biomaterials markets driving growth are connective and soft tissues, such as tendon and ligament repair (tendons connect muscle to bone and ligaments connect bone to bone), meniscus repair, bone grafts, resorbable technologies, and cartilage repair.

We believe that the number of procedures which might utilize our products is large. The total number of procedures of arthroscopy and soft-tissue repair (including shoulders, hands, knees, ankles, and elbows) in 2003 was estimated at approximately 2.6 million compared to approximately 2.3 million procedures in 2002 according to <u>The Ortho FactBook</u> (2006), published by Knowledge Enterprises, Inc.

Rotator cuff injuries represent a leading cause of shoulder instability and result in approximately 300,000 invasive procedures annually, according to MedTech Insight, an industry marketing research firm.

<u>The Ortho FactBook</u> notes that there were approximately 375,000 total hip procedures performed per year in the U.S. and 450,000 total knee procedures. The total hip and knee markets in aggregate yield almost \$5 billion annually and represent only an estimated 32% of the total market for soft tissue, musculoskeletal repair.

Also, the NDGA-based biomaterials and related processes under license may prove suitable for use in general surgical procedures for reinforcement of soft tissue where weakness exists or scar tissue formation is not desirable.

Though not yet in development, other possible non-orthopedic products are related to the use of our technology as wound care patches indicated for repair of ulcers, second-degree burns and adhesions, as well as general soft-tissue patches and slings, including general surgical reconstruction.

The market revenues for biomaterials in wound care are expected to rise at an accelerated compound annual growth rate of 16.5% from 2006-2013. Combination products (biomaterial dressings that also possess moist dressing, antimicrobials, or alignates) are further driving growth and gaining market share from other advanced wound dressing segments, according to the Frost and Sullivan US Interactive Wound Care Markets Report for 2008.

The market for general soft-tissue patches and slings is not heavily populated because few products have fully satisfied clinical needs and physicians and patients are demanding implants that resorb over time. In 2005, the general soft-tissue repair market for the products listed above was valued at over \$600 million in the United States and over \$500 million in Europe, with an anticipated growth rate of 14% through 2010, according to a 2006 market research report by Millennium Research Group.

#### Tendon and Ligament Repair Technologies

Advancements in tendon and ligament surgery have focused largely on new methods of graft fixation using interference screws and anchors, which have opened new approaches to repair. We believe there is a new wave of development for ligament and tendon replacements, including collagen matrices, cell-seeded polymer scaffolds, allografts, and fibroblast-seeded tendons and ligaments, that we believe will change how physicians treat these procedures. Therapeutic modalities we will focus on first are related to the treatment and reconstruction of digital flexor, hand and wrist tendons, Achilles tendon and for rotator cuff repair. Following clinical development of the above, we plan to focus on treatments for larger tendons, ligaments and joints, such as medial and lateral collateral

ligaments, the anterior cruciate ligament (ACL) and the posterior cruciate ligament (PCL) of the knee, Achilles tendon repair, quad/patellar tendon, chronic ankle and elbow instability and meniscal repair. Our products could potentially be used in other orthopedic categories.

5

#### PVA-Based Biomaterials and Salubria®

Salubria® biomaterial is a unique PVA and water-based biomaterial that has been used in other medical device applications and is cleared by the FDA for use in the United States as a nerve cuff. We have licensed the right to use Salubria® or similar PVA-based biomaterials from SaluMedica, LLC, for certain applications within the body (see Collaborations and License Agreements and Recent Events). The material, as SaRuhrias been sold in Europe for certain applications for over six years. The PVA-based hydrogel can be processed to have mechanical and physical properties similar to that of human tissues. The biostable hydrogel composition contains water in similar proportions to human tissue, mimicking human tissue as strength and compliance. For certain applications, the PVA-based hydrogel has been formulated to be wear-resistant and strong. The base organic polymer is known to be biocompatible and hydrophilic. These properties make it a candidate for use as an implant, and may prove suitable for development into medical products addressing various applications. The PVA-based hydrogel and products formed thereof are MRI compatible (allowing for Magnetic Resonance Imaging of a patient with no artifacts or abnormal safety precautions necessary). We have licensed the PVA-based hydrogel for use in the spine, hand, and rotator cuff, and recently, for the surgical sheet. Development of applications for use in the spine and surgical sheet is currently underway with SpineMedica, LLC; whereas development of hand and rotator cuff applications has not yet been initiated.

# Spine Anatomy and Disorders

The spine is considered by many orthopedic and neurosurgeons to be the most complex motion segment of the human body. It provides a balance between structural support and flexibility. It consists of 26 separate bones called vertebrae that are connected together by connective tissue to permit a normal range of motion. The spinal cord, the body s central nerve conduit, is enclosed within the spinal column. Vertebrae are paired into what are called motion segments that move by means of three joints: two facet joints and one spinal disc.

The four major categories of spine disorders are degenerative conditions, deformities, trauma and tumors. The largest market and the focus of initial SpineMedica product development is degenerative conditions of the disc space and facet joints. These conditions can result in instability, pressure and impingement on the nerve roots as they exit the spinal column, causing often severe and debilitating pain in the back, arms and/or legs.

# **Current Treatments for Spine Disorders**

We believe current surgical treatments for chronic back pain caused by disc disease, which includes joint fusion, the current standard of care, have several limitations. We believe the most common drawbacks encountered with the present procedures include increased stress and degeneration in adjacent levels of the spine and continued pain and stiffness or instability as a result of the implanted device, resulting in a failure rate of between 20-25%. Due to the limited alternatives currently available, approximately 572,000 spinal fusion procedures were performed in 2006 (according to iData Research Inc., U.S. Markets for Spinal Implants & Biomaterials) even with such failure rates. It is estimated that if the percentage-level of success was increased to be between 90-95%, the annual level of surgical procedures would increase to between \$20 to \$25 billion, according to orthopedic industry analyst Robin Young, of *Orthopedics This Week*.

In Europe, there are several artificial disc devices being marketed in the \$4,000 to \$8,000 price range. Presently in the United States, the FDA has approved two total lumbar disc implants, the Charité Disc Arthroplasty System by DePuy Spine (a division of Johnson & Johnson) and the ProDisc<sup>TM</sup>-L Total Disc Replacement by Synthes Spine, Inc. The products list at \$11,500 to \$15,000. Two total cervical disc implants have been approved, the Prestige® Cervical Disc System and the ProDisc<sup>TM</sup> -C by Medtronic Sofamor Danek and Synthes Spine, respectively. They range in price from \$9,000 to \$11,000, depending on geographic reimbursement rates. These devices have certain advantages over existing fusion or rigid fixation devices; however, as first generation metal implants, they do have certain limitations which present an opportunity for us to pursue using the technology licensed from SaluMedica, LLC or owned or developed by SpineMedica.

Interbody fusion implants/devices are numerous, with current US market pricing in the range of \$3,500 to \$7,000 per unit for PLIF (Posterior Lumbar Interbody Fusion) implants. Two are usually implanted per intervertebral level.

The current prescribed treatment for spine disorders depends on the severity and duration of the disorder. Initially, physicians typically prescribe non-operative procedures including bed rest, medication, lifestyle modification, exercise, physical therapy, chiropractic care and steroid injections. Non-operative treatment options are often

effective; however, other patients require spine surgery. According to Knowledge Enterprises, Inc., the number of spine surgery procedures grew to over 1.2 million per year in 2005 in the United States. The most common spine surgery procedures are: discectomy, the removal of all or part of a damaged disc; laminectomy, the removal of all or part of a lamina, or thin layer of bone, to relieve pinching of the nerve and narrowing of the spinal canal; and fusion, where two or more adjoining vertebrae are fused together to provide stability.

6

The two arthroplasty products SpineMedica currently has under development would initially address both the cervical and lumbar geographies. The cervical disc replacement product, made from the PVA-based hydrogel, would allow for restoration of natural motion while additionally supplying shock absorption. This shock absorption feature may reduce the likelihood of adjacent level disease and subsequent surgery. Insertion of the device into the diseased disc space would use existing surgical techniques. Additionally, management expects revision of this device to have less risk than competitors—devices, due to the lack of metal endplates on the SpineMedica product.

#### Spine Repair Technologies

Medtech Insight, LLC s report on United States Markets for Spinal Motion Preservation Devices, states that an estimated 50 million people in the United States suffer from back pain. This report also states that in 2004, more than 1 million spine surgeries were performed in the United States far more than the number of hip and knee replacements combined. Factors driving growth of the spine surgery products market include the growing number of people with degenerative disc disease, which typically is caused by gradual disc damage and often results in disc herniation and chronic, debilitating lower back pain. It is most common among otherwise healthy people in their 30s and 40s and affects approximately half of the United States population age 40 and older.

A disc herniation, or abnormal bulge or rupture, is often caused by degenerative disc disease but may also result from trauma and/or injury. As we age, the disc s *nucleus pulposus*, or the center of a spinal disc, loses its water content and the disc begins to degenerate, becoming drier, less flexible, and prone to damage or tears. By the time a person reaches age 80, the nucleus pulposus water content decreases to approximately 74%; during the first year of a person s life, the water content is approximately 90%. The *annulus fibrosus*, or the outer rim of a spinal disc, also may be damaged by general wear and tear or by injury and can cause bulging and impingement on adjacent nerve roots. *Fusion* 

During the 1990s, treatment for degenerative disc disease and trauma focused on products such as interbody fusion devices and pedicle screws for immobilizing the spine. Although spinal fusion has worked relatively well in alleviating back pain in many patients, it has limitations. For example, according to estimates by members of our physician advisory board, while a significant number of lumbar fusion patients receive some clinical benefit, many never experience significant relief of pain or complete recovery of function over time. Furthermore, fusion is a procedure that requires not only complete removal of the disc and bony endplates, but more importantly, eliminates any future options for treatment. Fusion also restricts motion of the spine and places more strain on adjacent vertebrae causing them to deteriorate more rapidly in a phenomenon called adjacent level disc disease. For this reason, physicians are often reluctant to advise younger patients to undergo fusion.

Restoring Mobility The Possibilities

The following chart describes the three basic approaches to motion preservation. The Total Disc Replacement and Dynamic Stabilization approaches are addressed by the first two products SpineMedica has under development.

| Approach               | Description  | Goal   |
|------------------------|--|--|
| Total Disc Replacement | Removal of the majority of the disc<br>and replacement with a mechanical<br>or polymer artificial disc   | Maintain disc height and restore motion of spinal segment.             |
| Nucleus Replacement    | Replacement of the disc s <i>nucleus</i> pulposus, using a variety of metals and ceramics, injectable fluids, hydrogels, inflatables, and elastic coils. | Restore disc height and shock-absorbing functions (with some designs). |
| Dynamic Stabilization  | Posterior column support unloads<br>the disc and allows a range of<br>motion using a variety of implants   | Reduce loads on the disc and correct the spinal balance and alignment. |

# Edgar Filing: MIMEDX GROUP, INC. - Form 10-K or flexible materials.

7

Restoring mobility and preventing adjacent level deterioration are the primary reasons for the interest in motion preservation devices over fusion. One motion preserving technology that has arisen as a promising alternative to fusion is artificial discs, also known as total disc replacement devices. Currently available artificial discs are mechanical devices designed to completely replace a diseased or damaged intervertebral spinal disc in order to relieve pain and restore normal spinal motion. Total disc replacements are being developed for both the cervical and lumbar region. The procedures typically involve complete removal of the disc (both the annulus and nucleus pulposus) and bone endplates, followed by insertion of an artificial disc.

Many companies are conducting research on artificial disc technology and working to develop the next generation of products which these companies expect will incorporate nonmetal cores that more closely replicate disc kinematics by allowing various degrees of motion. Our cervical disc product is one such technology that is in development. Some of our competitor s products have begun clinical trials. To take advantage of the benefits of both metal and nonmetal materials and overcome the drawbacks involved in using either of them alone, researchers have combined both types of materials in their designs. Most commonly this has taken the form of a metal-polymer-metal sandwich design. The majority of these devices use polymers that offer insignificant shock absorption, such as polyethylenes and polyurethanes. Our PVA-based hydrogel design does offer shock absorption which could potentially result in a superior outcome for the patient.

The first artificial disc marketed in the United States, was the Charité® lumbar total disc replacement by DePuy Spine, a Johnson & Johnson division. It is considered a first-generation design loosely-based on ball-and-socket articulating bearings. Typically, this and other first-generation designs for artificial discs involve two metal endplates with a weight-bearing core, composed of polyethylene. The endplates vary in configuration (e.g., convex/concave) and method of fixation (e.g., coated/uncoated, keel versus no keel, spikes/ridges) to the surrounding bone. There have been three additional total disc replacements approved for use in the US by the FDA, the most recent one being a cervical disc replacement from Synthes Spine, approved in December of 2007. This device, the ProDisc<sup>TM</sup>-C, is a metal-polyethylene-metal design.

After consultation with members of SpineMedica s Physician Advisory Board, we believe that the market may move away from the first generation artificial discs and toward more biomimetic discs, relying on hydrogels and various polymers, to replace all or a portion of the disc. The objective of implanting replacement material is to maintain or restore the physiologic, or normal functional, height of the intervertebral disc space, as well as the mobility and the mechanical function of the spine.

### The SpineMedica Acquisition

On July 23, 2007, MiMedx completed its acquisition of SpineMedica Corp. pursuant to an Agreement and Plan of Merger, and acquired all of the issued and outstanding capital stock of SpineMedica Corp. through a forward triangular merger into our subsidiary, SpineMedica, LLC. Each share of SpineMedica Corp. stock then outstanding was converted into the right to receive the merger consideration, as described below.

The merger consideration for one share of SpineMedica Corp. common stock was one share of MiMedx common stock. The merger consideration for one share of SpineMedica Corp. Series A Convertible Preferred Stock was one share of MiMedx Series B Convertible Preferred Stock and a warrant for one share of MiMedx common stock with an exercise price of \$0.01 per share. The warrants issued to Series B holders have now terminated without vesting in accordance with their terms.

# Assumption of Outstanding SpineMedica Corp. Stock Options and Warrants

MiMedx assumed each stock option to purchase shares of SpineMedica Corp. s common stock (each a SpineMedica Stock Option ) that was outstanding immediately prior to the SpineMedica acquisition, whether or not then vested or exercisable (each, an Assumed Option ). Each Assumed Option was converted into an option to acquire that number of shares of MiMedx common stock equal to the number of shares of SpineMedica Corp. common stock subject to such SpineMedica Stock Option. The exercise price per share, as well as all other terms and conditions, was the same for each Assumed Option as in each corresponding SpineMedica Stock Option.

Further, MiMedx assumed each warrant to purchase, acquire or otherwise receive SpineMedica Corp. shares, exclusive of SpineMedica Stock Options (each a SpineMedica Warrant ) outstanding immediately prior to the merger, whether or not then vested or exercisable (each, an Assumed Warrant ). Each Assumed Warrant was converted into a

warrant to acquire that number of MiMedx shares equal to the number of SpineMedica Corp. shares subject to such SpineMedica Warrant. The purchase price per MiMedx share, as well as all other terms and conditions, was the same for each Assumed Warrant as in each corresponding SpineMedica Warrant.

8

The options and warrants assumed by MiMedx in connection with the SpineMedica acquisition were assumed by the Company pursuant to the Merger.

# **Purchase Accounting Treatment**

We accounted for the SpineMedica acquisition using the purchase method of accounting. Under the purchase method, we recorded, at fair value, the acquired assets and assumed liabilities of SpineMedica Corp. To the extent the total purchase price exceeded the fair value of tangible and identifiable intangible assets acquired over the liabilities assumed, we recorded goodwill, totaling approximately \$858,000, based on the aggregate closing price of approximately \$12,010,000.

# **Physician Advisory Boards**

We have empanelled 32 key physician opinion leaders in relevant fields by asking these physicians to serve on one of our Physician Advisory Boards (PABs). Each has entered into a consulting agreement with MiMedx or SpineMedica. We plan for our PABs to include physicians who move medicine forward by scientific endeavor, such as publishing, teaching and developing new solutions to treat injury and diseases. Several members are chairmen of their respective departments at university medical schools, teaching institutions and fellowship programs. Our MiMedx PABs have been assembled consisting of two committees for the initial intended uses: orthopedics sports medicine (the Sports Committee) and upper-extremity and plastic surgery indications (the Hand Committee).

The Chairman of our MiMedx PAB is James Andrews, M.D., of Birmingham, Alabama, and Gulf Breeze, Florida. Dr. Andrews is one of the best known and most respected sports-medicine physicians in the world. He is the physician for three NFL football teams and several baseball teams and treats many of the highest-paid professional athletes from numerous teams and from a multitude of sports and is regularly profiled in newspapers and magazines. Dr. Andrews also runs a sought-after fellowship program. Dr. Andrews entered into a three-year consulting agreement with MiMedx on April 10, 2007. Under this agreement, Dr. Andrews receives compensation of \$75,000 per year and received a stock option grant for the purchase of up to 100,000 shares of our Common Stock at \$1.00 per share, one-third of which vested upon grant and one-third of which will vest on each of the next two annual anniversaries of grant.

The Hand Committee is chaired by Thomas Graham, M.D., Chairman of the National Hand Center located in Baltimore, Maryland. Dr. Graham is the team physician for the Georgetown Hoyas, the Toronto Blue Jays, the Washington Nationals, and the Philadelphia Fliers. The National Hand Center is the largest practice specializing in hand surgery in the United States. Additionally, the Center has been designated by The United States Congress as the National Center for the Treatment of the Hand and Upper Extremity. Dr. Graham entered into a three-year consulting agreement with MiMedx on September 21, 2007, pursuant to which he also transferred certain intellectual property to us. Under his agreement, Dr. Graham receives compensation of \$125,000 per year, received a stock option grant to purchase up to 200,000 shares of our Common Stock at an exercise price of \$2.40 per share, one-third of which vested upon grant and one-third of which will vest on each of the next two annual anniversaries of grant, and received a right to certain royalty payments. Dr. Graham also received a stock option grant under a previous consulting agreement dated March 8, 2007, for the purchase of up to 50,000 shares of our Common Stock at an exercise price of \$1.00 per share, one-third of which vested upon grant and one-third of which will vest on each of the next two annual anniversaries of grant. His previous consulting agreement was terminated upon execution of the new consulting agreement on September 21, 2007, except that his stock option grant was not terminated.

The Sports Committee is chaired by Lonnie Paulos, M.D. who is Head Physician for the Houston Texans NFL Football Team and The University of Houston; Consultant Physician for the Cincinnati Bengals NFL Football Team; and Team Physician for the U.S. Olympic Ski Team, the U.S. Olympic Speed Skating Federation, and the U.S. Gymnastics Federation. His contributions to the field of sports medicine include the development of three surgical methods, six surgical devices, and three knee braces.

Under consulting agreements we have entered into with other MiMedx PAB members, we have agreed to compensate each of them with a stock option grant for the purchase of up to 30,000 shares of our Common Stock at \$1.00 per share, one-third of which vests upon grant and one-third of which will vest on each of the next two anniversaries of grant. All MiMedx PAB members are also compensated \$200 per conference call. Hand Committee members receive \$2,000 in per diem compensation, and Sports Committee members receive \$2,500 in per diem compensation. The

maximum amounts allowed to be paid to PAB members are regulated by the Health Insurance Portability and Accountability Act, which we believe we are in compliance with.

9

Similarly, SpineMedica has assembled a group of leading orthopedic spine and neurosurgeons who are advising on the development of our spinal implants, instruments and surgical procedures. Our SpineMedica PAB members were compensated with a grant of 25,000 shares of Common Stock, which vested fully upon grant. In addition, each SpineMedica PAB member is compensated \$250 per conference call; \$2,500 per diem for meetings involving out of town travel; and \$1,000 per diem for meetings not involving travel.

The Chairman of the Spine PAB is Randal Betz, M.D. Dr. Betz holds hospital positions as Chief of Staff at Shriners Hospitals for Children and Medical Director of Shriners Spinal Cord Injury Unit. Additionally, Dr. Betz is on staff at Temple University Children s Medical Center and is a Professor of Orthopaedic Surgery at Temple University School of Medicine. Dr. Betz entered into a three-year consulting agreement with SpineMedica, effective September 1, 2005. Under this agreement, Dr. Betz receives compensation of \$50,000 per year and received a stock option grant for the purchase of up to 100,000 shares of our Common Stock at an exercise price of \$1.80 per share, which option is now fully vested, and received 50,000 shares of founders Common Stock.

SpineMedica also entered into a one-year consulting agreement with another of its PAB members, Ronald L. DeWald, M.D., effective January 1, 2006, which automatically renews on a year-to-year basis after its expiration. Under this agreement, Dr. DeWald receives compensation of \$25,000 per year and received a stock option grant for the purchase of up to 50,000 shares of our Common Stock at an exercise price of \$1.80 per share, which option is now fully vested.

#### **Government Regulation**

Our products are medical devices subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, under the Federal Food, Drug, and Cosmetic Act. FDA regulations govern, among other things, the following activities that we will perform:

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.

Each medical device that we wish to commercially distribute in the U.S. will likely require either 510(k) clearance or PMA approval prior to marketing from the U.S. Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act. Devices deemed to pose relatively less risk are placed in either class I or II, which requires the manufacturer to submit a premarket notification requesting permission for commercial distribution; this is known as 510(k) clearance. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously 510(k) cleared device or a preamendment class III device for which PMA applications have not been called, are placed in Class III requiring PMA approval.

Some of our products contain biologic materials. We believe that FDA will regulate our products as medical devices. However, 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 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 one of our 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 four to 12 months, but it can take significantly longer for submissions that include clinical data.

10

#### **Table of Contents**

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, 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 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 the FDA denies 510(k) clearance for one of our products, the product 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 or 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 part of the PMA review, the FDA will typically inspect the manufacturer s facilities for compliance with Quality System Regulation, or QSR, requirements, which impose elaborate testing, control, documentation and other quality assurance procedures. 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 last 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. 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 postapproval 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

#### Clinical Trials

A clinical trial is generally required to support a PMA 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 nonsignificant 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 IRB, at the clinical trial sites, and must comply with FDA regulations. To 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.

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.

11

#### Postmarket

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 is 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 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, postmarket surveillance, patient registries, and FDA guidelines that do not apply to class I devices.

We are 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 public 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.

#### International

International sales of medical devices 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 by us of certain of our 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 conformity marking, indicating that the device conforms with the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout Europe. 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. An assessment by a Notified Body in one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union.

# Export of Uncleared or Unapproved Devices

Export of devices eligible for the 510(k) clearance process, but not yet cleared to market, are 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 QS Regs., 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.

12

#### Regulatory Status of our Products

We have had no correspondence with the FDA regarding the regulatory pathway for any of our products (i.e. pre-510(k) or pre-IDE meetings). Both MiMedx and SpineMedica have products under development that may qualify for 510(k), such as NDGA-polymerized collagen implants and the vessel guard device made from PVA-based hydrogel, as well as other products that we believe require PMA clinical trials, such as the artificial cervical disc.

# Reimbursement Procedures, Profitability and Costs

Private and third-party payors often follow Medicare reimbursement policies, and these policies often follow FDA approval by one to two years, or more.

Arthroscopy and soft tissue repair are often profitable procedures for hospitals and surgery centers. This profit translates to incentive for medical professionals, hospitals and clinics to continue to leverage the return by prescribing arthroscopic procedures for the repair of soft tissue treatments over open procedures. Open surgical procedures often result in multi-night stays and consistently lower reimbursement rates.

According to <u>The Ortho FactBook</u>, many orthopedic procedures are currently not profitable for hospitals and surgery centers, such as the Total Hip Replacement, which cost hospitals on average \$3,214 per procedure. This means hospitals and surgery centers are reimbursed \$3,214 less than the cost associated with a total hip replacement.

We intend to retain a proven industry reimbursement consultant to aid in the reimbursement planning for our products. However, at this time there can be no assurance that reimbursement policies will provide an acceptable return on our products.

# Competition

#### MiMedx Products

There are several technologies currently on the market or anticipated to enter the market for ligament and tendon repair and/or replacements. Those technologies include collagen matrices, cell-seeded polymer scaffolds, cryopreserved allografts, fibroblast-seeded ligament analogs, and small intestinal submucosa.

Those technologies generally utilize one of two cross-linking agents, which are FDA-approved and used in the manufacturing of collagen for soft-tissue repair: gluteraldahyde or carbodiimide. These agents may prove superior to our NDGA-polymerized collagen. The current market leader is the Restore Orthobiologic Soft Tissue Implant from DePuy. It utilizes small intestinal submucosa of porcine origin.

Some other competitors include:

Developer Product Status

DePuy RESTORE Clinic

Advanced Tissue SciencesTendon/Lig RepairPilot (human, ACL)OrganogenesisFortaflexEuropean Clinical (ACL)ReGen BiologicsCollagen matricesPreclinical (animal)Biomet/OrganogenesisCuffPatchClinical (Rotator Cuff)

There are a few synthetic products, such as W.L. Gore s GoreTex, 3M Kennedy Ligament Augmentation Device (LAD), and Stryker s Meadox Dacron Ligament Augmentation Graft which were developed for use in Anterior Cruciate Ligament (ACL) reconstruction. These were first and second generation soft-tissue repair products and generally produce results that are less satisfactory than those containing soft-tissue constructs, because the materials tend to stretch and become deformed over time.

For general soft-tissue indication, competitors include:

| Developer         | Product                                  | Status                    |
|-------------------|--|---------------------------|
| DePuy             | BioBlanket Soft-Tiss                     | Received 510(k) Oct. 2006 |
| CryoLife          | ProPatch Soft-Tiss                       | Received 510(k) Dec. 2006 |
| Wright Medical    | Graft Jacket® Regenerative Tissue Matrix | Received 510(k)           |
| Pegasus Biologics | OrthADAPT Bioimplant                     | Received 510(k)           |
| Stryker           | Tissue Mend                              | Received 510(k)           |
|                   |  |                           |

#### SpineMedica Products

Currently, competition in cervical spine arthroplasty is limited to only a few total disc implants on the market in Europe and only two in the United States, the Prestige® and the ProDisc-C Disc Systems manufactured and distributed by Medtronic Sofamor Danek and Synthes Spine. However, there are many companies focused on the research and development of various versions of cervical total artificial discs.

The posterior lumbar interbody market is a market that many spine companies are addressing with fusion devices. SpineMedica s flexible interbody fusion device mated with a dynamic posterior stabilization system is designed to be a next generation device that resolves issues arising from using rigid interbody or posterior stabilization systems alone. We believe that the principal competitive factors in the spinal disc market include:

improved outcomes for spine pathology procedures;

acceptance by spine surgeons;

ease of use and reliability;

product price and qualification for reimbursement;

technical leadership and superiority;

effective marketing and distribution; and

speed to market.

SpineMedica s cervical disc and interbody products, when and if available for sale, and any future products we commercialize will be subject to intense competition. Many of our competitors and potential competitors have substantially greater financial, technical and marketing resources than we do, and they may succeed in developing products that would render our products obsolete or noncompetitive. In addition, many of these competitors have significantly greater operating histories and reputations than we do. Our ability to compete successfully will depend on our ability to develop proprietary products that reach the market in a timely manner, receive adequate reimbursement and are safer, less invasive and less expensive than alternatives available for the same purpose. Because of the size of the potential market, we anticipate that companies will dedicate significant resources to developing competing products.

Below are the primary competitors whose products we believe will compete with SpineMedica s initial products:

| Technology                       | Representative Product                | Company                                  |
|----------------------------------|---------------------------------------|--|
| Total Disc Replacement, cervical | Prestige®<br>ProDisc-C                | Medtronic Sofamor Danek<br>Synthes Spine |
| Posterior Lumbar Interbody       | PLIF Spacers<br>Puros® Symmetry® PLIF | Synthes<br>Zimmer                        |

Allograft System

Trabecular Metal PLIF Device Zimmer HRC Locking Cage Interbody Zimmer

**Fusion System** 

VG2® PLIF Allograft
SpaceVision PLIF Cage
Coreograft PLIF Allograft
SpaceVision
Alphatec Spine

AlloCraft PL Stryker

Vessel Guard Preclude Vessel Guard W.L.Gore

14

#### **Table of Contents**

Alternatively, orthopedic spine and neurosurgeons actively seek patient treatment alternatives and utilize various technologies during different stages of the patient care continuum. Until the recent success of non-fusion technologies, spine implant market manufacturers have focused almost exclusively on refining and improving spinal fusion techniques. Multiple fusion techniques and products are available to patients today.

#### **Collaborations and License Agreements**

# License Agreement between MiMedx, Shriners Hospitals for Children, and University of South Florida Research Foundation

We entered into a license agreement with Shriners Hospitals for Children and University of South Florida Research Foundation (collectively Licensor) in January 2007 for the worldwide, exclusive rights for all applications using NDGA-polymerized materials, including for reconstruction of soft tissue. We paid a one-time license fee of \$100,000, plus 560,000 shares of our Common Stock, and the Licensor will receive future additional milestone payments and continuing royalties based on sales of all licensed products.

# License Agreement between SpineMedica and SaluMedica, LLC

In August, 2005, SaluMedica, LLC granted SpineMedica Corp. an exclusive, perpetual, worldwide, non-terminable, royalty-free, transferable license under certain patents and patent application rights held by SaluMedica, LLC that relate to a PVA-based hydrogel. As a result of the merger, SpineMedica, LLC acquired the license. SpineMedica has the right to manufacture, market, use and sell medical devices and products incorporating the claimed technology for all neurological and orthopedic uses related to the human spine, including muscular and skeletal uses. Some of the licensed patents and patent application rights are owned by SaluMedica, LLC and at least one of these patent and patent application rights are licensed by SaluMedica, LLC from Georgia Tech Research Corporation. In connection with this license agreement, SpineMedica also acquired certain of SaluMedica, LLC s assets, including manufacturing and testing equipment and office equipment and obtained a license to use the trademarks SaluMedica and Salubria biomaterial.

#### License Agreement between SaluMedica, LLC and Georgia Tech Research Corporation

Some of the patents and patent application rights licensed to SpineMedica by SaluMedica, LLC are licensed to SaluMedica, LLC from Georgia Tech Research Corporation. SaluMedica, LLC and Georgia Tech Research Corporation have agreed that in the event the license agreement between them is terminated for any reason (other than the expiration of the patents), Georgia Tech Research Corporation will license the technology to SpineMedica for uses related to the human spine on substantially the same terms as granted to SaluMedica, LLC without further payment.

### Hand License with SaluMedica, LLC

MiMedx has a Technology License Agreement, as amended by a First Amendment to Technology License Agreement, as well as a related Trademark License Agreement, all dated August 3, 2007 (collectively, the Hand License ) that provides MiMedx with the exclusive, fully-paid, worldwide, royalty-free, irrevocable and non-terminable (except as provided in the Hand License), and sublicensable rights to develop, use, manufacture, market, and sell Salubria® biomaterial or similar PVA-based hydrogels for all neurological and orthopedic uses (including muscular and skeletal uses) related to the rotator cuff and the hand (excluding the wrist), but excluding the product Salubridge (which is made from Salubria® biomaterial and is currently approved for use by the U.S. Federal Drug Administration) (the Licensed Hand IP ). SaluMedica, LLC s rights in the Licensed Hand IP derive from and are subject to one or more licenses from Georgia Tech Research Corporation and, consequently, the Hand License is subject to those same licenses.

15

#### Surgical Sheet License with SaluMedica, LLC

MiMedx also has a Technology License Agreement and Trademark License Agreement dated March 31, 2008, as discussed above under Recent Events.

# **Intellectual Property**

# MiMedx Intellectual Property

Our licensed intellectual property includes patents associated with licensed technology related to NDGA coatings, devices, scaffolds, substrates, or other materials and polymer treated collagen material for medical devices, implants, prosthesis and constructs and methods for making medical devices.

Issued patents we have licensed include:

| Patent Number | Title                                | Filing Date  | <b>Issue Date</b>    | <b>Expiration Date</b> |
|---------------|--------------------------------------|--------------|----------------------|------------------------|
| 6,565,960     | Polymer<br>Composite<br>Compositions | June 1, 2001 | May 20, 2003         | June 1, 2021           |
| 6,821,530     | Polymer<br>Composite<br>Compositions | May 19, 2003 | November 23,<br>2004 | June 1, 2021           |

Pending patent applications we have licensed include:

| Patent | App | lication |
|--------|-----|----------|
| Patent | App | lication |

| Serial Number   | Title  | Filing Date       |
|---|--|-------------------|
| U.S. 11/685,528 and corresponding PCT application (PCT/US2007/063882) | Self-Assembling, Collagen Based Material for<br>Corneal Replacement  | March 13, 2007    |
| U.S. 11/821,320 and corresponding PCT application (PCT/US2007/014560) | Collagen Scaffolds, Medical Implants With Same and Methods of Use  | June 22, 2007     |
| U.S. 11/964,745 and corresponding PCT application (PCT/US2007/026381) | Woven and/or Braided Fiber Implants and<br>Methods of Making Same  | December 27, 2007 |
| U.S. 11/964,756 and corresponding PCT application (PCT/US2007/026361) | Methods of Making High-Strength NDGA Polymerized Collagen Fibers and Related Collagen-Prep Methods, Medical Devices and Constructs | December 27, 2007 |
| U.S. 11/964,830 and corresponding PCT application (PCT/US2007/026365) | Bioprosthesis for Replacement or<br>Augmentation of Tendons and Ligaments  | December 27, 2007 |
| U.S. 12/034,004 and corresponding PCT application (PCT/US2008/002230) | In Vivo Hydraulic Fixation Including<br>BioRivets Using Biocompatible Expandable<br>Fibers   | February 20, 2008 |

U.S. Provisional 61/030,768 Biostaples Suitable for Wrist Hand and Other February 22, 2008

Ligament Replacements or Repairs

U.S. Provisional 61/053,901 Medical Constructs of Twisted Lengths of May 19, 2008

Biocompatible Fibers and Methods of Making

Same

16

# SpineMedica Intellectual Property

Patent applications that are owned by SpineMedica include:

| Patent Application<br>Serial Number  |             | Title   |                   | Filing Date        |
|--|-------------|---|-------------------|--------------------|
| U.S. 10/658,932 and correspondence of the co | nding       | Flexible Spinal Disc  |                   | September 9, 2003  |
| U.S. 11/688,931  |             | Flexible Spinal Disc  |                   | March 21, 2007     |
| U.S. 11/626,399  |             | Prosthetic Wide Range Motion Methods of Fabricating                                 | on Facets and     | January 24, 2007   |
| U.S. 11/626,401 and correspondent of the PCT application (PCT/US2007/001933)   | nding       | Spinal Disc Implants with Flo<br>Methods of Fabricating Impla                       |                   | January 24, 2007   |
| U.S. 11/625,845  |             | Implantable Spinous Process<br>Devices, Including Cuffs, and<br>Fabricating Same    |                   | January 23, 2007   |
| U.S. 11/671,507  |             | Spinal Implants with Coopera<br>Anchors   | ating Suture      | February 6, 2007   |
| U.S. 11/753,755 and corresponder application (PCT/US2007/012517)   | nding       | Patient-Specific Spinal Impla<br>Systems and Methods                                | ints and Related  | May 25, 2007       |
| U.S. 11/768,933 and corresponded PCT application (PCT/US2007/014907)   | nding       | Spinal Implants with Coopera<br>Sutures   | ating Anchoring   | June 27, 2007      |
| U.S. 12/016,223 and correspondent application (PCT/US2008/000674)  | nding       | Methods and Systems for For<br>with Selectively Exposed Mes<br>and Related Implants |                   | January 18, 2008   |
| U.S. 12/101,390  |             | Surgical Instruments for Spin<br>and Related Methods                                | nal Disc Implants | April 11, 2008     |
| *U.S. Provisional 60/968,709<br>(Co-owned with SaluMedica,<br>LLC)   |             | Orthopaedic Cement Mixture<br>Weight Percent Polyvinyl Ald<br>(PVA) Solution        |                   | August 29, 2007    |
| U.S. Provisional 61/050,105<br>Issued patents SpineMedica h  | as licensec | Spinal Total Disc Replaceme<br>l include:   | nt (TDR) Implants | May 2, 2008        |
| Patent Number  | Title       | Filing Date   | <b>Issue Date</b> | Date of Expiration |

Edgar Filing: MIMEDX GROUP, INC. - Form 10-K

| 5,981,826 and corresponding foreign patents | Poly(vinyl alcohol)<br>cryogel  | September 17, 1997 | November 9, 1999 | U.S. Patent expires<br>on 09/17/2017 |
|---|---------------------------------|--------------------|------------------|--------------------------------------|
| 6,231,605                                   | Poly(vinyl alcohol)<br>hydrogel | March 17, 1999     | May 15, 2001     | 09/17/2017                           |
|   |                                 | 17                 |                  |                                      |

Pending patent applications that SpineMedica has licensed include:

| Patent Application<br>Serial Number | Title   | Filing Date      |
|-------------------------------------|---|------------------|
| U.S. 10/199,554                     | Poly(vinyl alcohol) hydrogel  | July 19, 2002    |
| U.S. 10/752,246                     | Poly(vinyl alcohol) hydrogel  | January 5, 2004  |
| U.S. 10/966,859                     | Poly(vinyl alcohol) hydrogel  | October 14, 2004 |
| U.S. 10/966,866                     | Poly(vinyl alcohol) hydrogel  | October 24, 2004 |
| U.S. 11/626,405                     | Methods Of Producing PVA Hydrogel Implants and Related Devices        | January 24, 2007 |
| U.S. 11/837,027                     | Methods of Making Medical Implants of Poly(Vinyl Alcohol)<br>Hydrogel | August 10, 2007  |

#### Patent Application Rights

The Flexible Spinal Disc application is directed to a flexible implantable device with a shape generally similar to that of a spinal intervertebral disc that is useful for replacement or treatment of a diseased or damaged intervertebral spinal disc. The patent application describes spinal disc implants with a volume to occupy space between vertebral bodies, has mechanical elasticity to provide motion between vertebral bodies, and sufficient strength to withstand the forces and loads on the vertebra. The device may be constructed to expand to restore the normal height of the intervertebral space. This application may not issue into a patent.

# Improvements to Licensed Technology

Any improvements to Salubria® biomaterial developed by SaluMedica, LLC during the life of the licensed patents are included as part of the license from SaluMedica, LLC. SpineMedica will own all improvements to the PVA-based hydrogel that we develop. However, SpineMedica will license these improvements to SaluMedica, LLC for no additional consideration, provided that the use of these improvements must be unrelated to all neurological and orthopedic uses related to the human spine or rotator cuff/hand, including muscular and skeletal uses, or to the surgical sheet.

# **Manufacturing**

In August, 2007, MiMedx moved into an operations and a pilot manufacturing facility, which includes a lab, in Tampa, Florida. As well, we plan to contract some of the manufacturing of the products that are developed and enter into strategic relationships for sales and marketing of products that we develop; however, we currently maintain our own manufacturing equipment and have the ability to manufacture our products in limited quantities.

SpineMedica also recently built-out and moved into an operations and a pilot manufacturing facility, including lab space, in Marietta, Georgia. SpineMedica engages in the manufacture of its own spinal disc implants and products, including the PVA-based hydrogel component.

We and our third-party manufacturers are subject to the FDA s quality system regulations, state regulations, and regulations promulgated by the European Union. For our implants and instruments, we plan to be FDA registered, CE marked and ISO certified. CE is an abbreviation for European Compliance. Our facility and the facilities of our third-party manufacturers are subject to periodic unannounced inspections by regulatory authorities, and may undergo compliance inspections conducted by the FDA and corresponding state 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. SpineMedica engages in the manufacture of its own spinal disc implants and products, including the PVA-based hydrogel component. Our current supply of critical raw materials for

the PVA-based biomaterial products is sufficient for at least one year of operation.

18

### **Marketing and Sales**

We plan to utilize our experienced management team to commercialize these medical technologies by advancing them through the proper regulatory approval processes, arranging for reliable and cost-effective manufacturing, and to ultimately either sell the product lines to others or market the products in Europe, the United States, and Asia.

### **Employees**

We currently have 39 employees, of whom 36 are full-time and 3 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

We are not involved in any litigation, nor are we aware of any threatened litigation.

### **Research and Development**

Our research and development efforts are initially focused on developing products for the hand, wrist, thumb, ankle and shoulder using NDGA biomaterials, a PVA-based hydrogel in the surgical repair of the hand and continuing development of the three spinal products. Our research and development staff currently consists of 19 employees. To support development, we have contracts with outside labs who aid us in our research and development process. Our research and development group has extensive experience in developing products related to our field of interest, and works with our Physician Advisory Boards 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. From our inception in November 2006 to March 31, 2008, we have spent approximately \$2,127,000 on research and development and \$7,177,000 on acquired in process research and development.

### **Surgeon Training and Education**

We devote significant resources to working with our Physician Advisory Boards. We believe that the most effective way to introduce and build market demand for our products will be by partnering with leading surgeons from around the globe in the use of our products. We have access to state-of-the-art cadaver operating theaters and other training facilities at some of the nation s leading medical institutions. We intend to continue to focus on working with leading surgeons in the United States. See Business-Physician Advisory Board.

### **Environmental Compliance**

We will incur significant costs in complying with good manufacturing practices and safe handling and disposal of materials used in our research and manufacturing activities. We do not anticipate the costs to comply with Federal, state and local environmental laws and regulations will be material.

19

### Item 1A. Risk Factors Risks Related to Our Business and Industry We are a high-risk startup venture.

We are in the development stage. We do not currently have any material assets, other than cash, certain laboratory equipment, and certain intellectual property rights. We have 39 employees, of whom 36 are full-time and 3 are part-time employees. We must be evaluated in light of the expenses, delays, uncertainties and complications typically encountered by development stage businesses, 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 must overcome these and other business risks to be successful. Our efforts may not be successful. We may never be profitable. Therefore, investors could lose their entire investment.

### We are in the early stage of product development.

The possible products we have the right to license have had only limited research in the fields of use we presently intend to commercialize. We will have to go through extensive research and testing to determine the safety and effectiveness of their proposed use. Our product candidates will require testing and regulatory clearances. Accordingly, the products we are developing are not yet ready for sale and may never be ready for sale. The successful development of any products is subject to the risks of failure inherent in the development of products based on innovative technologies. These risks include the possibilities that any or all of these proposed products or procedures are found to be ineffective or toxic, or otherwise fail to receive necessary regulatory clearances; that the proposed products or procedures are uneconomical to market or do not achieve broad market acceptance; that third parties hold proprietary rights that preclude us from marketing them; or third parties market a superior or equivalent product. We are unable to predict whether our research and development activities will result in any commercially viable products or procedures. Furthermore, due to the extended testing and regulatory review process required before marketing clearances can be obtained, the time frames for commercialization of any products or procedures are long and uncertain.

### We will need additional financing to meet our future capital requirements.

We will require significant additional funds, either through additional equity or debt financings or collaborative agreements or from other sources to engage in research and development activities with respect to our potential product candidates and to establish the personnel necessary to successfully manage us. We believe that our current cash and cash equivalents will be sufficient to meet our projected operating requirements for at least the next three to six months. However, obtaining the required regulatory approvals and clearances and the planned expansion of our business will be expensive and we will in the future seek funds from public and private stock or debt offerings, borrowings under lines of credit or other sources. Our capital requirements will depend on many factors, including:

the revenues generated by sales of our products, if any;

the costs associated with expanding our sales and marketing efforts, including efforts to hire independent agents and sales representatives;

the expenses we incur in developing and commercializing our products, including the cost of obtaining and maintaining FDA or other regulatory approvals; and unanticipated general and administrative expenses.

As a result of these factors, we may seek to raise additional funds and such funds may not be available on favorable terms, or at all. Furthermore, if we issue equity or debt securities to raise additional funds, our existing shareholders may experience dilution and the new equity or debt securities we issue may have rights, preferences and privileges senior to those of our existing shareholders. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our products or proprietary technologies, or grant licenses on terms that are not favorable to us. If we cannot raise funds on acceptable terms, we may not be able to develop or enhance our products, obtain the required regulatory clearances or approvals, execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated customer requirements. Any of these events could adversely affect our ability to achieve our development and

commercialization goals, which could have a material and adverse effect on our business, results of operations and financial condition.

20

We expect to continue to incur losses.

We have a limited operating history, and we have not generated any revenues from our products. Further, we have incurred losses since inception. We expect to incur losses for the foreseeable future. The principal causes of our losses are likely to be primarily attributable to personnel costs, working capital costs, research and development costs, brand development costs and marketing and promotion costs. We may never achieve profitability.

We are in a highly competitive industry and face competition from large, well-established medical device manufacturers as well as new market entrants.

Competition from other medical device companies and from research and academic institutions is intense, expected to increase, subject to rapid change, and significantly affected by new product introductions and other market activities of industry participants. In addition to competing with universities and other research institutions in the development of products, technologies and processes, we compete with other companies in acquiring rights to products or technologies from those institutions. There can be no assurance that we can develop products that are more effective or achieve greater market acceptance than competitive products, or that our competitors will not succeed in developing or acquiring products and technologies that are more effective than those being developed by us, that would render our products and technologies less competitive or obsolete.

With respect to the market for total disc implants, we expect to compete with Synthes Spine and Medtronic Sofamor Danek, which have significantly greater resources and longer operating histories than us.

Our competitors enjoy several competitive advantages over us, including some or all of the following:

products which have been approved by regulatory authorities for use in the United States and/or Europe and which are supported by long-term clinical data;

significantly greater name recognition;

established relations with surgeons, hospitals, other healthcare providers and third party payors;

large and established 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;

more expansive portfolios of intellectual property rights; and

greater financial, managerial and other resources for products research and development, sales and marketing efforts and protecting and enforcing intellectual property rights.

Our competitors products compete directly with our products if and when ours can be marketed. In addition, our competitors as well as new market entrants may develop or acquire new treatments, products or procedures that will compete directly or indirectly with our products. 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 failure to compete effectively in the market for spine surgery products would have a material and adverse effect on our business, results of operations and financial condition.

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. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. For example, our pending United States and foreign patent applications may not issue as patents in a form that will be advantageous to us or may issue and be subsequently successfully challenged by others and invalidated. In addition, our pending patent applications include

claims to material aspects of our products and procedures that are not currently protected by issued patents. Both the patent application process and the process of managing patent disputes can be time consuming and expensive. Competitors may be able to design around our patents or develop products which provide outcomes which are comparable or even superior to ours. Although we have taken steps to protect our intellectual property and proprietary technology, including entering into confidentiality agreements and intellectual property assignment agreements with some of our officers, employees, consultants and advisors, such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements. Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States.

21

### **Table of Contents**

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 our intellectual property rights or to defend our patents against challenge could be expensive and time consuming and could divert our management s attention. We may not have sufficient resources to enforce our intellectual property rights or to defend our patents rights against a challenge. The failure to obtain patents and/or protect our intellectual property rights could have a material and adverse effect on our business, results of operations, and financial condition. We may become subject to claims of infringement or misappropriation 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, in the future, assert infringement or misappropriation claims against us with respect to products we develop. Whether a product infringes a patent or misappropriates 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. Our potential competitors may assert that some aspect of our product infringes their patents. 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 infringe. There also may be existing patents or pending patent applications of which we are unaware that our products may inadvertently infringe.

Any infringement or misappropriation 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 are able to design around the patent. 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.

# Our patents and licenses may be subject to challenge on validity grounds, and our patent applications may be rejected.

We rely on our patents, patent applications, licenses and other intellectual property rights to give us a competitive advantage. Whether a patent is valid, or whether a patent application should be granted, is a complex matter of science and law, and therefore we cannot be certain that, if challenged, our patents, patent applications and/or other intellectual property rights would be upheld. If one or more of those patents, patent applications, licenses and other intellectual property rights are invalidated, rejected or found unenforceable, that could reduce or eliminate any competitive advantage we might otherwise have had.

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 the products we are developing, 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. Without access to these technologies or suitable design-around or alternative technology options, our ability to conduct our business could be impaired significantly.

### Our NDGA License Agreement 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.

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.

SaluMedica, LLC may license the PVA-based hydrogel, the material used to make SpineMedica's products and other products we are developing, and its trademark to third parties for use in applications unrelated to the spine, hand, rotator cuff, or surgical sheet applications. This may expose us to adverse publicity if these uses are not proven safe and effective.

Our licenses with SaluMedica, LLC allows us to use technology and/or know-how related to the material used to manufacture our applications related to the spine and other products we are developing in applications related to the hand and rotator cuff and surgical sheet, and allows us to use the Salubria<sup>®</sup> biomaterial trademark. SaluMedica, LLC may license the PVA-based hydrogel and rights related to the Salubria<sup>®</sup> biomaterial trademark to third parties for applications not related to the spine, hand, rotator cuff, or surgical sheet. If the use of Salubria<sup>®</sup> biomaterial or the PVA-based hydrogel by these third parties results in product liability claims or has other adverse effects in patients, surgeons and patients may associate these claims and effects with our products, even if our products are nevertheless proven safe and effective. If Salubria<sup>®</sup> biomaterial experiences adverse publicity or is not proven safe and effective in other applications, sales of our products could be harmed.

### We depend on key personnel.

We depend greatly on Steve Gorlin, Thomas D Alonzo, R. Lewis Bennett, Matthew J. Miller, Brian Splan, Thomas Koob, Ph.D., and Rebeccah Brown, Ph.D. We currently have 39 full-time and 3 part-time employees. Our success will depend, in part, upon our ability to attract and retain additional skilled personnel, which will require substantial additional funds. There can be no assurance that we will be able to find and attract additional qualified employees or retain any such personnel. Our inability to hire qualified personnel, the loss of services of our key personnel, or the loss of services of executive officers or key employees that that may be hired in the future may have a material and adverse effect on our business.

In addition, some of our executives and other employees only work for us on a part-time basis, and there is no assurance that they will be able to devote sufficient time to our operations to ensure optimal success. We currently have two or three-year employment agreements with our key employees, with the exception of R. Lewis Bennett and Rebeccah Brown, Ph.D., but there is no guarantee such agreements will not be terminated at an earlier date.

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;

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;

technical difficulties;

#### **Table of Contents**

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 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. Assuming our products reach the market, we may be unable to adjust spending in a timely manner to compensate for any unexpected revenue shortfall. Accordingly, any significant shortfall in revenues 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 revenues and operating results are and will remain difficult to forecast.

# The failure of government health administrators and private health insurers to reimburse patients for costs of services incorporating our potential products would materially and adversely affect our business.

Our success depends, in part, on the extent to which reimbursement for the costs of products to users will be available from government health administration authorities, private health insurers and other organizations. Significant uncertainty usually exists as to the reimbursement status of newly approved healthcare products. Adequate third party insurance coverage may be unavailable for us, our sublicensees or corporate partners to establish and maintain price levels sufficient for realization of an appropriate return on investment. Government and other third-party payers attempt to contain healthcare costs by limiting both coverage and the level of reimbursement of new products. Therefore, we cannot be certain that our products or the procedures performed with them will be covered or adequately reimbursed and thus we may be unable to sell our products profitably if third-party payors deny coverage or reduce their levels of payment below that which we project, or if our production costs increase at a greater rate than payment levels. If government and other third party payers do not provide adequate coverage and reimbursement for uses of the products incorporating our technology, the market s acceptance of our products could be adversely affected. We currently do not have, and may never develop, any commercialized products.

# We currently do not have any commercialized products or any significant source of revenue. We have invested substantially all of our time and resources in developing various products. Commercialization of these products, including NDGA and PVA-based hydrogel products, will require additional development, clinical evaluation, regulatory approval, significant marketing efforts and substantial additional investment before they can provide us with any revenue. Despite our efforts, our products may not become commercially successful products for a number of reasons, including:

we may not be able to obtain regulatory approvals for our products, or the approved indication may be narrower than we seek:

our products may not prove to be safe and effective in clinical trials;

physicians may not receive any reimbursement from third party payors, or the level of reimbursement may be insufficient to support widespread adoption of our products;

we may experience delays in our development program;

any products that are approved may not be accepted in the marketplace by physicians or patients;

we may not be able to manufacture any of our products in commercial quantities or at an acceptable cost; and

rapid technological change may make our products obsolete.

# We face the risk of product liability claims or recalls 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 testing, manufacturing and marketing of medical devices, including those which may arise from the misuse or malfunction of, or design flaws in, our 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 product in the market.

24

### **Table of Contents**

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.

# If we are unable to establish sales, marketing and distribution capabilities or enter into and maintain arrangements with third parties to sell, market and distribute our products, our business may be harmed.

We do not have a sales organization, and have no experience as a company in the marketing and distribution of medical devices. To achieve commercial success for our products, we must either sell rights to our product lines at favorable prices, develop a sales and marketing force, or enter into arrangements with others to market and sell our products. In addition to being expensive, developing such a sales force is time consuming, and could delay or limit the success of any product launch. We may not be able to develop this capacity on a timely basis or at all. Qualified direct sales personnel with experience in the medical device market are in high demand, and there is no assurance that we will be able to hire or retain an effective direct sales team. Similarly, qualified independent medical device representatives both within and outside the United States are in high demand, and we may not be able to build an effective network for the distribution of our product through such representatives. We have no assurance that we will be able to enter into contracts with representatives on terms acceptable to us. Furthermore, there is no assurance that we will be able to build an alternate distribution framework should we attempt to do so.

We may also need to contract with third parties in order to market our products. To the extent that we enter into arrangements with third parties to perform marketing and distribution services, our product revenue could be lower and our costs higher than if we directly marketed our products. Furthermore, to the extent that we enter into co-promotion or other marketing and sales arrangements with other companies, any revenue received will depend on the skills and efforts of others, and we do not know whether these efforts will be successful. If we are unable to establish and maintain adequate sales, marketing and distribution capabilities, independently or with others, we will not be able to generate product revenue, and may not become profitable.

# To be commercially successful, we must convince surgeons that our products are safe and effective alternatives to existing surgical treatments and that our products should be used in the procedures.

We believe surgeons may not widely adopt our products unless 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. Surgeons 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 payors; and

the time that must be dedicated to training.

In addition, we believe recommendations for and support of our products by influential surgeons 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, surgeons and hospitals may not use our products which would significantly reduce our ability to achieve expected revenues and would prevent us from becoming profitable.

### Any failure in our efforts to train surgeons could significantly reduce the market acceptance of our products.

There will be a learning process involved for surgeons to become proficient in the use of our products. It will be critical to the success of our commercialization efforts to train a sufficient number of surgeons and to provide them with adequate instruction in the use of our products. This training process may take longer than expected and may therefore affect our ability to generate sales. Convincing surgeons to dedicate the time and energy necessary for adequate training is challenging and we may not be successful in these efforts. If surgeons are not properly trained, they may misuse or ineffectively use our products. This may result in unsatisfactory patient outcomes, patient injury, negative publicity, or lawsuits against us, any of which could have an adverse effect on our business.

### **Table of Contents**

The FDA and other regulatory agencies actively enforce regulations prohibiting promotion of products for unapproved or off-label uses. Our promotional materials and training methods regarding surgeons must comply with FDA and other applicable laws and regulations regarding promotion for unapproved or off-label uses. If the FDA determines that our training constitutes promotion for unapproved or off-label uses, they could request that we modify our training or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalty.

We depend on a single or a limited number of third-party suppliers, and the loss of these third-party suppliers or their inability to supply us with adequate raw materials could adversely affect our business.

We rely on a limited number of third-party suppliers for the raw materials required for the production of our implant products. Furthermore, in some cases we rely on a single supplier. Our dependence on a limited number of third-party suppliers or on a single supplier, and the challenges we may face in obtaining adequate supplies of raw materials, involve several risks, including limited control over pricing, availability, quality, and delivery schedules. We cannot be certain that our current suppliers will continue to provide us with the quantities of these raw materials that we require or satisfy our anticipated specifications and quality requirements. Any supply interruption in limited or sole sourced raw materials could materially harm our ability to manufacture our products until a new source of supply, if any, could be identified and qualified. Although we believe there are other suppliers of these raw materials, we may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of our suppliers could delay the development and commercialization of our implant products, including limiting supplies necessary for clinical trials and regulatory approvals, or interrupt production of then existing products that are already marketed, which would have a material adverse effect on our business.

We also use collagen, a protein obtained from animal source tissue, as another significant material required to produce our products. We may not be able to obtain adequate supplies of animal source tissue, or to obtain this tissue from animal herds that we believe do not involve pathogen contamination risks, to meet our future needs or on a cost-effective basis. Any significant supply interruption could adversely affect the production of our products and delay our product development or clinical trial programs. These delays would have an adverse effect on our business.

### We will need to increase the size of 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 out business, results of operations and financial condition. We anticipate that a period of significant expansion will be required to address possible other acquisitions of business, products, or rights, and potential internal growth to handle licensing and research activities. 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 improve 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. Our current personnel, systems, procedures and controls may not adequately support our future operations. 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.

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

Government regulation of our business is extensive, and obtaining and maintaining the necessary regulatory approvals is uncertain, expensive and time-consuming.

The process of obtaining regulatory clearances or approvals to market a medical device from the U.S. Food and Drug Administration, or 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 4 to 12 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 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 revenues. 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.

26

Even if regulatory clearance is obtained, a marketed product is subject to continual review, and later discovery of previously unidentified problems or failure to comply with the applicable regulatory requirements may result in restrictions on a product s marketing or withdrawal of the product from the market as well as possible civil or criminal sanctions.

We expect to be required to conduct clinical trials for some of our products. We have no experience conducting clinical trials, they may proceed more slowly than anticipated, and we cannot be certain that our products will be shown to be safe and effective for human use.

In order to commercialize some of our products, we may be required to submit a PMA, which will require us to conduct clinical trials. Even if we seek FDA clearance of one our products through the 510(k) process, the FDA may require us to conduct a clinical trial in support of our 510(k). We will receive approval from the FDA to commercialize products requiring a clinical trial only if we can demonstrate to the satisfaction of the FDA, in well-designed and properly conducted clinical trials, that our product candidates are safe and effective and otherwise meet the appropriate standards required for approval for specified indications. Clinical trials are complex, expensive, time consuming, uncertain and subject to substantial and unanticipated delays. Before we may begin clinical trials that present a significant risk to subjects, we must submit and obtain FDA approval of an investigational device exemption, or IDE, that describes, among other things, the manufacture of, and controls for, the device and a complete investigational plan. Clinical trials may involve a substantial number of patients in a multi-year study. We may encounter problems with our clinical trials and any of those problems could cause us or the FDA to suspend those trials, or delay the analysis of the data derived from them.

A number of events or factors, including any of the following, could delay or prevent the completion of our clinical trials in the future and negatively impact or even foreclose our ability to obtain FDA approval for, and to introduce a particular product:

failure to obtain approval from the FDA or any foreign regulatory authority to commence an investigational study;

conditions imposed on us by the FDA or any foreign regulatory authority regarding the scope or design of our clinical trials:

delays in obtaining or in our maintaining required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;

insufficient supply of our products or other materials necessary to conduct our clinical trials; difficulties in enrolling patients in our clinical trials;

negative or inconclusive results from clinical trials, or results that are inconsistent with earlier results, that necessitate additional clinical studies;

serious or unexpected side effects experienced by patients in whom our products are implanted; or failure by any of our third-party contractors or investigators to comply with regulatory requirements or meet other contractual obligations in a timely manner.

Our clinical trials may not begin as planned, may need to be redesigned, and may not be completed on schedule, if at all. Delays in our clinical trials may result in increased development costs for our product candidates, which could cause our stock price to decline and limit our ability to obtain additional financing. In addition, if one or more of our clinical trials are delayed, competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced.

We have not yet conducted any clinical trials with our products, and any adverse results in our clinical trials could have a material adverse effect on our business.

There may be unexpected findings, particularly those that may only become evident from larger scale clinical trials, as compared with the smaller scale tests we intend to do initially. The occurrence of unexpected findings in connection with our clinical trials or any subsequent clinical trial required by our regulators may prevent or delay obtaining regulatory approval, and may adversely affect coverage or reimbursement determinations. Our regulators may also determine that additional clinical trials are necessary, in which case approval may be delayed for several months or even years while these trials are conducted. The clinical trials may not show that our products based on NDGA, PVA-based hydrogel, or any other products we develop are safe and effective. If we are unable to complete the

clinical trials necessary to successfully support our regulatory applications, our ability to commercialize our products, business, financial condition, and results of operations would be materially adversely affected.

27

### Our products contain biologic materials, and so may face additional obstacles to FDA clearance or approval.

To complete successful clinical trials, a product must meet the criteria for clinical approval, or endpoints, established in the clinical study. These endpoints are established in consultation with the FDA, following any applicable clinical trial design guidelines, to establish the safety and effectiveness for approval of devices subject to PMA approval, or to demonstrate the substantial equivalence of devices subject to 510(k) clearance. However, in the case of products which are novel or which target parts of the human body for which there are no FDA approved products, the scientific literature may not be as complete and there may not be established guidelines for the design of studies to demonstrate the effectiveness of such products. As a result, clinical trials considering such products may take longer than average and obtaining approval may be more difficult. Additionally, the endpoints established for such a clinical trial might be inadequate to demonstrate the safety and efficacy or substantial equivalence required for regulatory clearance because they do not adequately measure the clinical benefit of the product being tested. In certain cases additional data collected in the clinical trial or further clinical trials may be required by the FDA. Any delays in regulatory approval will delay commercialization of our products, which may have an adverse effect on our business.

The FDA regulates human therapeutic products in one of three broad categories: drugs, biologics or medical devices. The FDA is scrutiny of products containing biologic materials may be heightened. Although we anticipate that our products will be regulated in the U.S. as medical devices, we will use biological materials in the production of several devices. FDA may conclude that some of our products are combinations of devices and biologicals, or may conclude that some of our products are biologics rather than devices, potentially requiring a different and more time consuming premarket clearance mechanism. Use of this biological material in our products may result in heightened scrutiny of such product which may result in further delays in, or obstacles to, obtaining FDA clearance or approval.

# Subsequent modifications to our products may require new regulatory approvals, or may require us to cease marketing or recall the modified products until approvals are obtained.

Once our products receive FDA approval or clearance, subsequent modification to our products may require new regulatory approvals or clearances, including 510(k) clearances or premarket approvals, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification does not require a new clearance or approval. However, the FDA can review a manufacturer s decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We have made modifications to our products in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

If a manufacturer determines that a modification to a FDA-cleared device requires premarket clearance, then the manufacturer must file for a new 510(k) clearance or possibly a premarket approval application supplement. Where we determine that modifications to our products require a new 510(k) clearance or premarket approval application, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. Obtaining clearances and approvals can be a time consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

# If we or our suppliers fail to comply with the FDA s quality system regulations, the manufacture of our products could be delayed.

We and our suppliers are required to comply with the FDA s quality system regulations, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. The FDA enforces the quality system regulation through inspections. If we or our supplier fail a quality system regulations inspection or if any corrective action plan is not sufficient, FDA could take enforcement action, including any of the following sanctions, and the manufacture of our products could be delayed or terminated:

### **Table of Contents**

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 on PMA approvals that have already been granted;

refusal to grant export approval for our products; or

criminal prosecution.

Once our products are commercialized, we and our sales personnel, whether employed by us or by others, 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.

Once our products are commercialized, our relationships with surgeons, hospitals and the marketers of our products will be 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 in which we intend to market our products have similar fraud and abuse laws, imposing substantial penalties for violations. Any government investigation or a finding of a violation of these laws would likely result in a material adverse effect on the market price of our common stock, as well as our business, financial condition and results of operations.

Anti-kickback laws and regulations prohibit any knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for the referral of an individual or the ordering or recommending of the use of a product or service for which payment may be made by Medicare, Medicaid or other government-sponsored healthcare programs. We have formed Physician Advisory Boards consisting of an aggregate of 32 physicians 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 surgeons, including some who may make referrals to us or 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-surgeons, or received stock options from us as consideration for consulting services performed by them. We also may engage additional physicians on a consulting basis. While these transactions were structured with the intention of complying with all applicable laws, including the federal ban on physician self referrals, commonly known as the Stark Law, 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, or prohibit us from accepting referrals from these surgeons. Because our strategy relies on the involvement of physicians who consult with us on the design of our product candidates, 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.

29

### We face significant uncertainty in the industry due to government healthcare reform.

Political, economic and regulatory influences are subjecting the healthcare industry to fundamental changes. Reforms under consideration in the United States include mandated basic healthcare benefits, controls on healthcare spending, increases in insurance premiums and increased out-of-pocket requirements for patients, the creation of large group purchasing organizations that aim to reduce the costs of products that their member hospitals consume, and significant modifications to the healthcare delivery system. We anticipate that the U.S. Congress and state legislatures will continue to review and assess alternative healthcare delivery systems and payment methods. Due to uncertainties regarding the ultimate features of reform initiatives and the timing of their enactment and implementation, we cannot predict which, if any, of such reform proposals will be adopted, when they may be adopted or what impact reform initiatives may have on us.

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

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

As of June 9, 2008, our directors and executive officers together beneficially owned approximately 22% of our outstanding capital 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 our 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.

# Our Common Stock is and likely will remain subject to the SEC s Penny Stock rules, which may make our 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.

There is a minimal public market for our Common Stock. We cannot be certain more of a public market for our Common Stock will 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.

30

# 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, no securities analysts provide research coverage of our Common Stock, and securities analysts may elect not to provide such coverage in the future. 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 the our Common Stock. If securities analysts do not cover our Common Stock, the lack of research coverage may adversely affect our 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.

# A significant number of shares will become eligible for future sale by our shareholders and the sale of those shares could adversely affect the stock price.

Most of our outstanding shares, which are not currently eligible for resale, will become eligible for resale over a time period beginning in February 2009. Many holders of our Common Stock have registration rights.

If our shareholders whose shares are either registered for resale or become eligible for resale do sell their shares, or indicate an intention to sell, substantial amounts of our Common Stock in the public market after the legal restrictions on resale lapse, the trading price of our Common Stock could decline.

# We are now a development-stage company, making it difficult to comply with SEC requirements and to reliably predict future growth and operating results.

Our new management team is now responsible for our operations and reporting. This requires outside assistance from legal, accounting, investor relations, or other professionals that could be more costly than planned. We may also be required to hire additional staff to comply with additional SEC reporting requirements and compliance under the Sarbanes-Oxley Act of 2002. Our failure to comply with reporting requirements and other provisions of securities laws could negatively affect our stock price and adversely affect our results of operations, cash flow and financial condition.

Operating as a public company also requires us to make forward-looking statements about future operating results and to provide some guidance to the public markets. Our management has limited experience as a management team in a public company and as a result projections may not be made timely or set at expected performance levels and could materially affect the price of our shares. Any failure to meet published forward-looking statements that adversely affect the stock price could result in losses to investors, shareholder lawsuits or other litigation, sanctions or restrictions issued by the SEC or the stock market upon which our stock is traded.

### 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. The issuance of shares of our Common Stock upon the exercise of options may result in dilution to our shareholders.

#### **Table of Contents**

# We cannot be certain that our internal control over financial reporting is or will be effective or sufficient in the future.

Our ability to manage our operations and growth requires us to maintain effective operations, compliance and management controls, as well as internal control over financial reporting. Management has not completed its assessment of internal control and may not be able to implement necessary improvements to internal control over financial reporting in an efficient and timely manner and may discover deficiencies and weaknesses in existing systems and controls, especially when such systems and controls are tested by an increased rate of growth or the impact of acquisitions. In addition, upgrades or enhancements to computer systems could cause internal control weaknesses.

It may be difficult to design and implement effective internal control over financial reporting for combined operations as we integrate our operating subsidiaries, and perhaps other acquired businesses in the future. In addition, differences in existing controls of acquired businesses may result in weaknesses that require remediation when internal controls over financial reporting are combined.

If we fail to maintain an effective system of internal control or if management or our independent registered public accounting firm were to discover material weaknesses in internal control systems we may be unable to produce reliable financial reports or prevent fraud. If we are unable to assert that our internal control over financial reporting is effective at any time in the future, or if our independent registered public accounting firm is unable to attest to the effectiveness of internal controls, is unable to deliver a report at all, or can deliver only a qualified report, we could be subject to regulatory enforcement and investors may lose confidence in our ability to operate in compliance with existing internal control rules and regulations, either of which could result in a decline in our share price.

### We may become involved in securities class action litigation that could divert management s attention and harm our 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 our 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 our 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; and allowing the Board to fill vacancies and to fix the number of directors.

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

None

32

#### **Table of Contents**

### **Item 2. Properties**

We currently lease approximately 1,900 square feet of office space in Destin, Florida (see Certain Relationships and Related Transactions below) and recently built out approximately 5,000 square feet of space under a five-year lease in Tampa, Florida. The new Tampa headquarters, which we occupied in August 2007, consists of laboratory (2,000 feet) and manufacturing (3,000 feet) space. Also, we currently lease approximately 225 square feet of office space inside the Andrews Institute in Gulf Breeze, Florida, which is used for clinical development and teaching. For SpineMedica's operations, we lease approximately 12,200 square feet of office and lab space under a 4.5 year lease in Marietta, Georgia. We believe these facilities are adequate for our current activities. We do not own any real estate.

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

None

### Item 4. Submissions of Matters to a Vote of Security Holders

We filed a definitive proxy statement on Schedule 14A with the SEC on March 10, 2008 and held a special meeting of shareholders on March 31, 2008 in accordance with the proxy statement.

The shareholders, voting as separate classes, approved a reverse split whereby each share of our Common Stock was converted into 0.3234758 shares of Common Stock and each share of our Series A Preferred Stock was converted into 5 shares of Common Stock, such that each former MiMedx shareholder owned the same number of shares in the Company as such shareholder held in MiMedx prior to the Merger. Pre-split shares of Series A Preferred Stock totaling 2,504,992 and 6,000 were cast in favor of, and abstained from, the reverse split, respectively. Pre-split shares of Common Stock totaling 41,222,910 were cast in favor of the reverse split. No shares were cast against the reverse split.

Also at the special meeting, our shareholders, voting together as one class, approved a change in our state of incorporation from Nevada to Florida by the merger of Alynx, Co. with and into its wholly-owned subsidiary, MiMedx Group, Inc., a Florida corporation, pursuant to which: the name of Alynx, Co. was changed to MiMedx Group, Inc.; the Articles of Incorporation of MiMedx Group, Inc. became the Articles of Incorporation of the surviving company; and the Bylaws of MiMedx Group, Inc. became the Bylaws of the surviving company. Post-split shares of Common Stock totaling 25,889,579 were cast in favor of the redomestication merger, 25 shares abstained from the vote, and no shares voted against it.

The shareholders also authorized the Board of Directors or a committee thereof to adjourn or postpone the special meeting to a later date, if necessary, to solicit additional proxies if there were not sufficient votes in favor of the proposals submitted at the meeting. As there were sufficient votes to approve both proposals presented at the special meeting, this authority was not exercised.

33

#### **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 have traded since 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.

|                | Quarter | High* |      | Low* |      |
|----------------|---------|-------|------|------|------|
| Year Ended     |         |       |      |      |      |
| March 31, 2008 | First   |       | N/A  |      | N/A  |
|                | Second  | \$    | 0.96 | \$   | 0.96 |
|                | Third   | \$    | 0.96 | \$   | 0.96 |
|                | Fourth  | \$    | 6.52 | \$   | 0.96 |

\* Adjusted to reflect the reverse stock split effective on April 2, 2008.

Based upon information supplied from our transfer agent, there were approximately 816 shareholders of record of our Common Stock as of June 10, 2008.

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

### **Recent Sales of Unregistered Securities**

On February 22, 2008, we issued a stock option for 600,000 shares (as adjusted to reflect the reverse split) of our Common Stock, at an exercise price of \$5.44 (as adjusted to reflect the reverse split) per share, to Brian J. Splan, in connection with his appointment as President. These shares were issued to Mr. Splan in reliance upon Rule 506 of Regulation D of the Securities Act of 1933, by virtue of his position as our executive officer.

On March 31, 2008, we issued 400,000 shares of our Common Stock to SaluMedica, LLC in exchange for the licenses and other rights granted to us under a Technology License and Trademark License with SaluMedica, LLC. We did not register the aforementioned securities in reliance on an exemption pursuant to Section 4(2) of the Securities Act of 1933, inasmuch as the shares were issued in a private placement with a single investor who acquired them for investment purposes.

### Use of Proceeds from the Recent Sales of Unregistered Securities

There were no cash proceeds from our recent sales of unregistered securities.

### **Recent Purchases of Equity Securities**

We did not purchase any of our equity securities during the fourth quarter of 2008.

34

#### 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 conditions 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 revenues, if any, 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.

The Company is a development-stage company that has two operating subsidiaries: MiMedx and SpineMedica. MiMedx was formed to acquire a license for the use, adaptation and development of certain core technologies developed at the Shriners Hospitals for Children and the University of South Florida. This technology focuses on biomaterials for soft tissue repair, such as tendons, ligaments and cartilage, as well as other biomaterial-based products for numerous other medical applications. In July of 2007, SpineMedica was formed to acquire SpineMedica Corp., that had licensed from SaluMedica, LLC the rights to use a PVA-based hydrogel in spinal applications. MiMedx also has a license from SaluMedica, LLC to use a PVA-based hydrogel in the surgical repair of the rotator cuff and hand and to make surgical sheets.

The Company has generated no operating revenue and has a history of losses since its inception in November 2006. The Company incurred a net loss of approximately \$17,371,000 in the fiscal year ended March 31, 2008, or approximately \$(0.97) per share. Since its inception in November 2006, the Company has incurred a net loss of approximately \$18,022,000.

Over the next twelve months our plan of operation is to develop our core product platforms: NDGA-polymerized collagen and PVA-based implants for the spine, hand, and rotator cuff. This effort will include initiating management of our quality system, planning our process for obtaining FDA and other required regulatory approvals, engineering, prototype development, and pre-clinical testing. With respect to NDGA-polymerized collagen, over the course of the next year, the Company intends to perform required biocompatible testing which may be used in future FDA applications as well as conduct bench testing after further refinement of our tendon and ligament prototypes through collaboration with our Physician Advisory Board. With respect to PVA-based implants for spine, hand, and rotator cuff, over the course of the next year we will conduct bench, biocompatibility, and other testing on device prototypes focused on treatments for spine disorders. Furthermore, we may develop PVA-based implants for use in the hand and as a general patch, used in the surgical repair of the spine. We may also develop further conventional implants for the small extremities.

We are formulating an FDA strategy for future product marketing activities. For example, we intend to focus first on development products that are used in relatively low-risk procedures. We believe that the FDA may not require a multi-site, multi-year clinical trial (PMA clinical trial) for products deemed low-risk, such as anatomies which are not complicated or that do not place products under intense mechanical forces. For more complicated treatments, anatomies, or where products are placed under intense mechanical forces, such as our PVA-based cervical artificial disc, the FDA will require a PMA clinical trial. To date, we have not received any clearances to market products in the US or elsewhere. For product introductions outside the U.S., we must receive approval from the regulatory bodies in

the region or country in which we intend to market products.

We expect to invest in infrastructure development with respect to manufacturing scale-up and quality system implementation. This development will include adding capability to spool NDGA-polymerized fibers in quantities and lengths which are sufficient for large-scale weaving and braiding and other manufacturing systems. We plan to implement infrastructure in multiple stages as development progresses.

35

### **Table of Contents**

We also intend to analyze acquisition and partnership opportunities as they arise. Initially, we expect to focus on possibilities in the extremities, spine and general surgery segments.

To implement our business plan and generate revenue from other sources, we must develop products and obtain regulatory approvals for those products in many jurisdictions. We may not receive any such regulatory approvals. Due to this and a variety of other factors, many of which are discussed in this report under Risk Factors, we may be unable to generate significant revenues or margins, control operating expenses, or achieve or sustain profitability in future years.

# Results of Operations for the Year Ended March 31, 2008 and the Period from Inception (November 22, 2006) through March 31, 2007

### **Overview**

The Company had limited operations prior to securing financing from the sale of its Series A Preferred Stock under a private placement dated mid-February 2007 and the first outside investment capital being received in March 2007. During the period from inception (November 22, 2006) through March 31, 2007 ( 2007 Year End ), MiMedx s main focus was on seeking financing, hiring its initial employees, and securing the license agreement from Shiner s Hospitals for Children and the University of South Florida Research Foundation, Inc. Subsequent to the closing of the initial financing that was completed during the year ended March 31, 2008 ( 2008 Year End ), MiMedx continued to expand the number of employees, secured office space and began to expand its research and development of its licensed technology. Also during 2008 Year End, MiMedx merged with SpineMedica Corp. in July 2007 and subsequently merged in February 2008 with a publicly-traded shell company under the name of Alynx, Co. The operating expenses and research costs incurred during these periods reflect the increase in operating activity during this early stage of the Company s history.

### Research and Development Expenses

Research and development expenses of approximately \$2,013,000 for the 2008 Year End increased significantly compared to approximately \$114,000 for 2007 Year End. These costs consist primarily of internal personnel costs, fees paid to external consultants, and supplies and instruments used in our laboratories. As of March 31, 2007, we employed 4 employees devoted to research and development, most of whom started with the Company as of February or March of 2007. With the acquisition of SpineMedica in July 2007, the number of employees working in research and development increased to 11 and as of March 31, 2008, we had 17 employees in research and development. We also increased the number of external consultants from 13 as of March 31, 2007 to 32 as of March 31, 2008. Supplies and instruments used for research and development increased significantly as we expanded the staff and undertook additional research and development of our technologies. We anticipate continued increases in the area of research and development in the foreseeable future as we progress our technologies into clinical development to obtain approval from the FDA to market our technologies.

### Acquired In-Process Research and Development

As part of our acquisition of SpineMedica Corp., a total of approximately \$7,177,000 was allocated from the purchase price to acquired in-process research and development. This allocation of the purchase costs relate to research acquired relates to two products that were still under development and had not yet yielded a completed finished product. This amount was recognized as an expense in the year ended March 31, 2008.

### General and Administrative Expenses

General and administrative expenses for the 2008 Year End were approximately \$8,659,000 compared to approximately \$571,000 for the 2007 Year End. General and administrative expenses consist of professional fees consisting of legal and accounting fees, personnel costs, travel and entertainment and occupancy costs. During the 2008 Year End, professional fees of approximately \$3,895,000 were incurred as compared to approximately \$175,000 during the 2007 Year End. These professional fees are primarily attributed to merger and acquisition costs, costs incurred in filing patents, and accounting and reporting fees. The total of professional fees related to the Alynx merger approximated \$1,870,000 and included \$1,126,000 representing the fair value of common shares issued to certain persons as compensation for finders—services related to the transaction. Personnel costs incurred during the 2008 Year End were approximately \$3,148,000 compared to approximately \$257,000 for 2007 Year End and primarily relate to salaries, wages and benefits of our employees not involved in research and development. As of March 31, 2008 we

employed 15 personnel not related to research and development functions as compared to 9 as of March 31, 2007. Occupancy costs consist primarily of leasing office and lab space in Tampa, Florida and in Marietta, Georgia. The first lease we entered into was in April 2007. Prior to that, during the 2007 Year End, we operated out of the offices of our founder, for no consideration.

36

### **Table of Contents**

During the 2008 Year End, we recorded \$191,000 in depreciation expense and \$309,000 in amortization expense as compared to recording less than \$1,000 in depreciation expense and approximately \$15,000 in amortization in the 2007 Year End. We depreciate our assets on a straight-line basis, principally over five to seven years and amortize our intangible assets over a period of 10 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 at least annually we test goodwill impairment and periodically evaluate other intangibles for impairment based on events or changes in circumstances as they occur.

### Net Interest Income

We recorded net interest income of \$520,000 during 2008 Year End and approximately \$34,000 during 2007 Year End as a result of our investment of the net proceeds of our offerings of MiMedx Preferred Stock, which occurred from March 2007 through November 2007.

### **Share Based Compensation**

We follow the provisions of Statement of Financial Accounting Standards No. 123R Share-based Payments (FAS123R) 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). The total share based compensation recognized during the year ended March 31, 2008 approximated \$808,000.

### **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 intangible assets:

Intangible assets include licensing rights and are accounted for based on Financial Accounting Standard Statement No. 142 Goodwill and Other Intangible Assets (FAS 142). In that regard, goodwill is not amortized but is tested at least annually for impairment, or more frequently if events or changes in circumstances indicate that the asset might be impaired. Intangible assets with finite useful lives are amortized using the straight-line method over a period of 10 years, the remaining term of the patents underlying the licensing rights (considered to be the remaining useful life of the license).

### Impairment of long-lived assets:

We evaluate the recoverability of our long-lived assets (finite lived intangible asset and 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.

### Acquired in-process research and development:

In connection with the acquisition of SpineMedica, we determined that approximately \$7.2 million of the fair value of the acquisition price qualifies as in-process research and development, and as such, this amount was expensed as research and development expense on the acquisition date.

37

Share-based compensation:

We follow the provisions of Statement of Financial Accounting Standards No. 123R Share-based Payments (FAS123R) 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).

Research and development costs:

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

Fair value determination of privately-held securities:

The fair values of the common stock as well as the common stock underlying options and warrants granted as part of asset purchase prices or as compensation prior to the February 8, 2008 Alynx merger were estimated by management with input from an unrelated valuation specialist.

Determining the fair value of stock requires making complex and subjective judgments. We used the market approach to estimate the value of the enterprise at each date on which securities are issued or granted. The enterprise value was then allocated to preferred and common shares taking into account the enterprise value available to all shareholders and allocating that value among the various classes of stock based on the rights, privileges and preferences of the respective classes. There is inherent uncertainty in these estimates.

### **Recent Accounting Pronouncements**

In June 2006, the Financial Accounting Standards Board (FASB) announced FASB Interpretation No. 48 Accounting for Uncertainty in Income Taxes (FIN 48), which is effective for fiscal year 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with FASB Statement No. 109, Accounting for Income Taxes. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The adoption of FIN 48 did not result in any changes to either the beginning stockholders equity (April 1, 2007) or the Company s financial position.

In September 2006, the FASB issued Statement No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 clarifies the principle that fair value should be based on the assumptions that market participants would use when pricing an asset or liability. Additionally, it establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The adoption of SFAS 157 is not expected to have a material impact on our consolidated financial position, results of operations or cash flows. In February 2008, the FASB issued a staff position that delays the effective date of SFAS 157 for all nonfinancial assets and liabilities except for those recognized or disclosed at least annually.

In February 2007, the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159), which establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. The standard requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of the company's choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which the company has chosen to use fair value on the face of the balance sheet. The new Statement does not eliminate disclosure requirements included in other accounting standards, including requirements for disclosures about fair value measurements included in SFAS 157. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The adoption of SFAS 159 is not expected to have a material impact on our consolidated financial position, results of operations or cash flows.

In December 2007, the FASB issued Statements No. 141R, *Business Combinations* (SFAS 141R) and No. 160 *Noncontrolling Interests in Consolidated Financial Statements* an amendment of ARB No. 51 (SFAS 160). SFAS 141R expands the scope of acquisition accounting to all transactions under which control of a business is obtained. Among other things, SFAS 141R requires that contingent consideration as well as contingent assets and liabilities be recorded at fair value on the acquisition date, and also requires transaction costs and costs to restructure the acquired company be expensed. SFAS 160 requires, among other things, that noncontrolling interests be recorded as equity in

the consolidated financial statements. SFAS 141R and SFAS 160 are both effective January 1, 2009. The adoption of these standards will not have an impact on our 2008 and 2007 consolidated financial statements.

38

In March 2008, the FASB issued Statement No. 161, *Disclosures about Derivative Instruments and Hedging Activities* (SFAS 161), which requires enhanced disclosures about how these instruments and activities affect the entity s financial position, financial performance and cash flows. The standard requires disclosure of the fair values of derivative instruments and their gains and losses in a tabular format. It also provides more information about an entity s liquidity by requiring disclosure of derivative features that are credit risk-related. Finally, it requires cross-referencing within footnotes to enable financial statement users to locate important information about derivative instruments. SFAS 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. Because SFAS 161 requires enhanced disclosures but does not modify the accounting treatment of derivative instruments and hedging activities, we believe the adoption of this standard will have no impact on our financial position, results of operations or cash flows.

Dormanta dua by pariad

### **Contractual Commitments**

The table below sets forth our known contractual obligations as of March 31, 2008:

|                             | Payments due by period |              |              |             |         |
|-----------------------------|------------------------|--------------|--------------|-------------|---------|
|                             |                        | Less than    |              |             | After 5 |
| Contractual Obligations     | Total                  | 1 year       | 2 - 3 years  | 4 - 5 years | years   |
| Consulting Agreements       | \$ 602,000             | \$ 296,000   | \$ 306,000   | \$          | \$      |
| Employment Agreements       | 2,291,000              | 1,276,000    | 1,015,000    | • 4 5 0 0 0 |         |
| Operating Lease Obligations | 1,055,000              | 245,000      | 564,000      | 246,000     |         |
| Total                       | \$ 3,948,000           | \$ 1,817,000 | \$ 1,885,000 | \$ 246,000  | \$      |

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

We have no off-balance sheet arrangements.

### **Liquidity and Capital Resources**

Since inception, we have funded our start-up costs, operating costs and capital expenditures through issuances of stock.

We had approximately \$6,750,000 of cash and cash equivalents on hand as of March 31, 2008.

We estimate that the cash and cash equivalents on hand will be sufficient to fund operations for at least the next three to six months while the we undertake to expand our existing research and development efforts to commercialize our technologies and pursue FDA approval. We will require additional funds to pursue our business plan. Our working capital requirements will depend upon numerous factors, including the progress of our research and development programs, pre-clinical testing, clinical trials, timing and cost of seeking as well as achievement of regulatory milestones, and the ability to sell or license our technologies in the marketplace. In any event, we will require substantial funds in addition to those presently available to develop all of our programs to meet our business objectives. If we should identify other intellectual property, products or businesses which we wish to acquire, we will likely require additional capital to fund those acquisitions.

We are considering the possible issuance of additional shares of capital stock, in connection with a PIPE transaction, and are working toward such a financing transaction, but there can be no assurance that funds will be available, or that the price we can obtain will be acceptable. See Risk Factors for a discussion of the impact of a failure to obtain needed capital.

We expect to incur losses from operations for the foreseeable future. We expect that general and administrative expenses will continue to increase as we expand our finance and administrative staff, add infrastructure, and incur additional costs related to being an operating public company in the United States, including the costs of directors and officers insurance, investor relations programs and increased professional fees.

#### **Table of Contents**

#### 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

In the normal course of doing business we are not exposed to the risks associated with foreign currency exchange rates and changes in interest rates. We do not engage in trading market risk sensitive instruments or purchasing hedging instruments or other than trading instruments that are likely to expose us to significant market risk, whether interest rate, foreign currency exchange, commodity price or equity price risk.

Our exposure to market risk relates to our cash and investments.

The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we invest our excess cash in debt instruments of the U.S. Government and its agencies, bank obligations, repurchase agreements and high-quality corporate issuers, and, by policy, restrict our exposure to any single corporate issuer by imposing concentration limits. To minimize the exposure due to adverse shifts in interest rates, we maintain investments at an average maturity of generally less than three months.

40

#### **Table of Contents**

#### **Item 8. Financial Statements and Supplementary Data**

Report of Independent Registered Public Accounting Firm

**Board of Directors** 

MiMedx Group, Inc.

We have audited the accompanying consolidated balance sheet of MiMedx Group, Inc. and subsidiaries as of March 31, 2008, and the related consolidated statements of operations, stockholders—equity and cash flows for the year ended March 31, 2008 and the period from inception (November 22, 2006) through March 31, 2008. 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 audit.

We conducted our audit in accordance with auditing standards of the Public Company Accounting Oversight Board (United States of America). The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purposes of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly we express no such opinion. An audit also 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 audit provides 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 March 31, 2008 and the consolidated results of its operations and its cash flows for the year ended March 31, 2008 and the periods from inception (November 22, 2006) through March 31, 2008, in conformity with accounting principles generally accepted in the United States of America. The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company has incurred net losses and negative operating cash flows since inception and will require additional financing over a period of years to fund the continued development of products subject to its licensed technologies. The availability of such financing cannot be assured. These conditions raise substantial doubt about the Company s ability to continue as a going concern. Management s plans in regard to these matters are described in Note 3. The financial statements do not include any adjustments with respect to the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might result from the outcome of these uncertainties.

/s/ Cherry, Bekaert & Holland, L.L.P.

Tampa, Florida June 27, 2008

41

#### **Table of Contents**

#### Report of Independent Registered Public Accounting Firm

Board of Directors MiMedx Group, Inc.

We have audited the accompanying consolidated balance sheet of MiMedx Group, Inc. and subsidiaries as of March 31, 2007, and the related consolidated statements of operations, stockholders' equity and cash flows for the period from inception (November 22, 2006) through March 31, 2007. 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 audit.

We conducted our audit in accordance with auditing standards of the Public Company Accounting Oversight Board (United States of America). The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purposes of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly we express no such opinion. An audit also 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 audit provides 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 March 31, 2007 and the consolidated results of its operations and its cash flows for the period from inception (November 22, 2006) through March 31, 2007, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company has incurred net losses and negative operating cash flows since inception and will require additional financing over a period of years to fund the continued development of products subject to its licensed technologies. The availability of such financing cannot be assured. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are described in Note 3. The financial statements do not include any adjustments with respect to the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might result from the outcome of these uncertainties.

/s/ Aidman, Piser & Company, P.A.

Tampa, Florida February 8, 2008

42

## MIMEDX GROUP, INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE) CONSOLIDATED BALANCE SHEETS ASSETS

|  | March 31, |                      |                                  |
|--|-----------|----------------------|----------------------------------|
|  |           | 2008                 | 2007                             |
| Current assets: Cash and cash equivalents Due from related parties   | \$        | 6,749,609            | \$ 10,456,707<br>30,125          |
| Prepaid expenses and other current assets Investment, related party  |           | 189,253              | 931<br>172,800                   |
| Total current assets   |           | 6,938,862            | 10,660,563                       |
| Property and equipment, net of accumulated depreciation<br>Goodwill  |           | 1,452,436<br>857,597 | 7,265                            |
| Intangible assets, net Deposits  |           | 5,783,153<br>146,433 | 981,067<br>119,200               |
| Total assets   | \$        | 15,178,481           | \$11,768,095                     |
| LIABILITIES AND STOCKHOLDERS EQU   | ITY       |                      |                                  |
| Current liabilities: Accounts payable and accrued expenses Deferred interest income Due to related party   | \$        | 948,478              | \$ 970,117<br>164,278<br>500,000 |
| Total current liabilities  |           | 948,478              | 1,634,395                        |
| Commitments and contingency (Notes 6 and 10)   |           |                      |                                  |
| Stockholders equity: Convertible preferred stock Series A; \$.0001 par value; 0 (2008) and 20,000,000 (2007) shares authorized and 0 (2008) and 11,212,800 (2007) shares issued and outstanding Preferred stock; \$.001 par value; 5,000,000 (2008) and 0 (2007) shares authorized and 0 (2008 and 2007) shares issued and outstanding Common stock; \$.001 par value; 100,000,000 (2008) and 40,000,000 (2007) shares authorized and 36,864,534 (2008) and 14,000,000 (2007) shares |           |                      | 14,016,000                       |
| issued and outstanding Additional paid-in capital Stock subscriptions receivable   |           | 36,864<br>32,226,983 | 14,000<br>7,463<br>(1,233,750)   |

Edgar Filing: MIMEDX GROUP, INC. - Form 10-K

| Note receivable, related party                   |               | (2,007,644)   |
|--|---------------|---------------|
| Deficit accumulated during the development stage | (18,033,844)  | (662,369)     |
| Total stockholders equity                        | 14,230,003    | 10,133,700    |
| Total liabilities and stockholders equity        | \$ 15,178,481 | \$ 11,768,095 |

See notes to consolidated financial statements.

### MIMEDX GROUP, INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE) CONSOLIDATED STATEMENTS OF OPERATIONS

|   | Ma | Year<br>Ended<br>arch 31, 2008 | Period from<br>Inception<br>(November 22,<br>2006)<br>through<br>March 31, 2007 | Period from<br>Inception<br>(November 22,<br>2006)<br>through<br>March 31, 2008 |
|---|----|--------------------------------|---|---|
| Research and development expenses Acquired in-process research and development                  | \$ | 2,013,002                      | \$<br>113,897   | \$<br>2,126,899   |
| (Note 4) General and administrative expenses  |    | 7,177,000<br>8,659,405         | 570,626   | 7,177,000<br>9,230,031  |
| Loss from operations  |    | (17,849,407)                   | (684,523)   | (18,533,930)  |
| Other income (expense):<br>Interest income<br>Change in fair value of investment, related party |    | 519,707<br>(41,775)            | 33,746  | 553,453<br>(41,775)   |
| Loss before income taxes<br>Income taxes  |    | (17,371,475)                   | (650,777)   | (18,022,252)  |
| Net loss  | \$ | (17,371,475)                   | \$<br>(650,777)   | \$<br>(18,022,252)  |
| Net loss per common share<br>Basic and diluted  | \$ | (0.97)                         | \$<br>(0.08)  |   |
| Shares used in computing net loss per common share Basic and diluted                            |    | 17,909,903                     | 8,537,000   |   |

See notes to consolidated financial statements.

44

#### **Table of Contents**

## MIMEDX GROUP, INC. AND SUBSIDARIES (A DEVELOPMENT STAGE ENTERPRISE) CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY PERIOD FROM INCEPTION (NOVEMBER 22, 2006) THROUGH MARCH 31, 2008

| Preferre | ed Stock         | Preferr | ed Stock   | Common   | Stock  | Additional<br>Paid-in  | Stock<br>Subscriptions  | Note<br>Receivable<br>Related   |
|----------|------------------|---------|--|--|--|--|---|---|
| Shares   | Amount           | Shares  | Amount   | Shares   | Amount   | Capital  | oital Receivable  |   |
|          | \$               |         | \$   |  | \$   | \$   | \$  | \$  |
|          |                  |         |  | 12,880,000   | 12,880   |  |   |   |
|          |                  |         |  |  |  | 13,409   |   |   |
|          |                  |         |  |  |  | 17,980   |   |   |
|          |                  |         |  | 1,120,000  | 1,120  | 894,880  |   |   |
|          |                  |         |  | , ,  | ,  | ,  |   | (2,000,00   |
|          |                  |         |  |  |  | (918,806)  | (1,233,750)   | (7,64   |
|          |                  |         |  | 14,000,000   | 14,000   | 7,463  | (1,233,750)   | (2,007,64   |
|          | Preferre<br>Seri |         | Preferred Stock Preferred Stock Series B Series Shares Amount Shares | Preferred Stock Series B Series C  Shares Amount Shares Amount | Preferred Stock Series B Series C Common Shares Amount Shares \$ \$ 12,880,000 | Preferred Stock Series B Series C Common Stock  Shares Amount Shares Amount Shares Amount  \$ \$ \$ \$ 12,880,000 12,880 | Preferred Stock Series B         Preferred Stock Series C         Common Stock Common Stock         Additional Paid-in           Shares         Amount         Shares         Amount         Capital           \$         \$         \$         \$           12,880,000         12,880         13,409           17,980         17,980           (918,806)         (918,806) | Preferred Stock Series B       Preferred Stock Series C       Common Stock Common Stock       Additional Paid-in Subscriptions         Shares       Amount       Shares       Amount       Capital Receivable         \$       \$       \$       \$       \$         \$       \$       \$       \$       \$         \$       \$       \$       \$       \$         \$       \$       \$       \$       \$         \$       \$       \$       \$       \$         \$       \$       \$       \$       \$         \$       \$       \$       \$       \$         \$       \$       \$       \$       \$         \$       \$       \$       \$       \$         \$       \$       \$       \$       \$         \$       \$       \$       \$       \$         \$       \$       \$       \$       \$         \$       \$       \$       \$       \$         \$       \$       \$       \$       \$         \$       \$       \$       \$       \$         \$       \$       \$       \$       \$         \$       \$ |

Table of Contents 80

649,783 158,247 1,233,750

(41,25

5,922,397 7,402,996 2,911,117 2,911 2,316,908 2,048,89 1,285,001 3,855,000

1,200 1 2,159 11,257,996 (5,922,397) (7,402,996) (1,285,001) (3,855,000) 926,168 926 (926) 205,851 206 1,126,173 (25,273,996) 18,420,198 18,420 25,255,576

400,000 400 2,595,600

116,000

\$ 36,864,534 \$36,864 \$32,226,983 \$ \$

See notes to consolidated financial statements.

45

### MIMEDX GROUP, INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE) CONSOLIDATED STATEMENTS OF CASH FLOWS

|  | Year<br>Ended<br>March 31, 2008 | Period from Inception (November 22, 2006) through March 31, 2007 | Period from Inception (November 22, 2006) through March 31, 2008 |
|--|---------------------------------|--|--|
| Cash flows from operating activities:  | Φ (17.271.475)                  | Φ ((50,777)  | ф (10,000,050)   |
| Net loss Adjustments to reconcile net loss to net cash   | \$ (17,371,475)                 | \$ (650,777)   | \$ (18,022,252)  |
| flows from operating activities, net of effects of acquisition:  |                                 |  |  |
| Acquired in-process research and development   | 7,177,000                       |  | 7,177,000  |
| Depreciation   | 191,348                         | 807  | 192,155  |
| Amortization of intangible assets  | 308,914                         | 14,933   | 323,847  |
| Employee share-based compensation expense  | 649,783                         | 13,409   | 663,192  |
| Other share-based compensation expense   | 158,247                         | 17,980   | 176,227  |
| Issuance of common stock for transaction fees<br>Accrued interest on notes receivable, related                 | 1,126,379                       |  | 1,126,379  |
| party  | (41,250)                        | (7,644)  | (48,894)   |
| Change in fair value of investment, related party<br>Increase (decrease) in cash resulting from<br>changes in: | 41,775                          |  | 41,775   |
| Prepaid expenses and other current assets  | (169,244)                       | (931)  | (170,175)  |
| Accounts payable and accrued expenses  | (164,601)                       | 214,965  | 50,364   |
| Deferred interest income   | (43,200)                        |  | (43,200)   |
| Net cash flows from operating activities   | (8,136,324)                     | (397,258)  | (8,533,582)  |
| Cash flows from investing activities:  |                                 |  |  |
| Purchase of equipment  | (1,172,730)                     | (8,072)  | (1,180,802)  |
| Cash paid for intangible asset   |                                 | (100,000)  | (100,000)  |
| Cash paid for security deposits  | 6,569                           | (119,200)  | (112,631)  |
| Cash received in acquisition of SpineMedica  |                                 |  |  |
| Corp.  | 1,957,405                       |  | 1,957,405  |
| Cash paid for acquisition costs of SpineMedica   |                                 |  |  |
| Corp.  | (227,901)                       | (2 020 C:=)  | (227,901)  |
| Payments from (advances to) related party  | 30,125                          | (2,038,647)  | (2,008,522)  |
| Net cash flows from investing activities   | 593,468                         | (2,265,919)  | (1,672,451)  |

Cash flows from financing activities:

| Proceeds from (repayments of) related party     |                 |                  |                 |
|---|-----------------|------------------|-----------------|
| borrowing                                       | (500,000)       | 500,000          |                 |
| Proceeds from Series A preferred stock          | 1,233,750       | 12,782,250       | 14,016,000      |
| Proceeds from Series C preferred stock          | 3,855,000       |                  | 3,855,000       |
| Proceeds from common stock sale                 |                 | 1,288            | 1,288           |
| Proceeds from exercise of stock options         | 2,160           |                  | 2,160           |
| Offering costs paid in connection with Series A |                 |                  |                 |
| preferred stock offering                        | (755, 152)      | (163,654)        | (918,806)       |
| Net cash flows from financing activities        | 3,835,758       | 13,119,884       | 16,955,642      |
| Net change in cash                              | (3,707,098)     | 10,456,707       | 6,749,609       |
| Cash, beginning of period                       | 10,456,707      |                  |                 |
| Cash, end of period                             | \$<br>6,749,609 | \$<br>10,456,707 | \$<br>6,749,609 |

#### SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION

Cash paid for:

Interest \$ \$

Income taxes \$

See notes to consolidated financial statements.

46

#### **Table of Contents**

# MIMEDX GROUP, INC. AND SUBSIDIARIES (A DEVELOPMENT STAGE ENTERPRISE) STATEMENTS OF CASH FLOWS (CONTINUED) SUPPLEMENTAL SCHEDULE OF NON-CASH INVESTING AND FINANCING ACTIVITIES

During the period ended March 31, 2007, the Company financed \$755,152 of preferred stock offering costs (included in accounts payable at March 31, 2007).

During the period ended March 31, 2007, the Company issued 1,120,000 shares of common stock valued at \$896,000, in connection with the purchase of an intangible asset.

During the year ended March 31, 2008, the Company acquired 100% of the capital stock of SpineMedica Corp. for shares of common and preferred stock (Note 4).

During the year ended March 31, 2008, the Company issued 400,000 shares of common stock valued at \$2,596,000, in connection with the purchase of an intangible asset.

During the year ended March 31, 2008, the Company issued stock options to acquire 200,000 shares of common stock valued at \$116,000, in connection with the purchase of an intangible asset.

During the year ended March 31, 2008, the Company issued 205,851 shares of common stock valued at \$1,126,379, in connection with transaction costs related to the Alynx merger.

See notes to consolidated financial statements.

47

#### **Table of Contents**

# MIMEDX GROUP, INC. (A DEVELOPMENT STAGE ENTERPRISE) NOTES TO CONSOLIDATED FINANCIAL STATEMENTS YEAR ENDED MARCH 31, 2008 AND PERIOD FROM INCEPTION (NOVEMBER 22, 2006) THROUGH MARCH 31, 2008 AND 2007

#### 1. Formation and nature of business:

Nature of business:

MiMedx, Inc. (MiMedx) was incorporated in Florida in 2006. MiMedx entered into an Agreement and Plan of Merger (Merger Agreement) with a publicly-traded Nevada Corporation, Alynx, Co. (Alynx), a public shell company, on February 8, 2008. As a result of this transaction, MiMedx shareholders owned approximately 97% of the outstanding shares, thus giving MiMedx substantial control.

Under U.S. generally accepted accounting principles ( GAAP ), MiMedx was deemed to be the accounting acquirer since the shareholders of MiMedx own a substantial majority of the issued and outstanding shares, and thus this reverse merger was accounted for as a capital transaction.

On March 31, 2008, MiMedx Group, Inc., a Florida Corporation, and Alynx merged. As a result of this transaction, MiMedx Group, Inc. became the surviving corporation. The Company refers to MiMedx Group, Inc., a development stage company, as well as its two operating subsidiaries: MiMedx and SpineMedica, LLC.

MiMedx acquired a license for the use, adoption and development of certain core technologies developed at the Shriners Hospital for Children and the University of South Florida Research Foundation. This technology focuses on biomaterials for soft tissue repair, such as tendons, ligaments and cartilage, as well as other biomaterial-based products for numerous other medical applications. The development of the licensed technologies will require continued research and development and, ultimately, the approval of the U.S. Food and Drug Administration (FDA) and/or foreign regulatory authorities in order for the Company to be able to generate revenues from the sale of its products. This process is expected to take at least two to four years, and there can be no assurance that the Company will be successful in its efforts to commercialize that licensed technology.

On July 23, 2007, MiMedx acquired SpineMedica Corp. through its wholly-owned subsidiary, SpineMedica, LLC (SpineMedica) (Note 4). SpineMedica Corp. was incorporated in the State of Florida on June 9, 2005 and its successor SpineMedica, LLC was incorporated in the State of Florida on June 27, 2007 and holds a license for the use of certain developed technologies related to spine repair. SpineMedica also owns certain assets (equipment) for the production of products based on a poly-vinyl alcohol-based hydrogel, similar to Salubria® biomaterial. Salubria® biomaterial has been used in other medical device applications and is cleared for use in the United States by the Food and Drug Administration (FDA) as a nerve cuff. The development of the licensed technologies will require continued research and development and, ultimately, the approval of the FDA and/or foreign regulatory authorities in order for the Company to be able to generate revenues from the sale of its products. This process is expected to take from twelve months up to seven years depending on the type of product and regulatory pathway, and there can be no assurance that SpineMedica will be successful in its efforts to commercialize the licensed technology. SpineMedica is also pursing clearance by foreign regulatory authorities to commercialize its first product outside the United States. This process also depends on the type of product and is expected to take twelve months for less regulated products and approximately two years for more regulated products.

Future products developed by SpineMedica may fall within less regulated classifications, allowing for earlier commercialization in the United States.

The Company currently operates in one business segment, musculoskeletal products, which will include the design, manufacture and marketing of four major market categories: soft-tissue reconstructive products, fixation devices, spinal products and joint reconstruction products including tendons and ligaments of the hand and upper and lower extremity joint markets, and procedure-specific instrumentation required to implant reconstructive systems. Fixation devices may include internal, bone-to-bone fixation devices that do not address the spine. Spinal products include artificial spinal discs to treat cervical pain and degeneration as well as lumbar indications, facet arthroplasty, intervertebral spacers, spinous process spacers, and other spinal systems and implants, as well as orthobiologics.

48

#### **Table of Contents**

The Company is a development stage enterprise and will remain as such until such time as significant revenues are generated, if ever.

#### 2. Significant accounting policies:

*Use of estimates:* 

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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 revenues and expenses during the reporting period. Actual results could differ from those estimates.

Principles of consolidation:

The financial statements include the accounts of MiMedx Group, Inc. and its wholly-owned subsidiary MiMedx and, subsequent to July 23, 2007, its wholly-owned subsidiary, SpineMedica. All significant inter-company balances and transactions have been eliminated.

Concentration of credit risk:

Cash and cash equivalents are maintained with major financial institutions in the United States. Deposits with these banks exceed the amount of insurance provided by the FDIC on such deposits. Generally, these deposits may be redeemed upon demand.

Cash and cash equivalents:

Cash and cash equivalents include all highly liquid investments with an original maturity of three months or less.

*Investment, related party:* 

Investment, related party at March 31, 2007 consisted of a common stock warrant in SpineMedica Corp. and was classified as an available for sale security and recorded at its fair value. The warrant was cancelled in connection with the acquisition of SpineMedica Corp. on July 23, 2007 (see Note 4). The carrying value of the warrant on that date was recognized as part of the purchase consideration.

Goodwill and intangible assets:

Goodwill is not amortized but is tested at least annually for impairment, or more frequently if events or changes in circumstances indicate that the asset might be impaired. Intangible assets with finite useful lives are amortized using the straight-line method over a period of 10 years, the remaining term of the patents underlying the licensing rights and intellectual property (considered to be the remaining useful life of the assets).

*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 (finite lived intangible assets and 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. There have been no impairment losses in the periods presented.

49

#### **Table of Contents**

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.

Acquired in-process research and development:

In connection with the acquisition of SpineMedica, the Company determined that approximately \$7.2 million of the fair value of the acquisition price qualified as in-process research and development, and as such, this amount was expensed as research and development expense on the acquisition date (see Note 4).

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.

Share-based compensation:

The Company follows the provisions of Statement of Financial Accounting Standards No. 123R Share-based Payments (SFAS123R) 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).

Fair value of financial instruments:

The fair value of due from related parties and note receivable, related party approximates its carrying amount due to its short-term maturity. The carrying value of due to related party and accounts payable and accrued expenses approximate their fair value due to the short-term nature of these liabilities.

Fair value determination of privately-held securities:

Prior to February 8, 2008, the fair values of the common stock as well as the common stock underlying options and warrants granted as part of asset purchase prices or as compensation were estimated by management with input from an unrelated valuation specialist. Determining the fair value of stock requires making complex and subjective judgments. The Company used the market approach to estimate the value of the enterprise at each date on which securities were issued or granted. The enterprise value was then allocated to preferred and common shares taking into account the enterprise value available to all stockholders and allocating that value among the various classes of stock based on the rights, privileges and preferences of the respective classes. There is inherent uncertainty in these estimates.

*Net loss per share / Reverse stock split* 

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

of common and dilutive common equivalent shares from stock options, warrants and convertible preferred stock using the treasury stock method.

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 preferred stock would be anti-dilutive. All share and per share amounts for all periods presented have been adjusted to give effect to the reverse stock split discussed in Note 7.

50

#### **Table of Contents**

The following table sets forth the computation of basic and diluted net loss per share for the year ended March 31, 2008 and the period from inception (November 22, 2006) to March 31, 2007:

|   | 2008            | 2007         |
|---|-----------------|--------------|
| Net loss  | \$ (17,371,475) | \$ (650,777) |
| Denominator for basic earnings per share-weighted average shares                                    | 17,909,903      | 8,537,000    |
| Effect of dilutive securities: Stock options and warrants outstanding (a)                           |                 |              |
| Denominator for diluted earnings per share weighted average shares adjusted for dilutive securities | 17,909,903      | 8,537,000    |
| Loss per common share basic and diluted   | \$ (0.97)       | \$ (.08)     |

(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:

Stock options, warrants, and convertible preferred stock

\*Recently issued accounting pronouncements:

2008

4,955,581

12,146,880

In June 2006, the Financial Accounting Standards Board (FASB) announced FASB Interpretation No. 48 Accounting for Uncertainty in Income Taxes (FIN 48), which is effective for fiscal year 2007. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with FASB Statement No. 109, Accounting for Income Taxes. FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The adoption of FIN 48 did not result in any changes to either the beginning stockholders equity (April 1, 2007) or the Company s financial position.

In September 2006, the FASB issued Statement No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 clarifies the principle that fair value should be based on the assumptions that market participants would use when pricing an asset or liability. Additionally, it establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. SFAS 157 is effective for financial statements issued for fiscal years beginning

after November 15, 2007. The adoption of SFAS 157 on April 1, 2008 is not expected to have a material impact on the Company s consolidated financial position, results of operations or cash flows. In February 2008, the FASB issued a staff position that delays the effective date of SFAS 157 for all nonfinancial assets and liabilities except for those recognized or disclosed at least annually.

In February 2007, the FASB issued Statement No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159), which establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. The standard requires companies to provide additional information that will help investors and other users of financial statements to more easily understand the effect of the company s choice to use fair value on its earnings. It also requires entities to display the fair value of those assets and liabilities for which the company has chosen to use fair value on the face of the balance sheet. The new Statement does not eliminate disclosure requirements included in other accounting standards, including requirements for disclosures about fair value measurements included in SFAS 157. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The adoption of SFAS 159 on April 1, 2008 is not expected to have a material impact on the Company s consolidated financial position, results of operations or cash flows.

51

#### **Table of Contents**

In December 2007, the FASB issued Statements No. 141R, *Business Combinations* (SFAS 141R) and No. 160 *Noncontrolling Interests in Consolidated Financial Statements* an amendment of ARB No. 51 (SFAS 160). SFAS 141R expands the scope of acquisition accounting to all transactions under which control of a business is obtained. Among other things, SFAS 141R requires that contingent consideration as well as contingent assets and liabilities be recorded at fair value on the acquisition date, and also requires transaction costs and costs to restructure the acquired company be expensed. SFAS 160 requires, among other things, that noncontrolling interests be recorded as equity in the consolidated financial statements. SFAS 141R and SFAS 160 are both effective January 1, 2009. The adoption of these standards will not have an impact on the Company s 2008 and 2007 consolidated financial statements.

In March 2008, the FASB issued Statement No. 161, *Disclosures about Derivative Instruments and Hedging Activities* (SFAS 161), which requires enhanced disclosures about how these instruments and activities affect the entity s financial position, financial performance and cash flows. The standard requires disclosure of the fair values of derivative instruments and their gains and losses in a tabular format. It also provides more information about an entity s liquidity by requiring disclosure of derivative features that are credit risk-related. Finally, it requires cross-referencing within footnotes to enable financial statement users to locate important information about derivative instruments. SFAS 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. Because SFAS 161 requires enhanced disclosures but does not modify the accounting treatment of derivative instruments and hedging activities, the Company believes the adoption of this standard will have no impact on its financial position, results of operations or cash flows.

#### 3. Liquidity and management s plans:

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. For the period from inception (November 22, 2006) through March 31, 2008 the Company experienced net losses of \$18,022,252 and cash used in operations of \$8,533,582. As of March 31, 2008, the Company has not emerged from the development stage. In view of these matters, the ability of the Company to continue as a going concern is dependent upon the Company s ability to generate additional financing sufficient to support its research and development activities, approval of developed products for sale by regulatory authorities, including the FDA, and ultimately to generate revenues sufficient to cover all costs. Since inception, the Company has financed its activities principally from the sale of equity securities and related party advances. The Company may seek to raise additional funds and such funds may not be available on favorable terms, or at all. Furthermore, if the Company issues equity or debt securities to raise additional funds, existing shareholders may experience dilution and the new equity or debt securities it issues may have rights, preferences and privileges senior to those of existing shareholders. In addition, if the Company raises additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to products or proprietary technologies, or grant licenses on terms that are not favorable. If the Company cannot raise funds on acceptable terms, the Company may not be able to develop or enhance products, obtain the required regulatory clearances or approvals, execute the Company s business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated customer requirements. Any of these events could adversely affect the Company s ability to achieve the Company s development and commercialization goals, which could have a material and adverse effect on the Company s business, results of operations and financial condition.

#### 4. SpineMedica Corp. acquisition:

On July 23, 2007, MiMedx purchased 100% of the capital stock of SpineMedica Corp. through a newly formed subsidiary, SpineMedica, LLC. SpineMedica s results of operations and cash flows are included in the accompanying financial statements from July 23, 2007 through March 31, 2008.

The acquisition was accounted for as a purchase and was accomplished through the issuance of 2,911,117 Common Shares of MiMedx (for the acquisition of the SpineMedica Corp. s Common Shares) and the issuance of 5,922,397 Series B Convertible Preferred Shares of MiMedx and 5,922,398 Common Stock Warrants (for the acquisition of SpineMedica Corp. Preferred Stock).

The Series B preferred stockholders had voting rights identical to those of common stockholders, were entitled to dividends only when, or if, declared by the Board of Directors and had preference over the common stockholders in the event of the Company s liquidation.

The Series B Preferred Stock was convertible into Common Stock of MiMedx at the option of the holder at any time on a one share for one share basis, subject to adjustment for stock splits, stock dividends, recapitalizations and the like. All preferred stock automatically was to convert to common stock upon the Company becoming a publicly traded company, an upstream merger or consolidation, a sale of substantially all the Company s assets or the consent of holders of the majority of the then outstanding shares of Series B Preferred Stock. As a result of the Alynx merger transaction, discussed in Note 7, all Series B Preferred Stock was exchanged for New Series A Preferred Stock.

52

#### **Table of Contents**

The Common Stock Warrants were exercisable at \$.01 per share from January 2009 through January 2010 and were automatically cancelled under any of the following conditions:

Preferred Stock sales for at least \$3.00 per share

Sale of a controlling interest in the Company of at least \$3.00 per share

Issuance of securities by the Company with \$2,000,000 minimum proceeds at a minimum price of \$3.00 per share

Trading of the Series B Preferred Stock on a national or regional exchange, quotation system, or the OTCBB at a closing price of at least \$3.00 per share for 15 out of 20 days on a rolling basis.

These Common Stock Warrants were cancelled on September 30, 2007 as the result of the Series C Convertible Preferred Stock sale (Note 7).

In addition, the Company assumed 1,333,750 common stock options and 175,251 common stock warrants to the holders of an equal number of SpineMedica Corp. options and warrants in connection with the acquisition. Terms of those options and warrants are summarized as follows:

#### Stock options:

| Exercise price            | \$1.80       |
|---------------------------|--------------|
|                           | April 2011 - |
| Range of expiration dates | April 2017   |
|                           |              |
| Warrants:                 |              |
| Exercise price            | \$1.80       |
|                           | October      |
| Expiration date           | 2010         |

Finally, the Company s note receivable, related party, deferred interest income related thereto and common stock warrant in SpineMedica (recorded as investment, related party) were cancelled pursuant to this transaction.

The SpineMedica acquisition was accounted for as a purchase and is summarized as follows (in thousands \$):

| Purchase price components:                                       |    |        |
|--|----|--------|
| Common stock issued  | \$ | 2,300  |
| Preferred stock issued   |    | 7,403  |
| Common stock warrants issued                                     |    | 20     |
| Expenses incurred on acquisition                                 |    | 238    |
| Cancellation of note receivable from and warrants in SpineMedica |    | 2,049  |
|  |    |        |
| Total consideration  | \$ | 12,010 |
|  |    |        |
| Allocation of mushoos union                                      |    |        |
| Allocation of purchase price:                                    | Ф  | 1.057  |
| Cash (acquired at closing)                                       | \$ | 1,957  |
| Prepaid expenses and other current assets                        |    | 19     |
| Property and equipment   |    | 464    |
| Intangible assets (licenses - 10 year amortization period)       |    | 2,399  |
| Deposits   |    | 34     |
| Current liabilities  |    | (898)  |

| Net assets received                     | 3,975        |
|---|--------------|
| Goodwill                                | 858          |
| In-process research and development (1) | 7,177        |
|   |              |
|   | \$<br>12,010 |

(1) The in-process research and development (IPR&D) acquired was related to two products, a cervical total disc replacement device and a posterior lumbar interbody fusion

device.

53

#### **Table of Contents**

Significant assumptions used in connection with the determination of the value of the IPR&D were as follows:

Material cash inflows from the products were anticipated to commence in 2008.

Material anticipated changes from historical pricing and margins were not considered as there was no history for the products. There were projected increases in expenditures associated with the products development over the historical levels in order to advance the products through any regulatory agencies. The risk adjusted discount rate applied to the estimated future cash flows was 43%.

The following pro-forma information presents a summary of the Company s consolidated results of operations as if the SpineMedica acquisition had occurred at inception (November 22, 2006):

|                      |                 | Period from    | Period from     |
|----------------------|-----------------|----------------|-----------------|
|                      |                 | Inception      | Inception       |
|                      |                 | (November 22,  | (November 22,   |
|                      | Year            | 2006)          | 2006)           |
|                      | Ended           | through        | through         |
|                      | March 31, 2008  | March 31, 2007 | March 31, 2008  |
| Loss from operations | \$ (12,482,000) | \$ (9,233,000) | \$ (21,715,000) |
| Net loss             | (12,073,000)    | (9,202,000)    | \$ (21,275,000) |

#### 5. Property and equipment:

Property and equipment consist of the following at March 31,:

|                               | 2008         | 2007     |
|-------------------------------|--------------|----------|
| Leasehold improvements        | \$ 746,382   | \$       |
| Furniture and equipment       | 897,642      | 8,072    |
|                               | 1,644,024    | 8,072    |
| Less accumulated depreciation | (191,588)    | (807)    |
|                               | \$ 1,452,436 | \$ 7,265 |

#### 6. Intangible assets and royalty agreement:

Intangible assets activity is summarized as follows:

|                | License (a) | License (b) | License (c) | Intellectual<br>Property (d) | Total     |
|----------------|-------------|-------------|-------------|------------------------------|-----------|
| Inception      |             |             |             |                              |           |
| Additions      | 996,000     |             |             |                              | 996,000   |
| Amortization   | (14,933)    |             |             |                              | (14,933)  |
| March 31, 2007 | 981,067     |             |             |                              | 981,067   |
| Additions      |             | 2,399,001   | 2,596,000   | 116,000                      | 5,111,001 |
| Amortization   | (99,601)    | (203,514)   |             | (5,800)                      | (308,915) |
| March 31, 2008 | 881,466     | 2,195,487   | 2,596,000   | 110,200                      | 5,783,153 |

(a) On January 29,

2007, the

Company

acquired a

license from

**Shriners** 

Hospitals for

Children and

University of

South Florida

Research

Foundation, Inc.

which is further

discussed in

Note 1. The

acquisition price

of this license

was a one-time

fee of \$100,000

and 1,120,000

shares of

common stock

valued at

\$896,000 (based

upon the

estimated fair

value of the

common stock

on the

transaction

date). Within

thirty 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. This

amount is not

recorded as a

liability as of

March 31, 2008

based on its contingent nature. The Company will also be required to pay a royalty of 3% on all commercial sales revenues of the licensed products.

- (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. (see Notes 1 and 4).
- (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 acquisition price of the asset was 400,000 shares of common stock valued at

\$2,596,000 (based upon the closing price of the common stock on the transaction date). The agreement also provides for the issuance of an additional 600,000 shares upon the Company meeting certain milestones related to future sales. At March 31, 2008, there are no amounts accrued for this obligation due to its contingent nature.

(d) During the year ended March 31, 2008, the Company issued 200,000 stock options valued at \$116,000 for certain technologies relating to medical device designs for products used in hand surgery. The agreement also provides for royalty payments upon approval and sale of certain products (Note 10). At March 31, 2008, there are no

amounts accrued for this obligation due to its contingent nature.

Expected future amortization of intangible assets is as follows:

| Year ending March 31, |              |
|-----------------------|--------------|
| 2009                  | \$ 666,821   |
| 2010                  | 666,821      |
| 2011                  | 666,821      |
| 2012                  | 666,821      |
| 2013                  | 666,821      |
| Thereafter            | 2,449,048    |
|                       |              |
|                       | \$ 5,783,153 |

#### 7. Stockholders equity:

Alynx merger transaction:

On January 29, 2008 MiMedx entered into an Agreement and Plan of Merger ( Merger Agreement ) with Alynx. The merger transaction became effective on February 8, 2008.

In accordance with the Merger Agreement, Alynx issued 52,283,090 shares of common stock to MiMedx shareholders based on a conversion rate of 3.091421 for each share of MiMedx common stock. All Preferred Stock of MiMedx (Series A, B and C) was exchanged for a Series A Preferred Stock of Alynx based on a conversion rate of one share of Alynx Series A Preferred Stock for every five shares of MiMedx Preferred Stock . The Alynx Series A preferred stock was convertible into common stock and contained no cash redemption features. As of March 31, 2008, all of the Alynx Series A Preferred Stock shares were converted into common shares of the Company at a rate of five shares of Common Stock of the Company for every one share of Series A Preferred Stock of Alynx.

The Company incurred approximately \$1,870,000 of merger costs related to the merger acquisition. These costs, (including 205,851 shares of common stock which had a value of approximately \$1,126,000) are included in general and administrative expenses in the statement of operations for the year ended March 31, 2008.

55

#### **Table of Contents**

Because Alynx had *de minimis* operations, the merger transaction was accounted for as a reverse acquisition (recapitalization) whereby MiMedx was deemed to be the acquirer for accounting purposes.

Reverse Stock Split:

On March 31, 2008, with shareholder approval, the Company affected a reverse stock split. Each share of common stock was converted into .3234758 shares of post reverse split shares of common stock. All share amounts have been retro-actively adjusted for all periods presented.

Conversion of Alynx Series A Preferred Stock:

The following series of preferred stock were issued prior to the Alynx merger transaction and, as previously discussed, were all redeemed through the issuance of Alynx Series A Preferred Stock:

Preferred Series A stock:

During the period ended March 31, 2007, MiMedx issued 11,212,800 shares of Series A Convertible Preferred Stock for \$13,097,194 (\$14,016,000 net of \$918,806 transaction expenses). Additionally, the placement agent received detachable warrants to acquire up to 524,080 shares of the Company s common stock at \$1.25 per share with a fair value of \$183,428 on the date of issuance. The warrants expire on April 15, 2012.

The preferred stockholders had voting rights identical to those of common stockholders, were entitled to dividends only when, or if, declared by the Board of Directors and had preference over the common stockholders in the event of the Company s liquidation.

The preferred stock was convertible into common stock at the option of the holder at any time on a one share for one share basis, subject to adjustment for stock splits, stock dividends, recapitalizations and the like.

This preferred stock was to automatically convert to common stock upon the Company becoming a publicly traded company, an upstream merger or consolidation, a sale of substantially all the Company s assets or the consent of holders of the majority of the then outstanding shares of Series A Preferred Stock. There was no beneficial conversion feature associated with this transaction.

Preferred series B stock:

In connection with the SpineMedica acquisition the Company issued 5,922,397 shares of Series B Convertible Preferred Stock. See Note 4.

Preferred series C stock:

The Company sold 1,285,001 shares of Preferred Series C Stock for \$3,855,000 or \$3.00 per share in September and October 2007. Preferred Series C stockholders had voting rights

identical to those of common stockholders, were entitled to dividends only when, or if, declared by the Board of Directors and had preference over the common stockholders in the event of the Company s liquidation. The preferred stock was convertible into common stock at the option of the holder at any time on a one share for one share basis, subject to adjustment for stock splits, stock dividends, recapitalizations and the like.

This preferred stock was to automatically convert to common stock upon the Company becoming a publicly traded company, an upstream merger or consolidation, a sale of substantially all the Company s assets or the consent of holders of the majority of the then outstanding shares of Series C preferred stock.

56

#### **Table of Contents**

#### Registration rights agreement:

Certain shareholders of the Company presently have registration rights covering 18,420,200 shares of the Company s common stock. Such rights are contingent upon the Company receiving in the aggregate a minimum of \$10,000,000 in cash from the sale of the Company s securities that are registered under Section 12 of the Exchange Act. The majority of the holders of the registration rights can demand the Company use its best efforts to register such shares, up to two occasions but not more than once in any 12-month period, subject to certain restrictions, commencing nine months after the completion of such financing. The holders of those shares also have certain piggyback registration rights. These registration rights shall expire upon the earlier of the fifth anniversary from when the Company has its first underwritten public offering or the date when the holder of such shares shall be able to sell their registrable shares under Rule 144. Pursuant to a separate agreement, the holders of an additional approximately 17,600 shares of the Company s common stock have similar piggyback registration rights.

Note receivable and investment, related party:

During March 2007, the Company loaned SpineMedica \$2,000,000. SpineMedica was related to the Company due to the existence of certain relationships among common stockholders with those of the Company. The loan was due on March 12, 2008, including interest at prime (7.75% at March 31, 2007) and was included in the Statement of Stockholders Equity. This note was collateralized by 1,800,000 shares of SpineMedica common stock and rights to SpineMedica s license with SaluMedica, LLC. In addition to the note receivable, the Company also received a warrant dated March 12, 2007 to acquire 270,000 shares of SpineMedica common stock with an expiration of six years and a fair value at both March 12 and 31, 2007 of \$172,800. The warrant was classified as investment, related party in the accompanying March 31, 2007 balance sheet and was considered an available for sale security. This note and warrant were terminated as part of the SpineMedica acquisition in July 2007 (Note 4).

Stock incentive plan:

The Company has three share-based compensation plans (the 2006 Plan , Assumed 2007 Plan and Assumed 2005 Plan which provides 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 2007 Plan that were outstanding at March 31, 2008 were 1,333,750 and the maximum number of shares of common stock which can be issued under the 2006 Plan is 5,500,000 at March 31, 2008.

57

#### **Table of Contents**

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

|  |           | Range of Exercise | Weighted-<br>average<br>Option<br>Price Per | Intrinsic  |
|--|-----------|-------------------|---|------------|
|  | Shares    | Prices            | Share                                       | Value      |
| Balance at November 22, 2006   |           | \$                | \$  |            |
| Options granted  | 410,000   | .0001 - 1.00      | .66   |            |
| Outstanding at March 31, 2007  | 410,000   | .0001 - 1.00      | .66   |            |
| Options exercisable at March 31, 2007                                    | 177,500   | .0001 - 1.00      | .80   | \$ 110,586 |
| Options granted April 1, 2007 - March 31, 2008                           | 3,102,500 | 1.00 - 5.44       | 2.51  |            |
| SpineMedica outstanding options assumed at July 23, 2007 by MiMedx, Inc. | 1,333,750 | 1.80              | 1.80  |            |
| Options expired April 1, 2007 - March 31, 2008                           | (600,000) | 1.80 - 2.40       | 1.93  |            |
| Options outstanding at March 31, 2008                                    | 4,246,250 | .0001 - 5.44      | 2.19  |            |
| Options exercisable at March 31, 2008                                    | 2,036,667 | \$ .0001 - 5.44   | \$ 4.56                                     | \$ 964,598 |

Following is a summary of stock options outstanding and exercisable at March 31, 2008:

|                       |             | Options Outstanding Weighted- |         |          | Options E   | xercisab | le         |
|-----------------------|-------------|-------------------------------|---------|----------|-------------|----------|------------|
|                       |             | Average                       | Weig    | ghted-   |             | We       | ighted-    |
|                       | Number      | Remaining                     | Ave     | erage    | Number      | Av       | verage     |
| <b>Exercise Price</b> | Outstanding | Contractual Life              | Exercis | se Price | Exercisable | Exerc    | eise Price |
| \$.0001 1.00          | 1,270,000   | 3.94                          | \$      | .89      | 529,167     | \$       | .87        |
| 1.80 2.40             | 2,376,250   | 6.39                          |         | 2.06     | 1,357,500   |          | 1.93       |
| 5.44                  | 600,000     | 4.90                          |         | 5.44     | 150,000     |          | 5.44       |
|                       |             |                               |         |          |             |          |            |
|                       | 4,246,250   | 5.45                          |         | 2.19     | 2,036,667   |          | 4.56       |

58

#### **Table of Contents**

A summary of the status of the Company s unvested stock options follows:

| Unvested Stock Options  | Shares             | Weighted<br>Average<br>Grant Date<br>Fair Value |
|---|--------------------|---|
| Balance at November 22, 2006  |                    | \$  |
| Granted   | 410,000            | .20   |
| Vested  | (177,500)          | .24   |
| Unvested at March 31, 2007  SpineMedica unvested options assumed at July 23, 2007 by MiMedx, Inc. | 232,500<br>376,875 | .17<br>1.80                                     |
| Granted   | 3,102,500          | .80   |
| Vested  | (902,292)          | .46   |
| Expired   | (600,000)          | .30   |
| Unvested at March 31, 2008  | 2,209,583          | .49   |

Total unrecognized compensation expense at March 31, 2008 was approximately \$1,925,000 and will be charged to expense through March 2011.

The fair value of the options granted was estimated on the date of grant using the Black-Scholes 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 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 option-pricing model are set forth in the following table:

|                          | Year Ended       | Period Ended     |
|--------------------------|------------------|------------------|
|                          | March 31, 2008   | March 31, 2007   |
| Dividend yield           | 0%               | 0%               |
| Expected volatility      | 45.53% to 64.97% | 59.29% to 59.89% |
| Risk free interest rates | 2.24% to 5.10%   | 4.54% to 4.74%   |
| Expected lives           | 2.75 to 5 years  | 1.5 to 3.5 years |

The weighted-average grant date fair value for options granted during the year ended March 31, 2008, and the period from inception (November 22, 2006) through March 31, 2007, was approximately \$1.07, and \$.17, respectively.

#### Warrants:

The Company grants common stock warrants in connection with direct equity shares purchases by investors as an additional incentive for providing long term equity capital to the Company and as additional compensation to consultants and advisors. The warrants are granted at negotiated prices in connection with the equity share purchases and at the market price of the common stock in other instances. The warrants have been issued for terms of five years. Common Stock warrants issued, redeemed and outstanding during the year ended March 31, 2008 and for the period from inception (November 22, 2006) thru March 31, 2007 are as follows:

|   |             | $\mathcal{C}$ | ted Average xercise |
|---|-------------|---------------|---------------------|
|   | Number      | Price         | per Share           |
| Warrants outstanding at November 22, 2006                     |             | \$            |                     |
| Warrants issued during the period ended March 31, 2007        | 524,080     |               | 1.25                |
| Warrants outstanding at March 31, 2007                        | 524,080     | \$            | 1.25                |
| Warrants assumed by MiMedx on July 23, 2007 (Note 4)          | 175,251     |               | 1.80                |
| Warrants issued on July 23, 2007 (Note 4)                     | 5,922,398   |               | .01                 |
| Warrants cancelled during the year ended March 31, 2008 (Note |             |               |                     |
| 4)  | (5,922,398) |               | .01                 |
| Warrants issued during the year ended March 31, 2008          | 10,000      |               | 3.00                |
| Warrants outstanding at March 31, 2008                        | 709,331     | \$            | 1.41                |

#### 8. Income taxes:

Significant items comprising the Company's deferred tax assets and liabilities are as follows at March 31,:

|                                   | 2008        | 2007      |
|-----------------------------------|-------------|-----------|
| Deferred tax assets:              |             |           |
| Share-based compensation expense  | \$ 398,000  | \$ 12,000 |
| Furniture, software and equipment | 283,000     |           |
| Accrued expenses                  | 51,000      |           |
| Net operating loss carryforward   | 5,251,000   | 231,000   |
|                                   | 5,983,000   | 243,000   |
| Deferred tax liabilities:         |             |           |
| Intangible assets                 | (78,000)    |           |
| Valuation allowance               | (5,905,000) |           |
|                                   | \$          | \$        |

#### **Table of Contents**

The reconciliation of the Federal statutory income tax rate of 34% to the effective rate is as follows at March 31:

|                                     | 2008     | 2007     |
|-------------------------------------|----------|----------|
| Federal statutory rate              | 34.00%   | 34.00%   |
| State taxes, net of federal benefit | 3.96%    | 3.96%    |
| Acquisition adjustment              | 17.08%   | %        |
| Permanent difference                | (22.45%) | (0.80%)  |
| Valuation allowance                 | (32.59%) | (37.16%) |
|                                     | %        | %        |

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

The Company has incurred net losses since its inception and, therefore, no current income tax liabilities have been incurred for the periods presented. The amount of unused tax losses available to carry forward and apply against taxable income in future years totaled approximately \$13,800,000 at March 31, 2008. The loss carry forwards expire in 2028. Due to the Company s losses, management has established a valuation allowance equal to the amount of net deferred tax assets since management cannot determine that realization of these benefits is more likely than not.

Under Section 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a loss corporation, as defined, there are annual limitations on the amount of the net operating loss and other deductions which are available to the Company. At this time the Company has not yet determined whether some of these losses may be subject to these limitations.

## 9. Related party transactions:

Due to related party:

Due to related party at March 31, 2007 consisted of a short-term \$500,000 unsecured, non-interest bearing advance from the Chairman of the Board. This amount was repaid in April 2007.

Due from related parties:

Due from related parties at March 31, 2007 consisted of:

| Due from Dimensional Research, Inc. (a) | \$<br>28,734 |
|---|--------------|
| Due from Surgi-Vision, Inc. (a)         | 1,391        |
|   | \$<br>30.125 |

(a) Non-interest

bearing,

unsecured

advances due

from companies

related through

partial common

ownership.

Amounts were

repaid as of

March 31, 2008.

See Note 7 for *Note receivable and investment, related party.* 

Related party expense:

The Company incurred expenses of approximately \$105,000 during the year ended March 31, 2008 related to aircraft use from an entity owned by the Chairman of the Board.

The Company incurred expenses of approximately \$25,000 during the year ended March 31, 2008 related to the lease of office space from an entity owned by the Chairman of the Board.

61

## **Table of Contents**

The Company incurred expenses of approximately \$290,000 during the year ended March 31, 2008 for legal fees provided by an entity in which one of our Board Members serves as a partner.

All the above related party expenses were included in general and administrative expenses in the accompanying consolidated statements of operations.

The Company incurred no related party expenses during the period ended March 31, 2007.

#### 10. Commitments:

Consulting agreements:

The Company has entered into consulting agreements with individuals to provide consulting and advisory services to the Company. The agreements provide for terms of three years.

At March 31, 2008 the minimum future consulting payments due under non-cancellable consulting agreements with remaining terms in excess of one year are as follows:

| 2009 | \$<br>296,000 |
|------|---------------|
| 2010 | 275,000       |
| 2011 | 31,000        |

Total minimum payments \$ 602,000

Under one consulting agreement the Company will also be required to pay a royalty upon approval and sale of certain products (Note 6).

Employment agreements:

The Company has entered into employment agreements with terms ranging from one to three years. At March 31, 2008 the minimum future employment payments due under these agreements are as follows:

| Years ending March 31, |              |
|------------------------|--------------|
| 2009                   | \$ 1,276,000 |
| 2010                   | 1,015,000    |

Total minimum payments \$ 2,291,000

#### Leases:

The Company leases office space in Tampa, Florida and Marietta, Georgia. These leases expire during 2013 and 2012, respectively.

Future minimum lease payments under these operating leases are as follows:

| Years ending March 31, |  |
|------------------------|--|
| 2000                   |  |

| 2009 | \$<br>245,000 |
|------|---------------|
| 2010 | 279,000       |
| 2011 | 285,000       |
| 2012 | 190,000       |
| 2013 | 56,000        |

Total minimum payments \$ 1,055,000

Rent expense on all operating leases for the periods ended March 31, 2008 and 2007, was approximately \$162,000 and \$5,000, respectively.

# Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure None

#### **Item 9A(T). Controls and Procedures**

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

We have not included a management s report on internal control over financial reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15 and 15d-15 under the Exchange Act (ICFR). Our ICFR should be designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles.

The Company s predecessor, Alynx, Co., was previously a shell company with the objective to acquire an operating business. As such, it only had to maintain internal and disclosure controls on a very limited number of activities, and also, was in a transition period for newly public companies established by the SEC for compliance with the internal control over financial reporting requirements of Section 404 of SOX. On February 8, 2008, Alynx, Co. acquired MiMedx, Inc., a privately held, development-stage company, and its affiliated companies, in a transaction accounted for as a reverse merger (the Acquisition). Upon the consummation of the Acquisition, Alynx, Co. s former internal controls and management were entirely supplanted by those of MiMedx, Inc. and its affiliates. In effect, this annual report on Form 10-K for the year ending March 31, 2008 is the first annual or quarterly report that has been filed with respect to the assets and operations of MiMedx.

Our new and current management acknowledges that they are responsible for establishing and maintaining adequate internal control over financial reporting for the Company. Because of the abbreviated period of less than two months during which the Company, operating as MiMedx, was a reporting company during the fiscal year ended March 31, 2008, management had not completed as of March 31, 2008, an assessment of the Company s internal control over financial reporting under a recognized control framework. That assessment process is ongoing and will be completed during the 2009 fiscal year. Accordingly, the Company will include management s report on its assessment regarding internal control over financial reporting in its next annual report. As of the date of this filing, management has not identified any material weaknesses.

This annual report on Form 10-K does not include an attestation report of the Company s registered public accounting firm regarding internal control over financial reporting due to a transition period established by the rules of the SEC. We anticipate that our internal control system will be designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of published financial statements. The steps management expects to undertake include a top-down risk assessment of all risks associated over financial reporting and disclosure, the identification and ranking of risks and the corresponding financial accounts and business processes. Additionally, the associated system applications will be identified, as well as the controls over information technology and general computer controls. Company-wide controls will also be identified and documented. This control environment will be reviewed and assessed to allow management to conclude regarding the effectiveness of the design of the controls as well the operating effectiveness. In making its assessment of internal control over financial reporting, management anticipates using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control Integrated Framework. We have hired new accounting personnel. In addition, we are in the process of implementing a comprehensive new accounting software system and are in the process of retaining the services of a consulting business specializing in audit, compliance, financial management, and support.

All internal control over financial reporting, no matter how well designed, have inherent limitations, including the possibility of human error and the circumvention or overriding of controls. Therefore, even effective internal control over financial reporting can provide only reasonable assurance with respect to financial statement preparation and presentation. Further, because of changes in conditions, the effectiveness of internal controls over financial reporting may vary over time.

Notwithstanding the foregoing, we believe that the financial statements and other information included in this annual report on Form 10-K fairly present in all material respects our financial position, business, and results of operations.

#### **Table of Contents**

#### **Changes in Internal Control over Financial Reporting**

As described above, the Company s predecessor, Alynx, Co., was previously a publicly traded shell corporation that had no operating activities, and upon consummation of the Acquisition, the Company s legacy ICFR and management were entirely supplanted by those of MiMedx, a private company that did not have to perform an assessment of ICFR. Accordingly, as a result of the Acquisition, all of the ICFR during the fiscal year ended March 31, 2008 that have materially affected, or are reasonably likely to materially affect, the Company s ICFR have changed, and the controls, processes and systems in place at the Company prior to the Acquisition should no longer be relied upon.

## **Evaluation of Disclosure Controls and Procedures**

Our management is responsible for establishing and maintaining a system of disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Exchange Act of 1943, as amended) that is designed to ensure that information required to be disclosed by the Company in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer s management, including its principal executive officer or officers and principal financial officer or officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Under the supervision and participation of our management, including our Chief Executive Officer and Chief Financial Officer, for the reasons set forth above we have been unable to complete an evaluation of the effectiveness of our disclosure controls and procedures as such term in defined under Rules 13a-15 and 15d-15 of the Exchange Act and are still in the process of conducting such an evaluation. We believe that we will have effective internal controls to meet this requirement prior to the filing of our annual report for the year ended March 31, 2009.

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

None.

64

#### **PART III**

#### Item 10. Directors, Executive Officers and Corporate Governance

Information required by this Item will be contained in our definitive proxy statement relating to our Annual Meeting of Shareholders under the captions Corporate Governance, Executive Officers, Nominees for Election of Directors and Section 16(a) Beneficial Ownership Reporting Compliance, or similar captions which are incorporated herein by reference.

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

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

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

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

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters
Information required by this Item will be contained in our definitive proxy statement relating to our Annual Meeting
of Shareholders under the captions Security Ownership of Certain Beneficial Owners and Management, Executive
Compensation, and Equity Compensation Plan Information, which is incorporated herein by reference.

## Item 13. Certain Relationships and Related Transactions, and Director Independence

Information required by this Item will be contained in our definitive proxy statement relating to our Annual Meeting of Shareholders under the caption Certain Relationships and Related Transactions, which is incorporated herein by reference.

#### **Item 14. Principal Accounting Fees and Services**

Information required by this Item will be contained in our definitive proxy statement relating to our Annual Meeting of Shareholders under the captions Ratification of Appointment of Independent Registered Public Accounting Firm and Corporate Governance, which are incorporated herein by reference.

65

#### **PART IV**

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

#### (a) Financial Statements.

The following consolidated financial statements and supplementary data of the Company and its subsidiaries, required by Part II, Item 8 are filed herewith:

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of March 31, 2008 and March 31, 2007

Consolidated Statements of Operations for the year ended March 31, 2008 and the periods from inception (November 22, 2006) through March 31, 2007 and 2008.

Consolidated Statements of Shareholders Equity and for the year ended March 31, 2008 and the period from inception (November 22, 2006) through March 31, 2007.

Consolidated Statements of Cash Flows for the year ended March 31, 2008 and the periods from inception (November 22, 2006) through March 31, 2007 and 2008.

Notes to Consolidated Financial Statements

#### (b) Exhibits.

The exhibits filed herewith or incorporated by reference are listed on the Exhibit Index included at the end of this report.

66

#### **Table of Contents**

#### **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this amendment to be signed on its behalf by the undersigned, thereunto duly authorized.

## MIMEDX GROUP, INC.

Date: June 27, 2008 By: /s/ John C. Thomas, Jr.

John C. Thomas, Jr. Chief Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| Signature / Name        | Title   | Date          |
|-------------------------|---|---------------|
| /s/ Thomas W. D. Alonzo | Chief Executive Officer (principal executive officer) | June 27, 2008 |
| Thomas W. D Alonzo      | •   |               |
| /s/ John C. Thomas, Jr. | Chief Financial Officer and Secretary                 | June 27, 2008 |
| John C. Thomas, Jr.     | (principal financial and accounting officer)          |               |
| /s/ Steve Gorlin        | Chairman of the Board                                 | June 27, 2008 |
| Steve Gorlin            |   |               |
| /s/ Kurt M. Eichler     | Director  | June 27, 2008 |
| Kurt M. Eichler         |   |               |
| /s/ Charles E. Koob     | Director  | June 26, 2008 |
| Charles E. Koob         |   |               |
| /s/ Larry W. Papasan    | Director  | June 27, 2008 |
| Larry W. Papasan        |   |               |
| /s/ Ronald G. Wallace   | Director  | June 27, 2008 |
| Ronald G. Wallace       |   |               |
|                         | 67  |               |

## **EXHIBIT INDEX**

| Exhibit Number | Description  |
|----------------|--|
| 2.1 (1)        | Agreement and Plan of Merger, dated as of January 29, 2008, between Alynx, Co., MMX Acquisition Corp., and MiMedx, Inc.  |
| 2.2 (1)        | Articles of Merger, dated February 8, 2008, between MMX Acquisition Corp. and MiMedx, Inc.   |
| 2.2 (2)        | Agreement and Plan of Merger, dated as of March 10, 2008, between Alynx, Co. and MiMedx Group, Inc.  |
| 3.1 (3)        | Articles of Incorporation of MiMedx Group, Inc.  |
| $3.2^{(3)}$    | Bylaws of MiMedx Group, Inc.   |
| 4.1 (1)        | Amended and Restated Registration Rights Agreement dated July 23, 2007 between MiMedx, Inc. and the holders of Preferred Stock   |
| 4.2 (1)        | Registration Rights Agreement dated February 8, 2008 between Alynx, Co. and certain Alynx shareholders   |
| 4.3 (1)        | Form of Warrant to purchase MiMedx common stock  |
| 10.1 (1)*      | MiMedx, Inc. 2006 Stock Incentive Plan   |
| 10.1 (1) *     | Declaration of Amendment to MiMedx, Inc. 2006 Stock Incentive Plan   |
| 10.2 (1) *     | Form of Incentive Award Agreement under the MiMedx, Inc. 2006 Stock Incentive Plan, including a list of officers and directors receiving options thereunder  |
| 10.3 (1) *     | Form of Nonqualified Incentive Award Agreement under the MiMedx, Inc. 2006 Stock Incentive Plan, including a list of officers and directors receiving options thereunder   |
| 10.4 (1) *     | MiMedx, Inc. 2005 Assumed Stock Plan (formerly the SpineMedica Corp. 2005 Employee, Director and Consultant Stock Plan)  |
| 10.5 (1) *     | Declaration of Amendment to MiMedx, Inc. 2005 Assumed Stock Plan (formerly the SpineMedica Corp. 2005 Employee, Director and Consultant Stock Plan)  |
| 10.6 (1) *     | Form of Incentive Award Agreement under the MiMedx, Inc. Assumed 2005 Stock Plan (formerly the SpineMedica Corp. 2005 Employee, Director and Consultant Stock Plan), including a list of officers and directors receiving options thereunder |
| 10.7 (1) *     | Form of Nonqualified Incentive Award Agreement under the MiMedx, Inc. Assumed 2005<br>Stock Plan (formerly the SpineMedica Corp. 2005 Employee, Director and Consultant Stock<br>Plan)   |
| 10.8 (1) *     | MiMedx, Inc. Assumed 2007 Stock Plan (formerly the SpineMedica Corp. 2007 Stock Incentive Plan)  |
| 10.9 (1) *     | Declaration of Amendment to MiMedx, Inc. Assumed 2007 Stock Plan (formerly the SpineMedica Corp. 2007 Stock Incentive Plan)  |
| 10.10 (1) *    | Form of Incentive Award Agreement under the MiMedx, Inc. Assumed 2007 Stock Plan (formerly the SpineMedica Corp. 2007 Stock Incentive Plan)  |
| 10.11 (1) *    | Form of Nonqualified Incentive Award Agreement under the MiMedx, Inc. Assumed 2007 Stock Plan (formerly the SpineMedica Corp. 2007 Stock Incentive Plan)   |
| 10.12 (1)      | Form of MiMedx, Inc. Employee Proprietary Information and Inventions Assignment Agreement  |
| 10.13 *(1)     | Employment Agreement between MiMedx, Inc. and Steve Gorlin   |
| 10.14 *(1)     | Employment Agreement between MiMedx, Inc. and John C. Thomas, Jr.  |
| 10.15 *(1)     | Employment Agreement between MiMedx, Inc. and Matthew J. Miller  |
| 10.16 *(1)     | Employment Agreement between MiMedx, Inc. and Thomas W. D. Alonzo  |
| 10.17 *(1)     | Employment Agreement between MiMedx, Inc. and Maria Steele   |
| 10.18 *(1)     | Employment Agreement between MiMedx, Inc. and Thomas Koob, Ph.D.   |

| 10.19 *(1) | Employment Agreement between MiMedx, Inc. and Louise Focht                             |
|------------|--|
| 10.20 *(4) | Employment Agreement between Alynx, Co. and Brian Splan                                |
| 10.21 (1)  | Sublease Agreement between MiMedx, Inc. and The Gorlin Companies, LLC dated April 1,   |
|            | 2007   |
| 10.22 (1)  | Lease Agreement between MiMedx, Inc. and the Andrews Institute Medical Park, LLC dated |
|            | June 12, 2007  |

68

## **Table of Contents**

| Exhibit Number | Description  |
|----------------|--|
| 10.23 (1)      | Lease between MiMedx, Inc. and University of South Florida Research Foundation,  |
|                | Incorporated dated March 6, 2007   |
| 10.24 (1)      | Amendment to Lease Agreement between MiMedx, Inc. and the Andrews Institute Medical                                      |
|                | Park, LLC dated June 12, 2007  |
| 10.25 (1)      | Agreement and Plan of Merger among MiMedx, Inc., SpineMedica Corp., and SpineMedica,                                     |
|                | LLC dated as of July 23, 2007  |
| 10.26 (1)      | Consulting Agreement between MiMedx, Inc. and James Andrews, M.D.  |
| 10.27 #        | Consulting Agreement between MiMedx, Inc. and Thomas Graham, M.D.  |
| 10.28 (1)      | Consulting Agreement between MiMedx, Inc. and Joseph Story, M.D.   |
| 10.29 (1)      | Form of MiMedx, Inc. Physician Advisory Board Consulting Agreement   |
| 10.30 (1)      | Joint Development Agreement between MiMedx, Inc. and Offray Specialty Narrow Fabrics,                                    |
|                | Inc. dated October 18, 2007  |
| 10.31 (1)      | Collaborative Research and Evaluation Agreement between MiMedx, Inc. and Regeneration                                    |
|                | Technologies, Inc. dated November 1, 2007  |
| 10.32 (1)      | Technology License Agreement between MiMedx, Inc., Shriners Hospitals for Children, and                                  |
|                | University of South Florida Research Foundation dated January 29, 2007   |
| 10.33 (1)      | Technology License Agreement between SpineMedica Corp. and SaluMedica, LLC dated   |
|                | August 12, 2005  |
| 10.34 (1)      | Trademark License Agreement between SaluMedica, LLC and SpineMedica Corp. dated  |
|                | August 12, 2005  |
| 10.35 (1)      | Technology License Agreement between SpineMedica Corp. and SaluMedica, LLC dated   |
| 40             | August 3, 2007   |
| 10.36 (1)      | First Amendment Technology License Agreement between SpineMedica Corp. and   |
| (1)            | SaluMedica, LLC dated August 3, 2007   |
| 10.37 (1)      | Trademark License Agreement between SaluMedica, LLC and SpineMedica Corp dated   |
| 10.20 (1)      | August 13, 2007  |
| 10.38 (1)      | Acknowledgement of Georgia Tech Research Corporation dated August 12, 2005   |
| 10.39 (1)      | License Agreement between Georgia Tech Research Corporation and Restore Therapeutics,                                    |
| 10.40 (1)      | Inc. dated March 5, 1998   |
| 10.40 (1)      | First Amendment to License Agreement between Georgia Tech Research Corporation and                                       |
| 10 41 (1)      | Restore Therapeutics, Inc. dated November 18, 1998   |
| 10.41 (1)      | Second Amendment to License Agreement between Georgia Tech Research Corporation and                                      |
| 10.42 (1)      | SaluMedica, LLC (f/k/a Restore Therapeutics, Inc.) dated February 28, 2005   |
| 10.42          | Third Amendment to License Agreement between Georgia Tech Research Corporation and SaluMedica, LLC dated August 12, 2005 |
| 10.43 (1)      | Assignment of Invention and Non-Provisional Patent Application from David N. Ku to                                       |
| 10.43          | SpineMedica Corp. dated August 11, 2005  |
| 10.44 (1)      | Assignment of Invention and Non-Provisional Patent Application from SaluMedica, LLC to                                   |
| 10.77          | SaluMedica, LLC dated August 12, 2005  |
| 10.45 (1)      | Form of SpineMedica, Corp. Employee Proprietary Information and Inventions Assignment                                    |
| 10.43          | Agreement  |
| 10.46 (1)      | Purchase Agreement between SpineMedica Corp. and SaluMedica, LLC dated March 12, 2007                                    |
| 10.47 (1)      | Letter Agreement between MiMedx, Inc. and SaluMedica, LLC dated June 26, 2007  |
| 10.48 (1)      | Materials Transfer Agreement dated March 28, 2007 between Kensey Nash Corporation and                                    |
| 20.10          | MiMedx, Inc.   |
| 10.49 (1)      | Materials Transfer Agreement dated June 7, 2007 between Kensey Nash Corporation and                                      |
|                | MiMedx, Inc.   |
|                |  |

| 10.50 (1) | Industrial Lease Agreement between SpineMedica Corp. and Franklin Forest Investors, LLC dated April 25, 2007   |
|-----------|--|
| 10.51 (1) | Sublease and Agreement dated April 9, 2007 between CCA Global Partners, Inc. (f/k/a Carpet Co-op of America Association) and SpineMedica, Corp. & Landlord consent |
| 10.52 (5) | Investment Agreement dated March 31, 2008 between MiMedx Group, Inc. and SaluMedica, LLC   |
| 10.53 (5) | Technology License Agreement dated March 31, 2008 between MiMedx Group, Inc. and SaluMedica, LLC   |

69

#### **Table of Contents**

| <b>Exhibit Number</b> | Description  |
|-----------------------|--|
| 10.54 (5)             | Trademark License Agreement dated March 31, 2008 between MiMedx Group, Inc. and                |
|                       | SaluMedica, LLC  |
| 10.55 (6)             | Cost Recovery and Revenue Sharing Letter Agreement dated May 22, 2008 between MiMedx,          |
|                       | Inc. and Thomas J. Graham, M.D.  |
| 10.56 (6)             | Finder s Fee Letter Agreement dated May 22, 2008 between MiMedx, Inc. and Thomas J.            |
|                       | Graham, M.D.   |
| 10.57 *#              | Assignment and Assumption of Employment Agreement of Steve Gorlin between MiMedx               |
|                       | Group, Inc. and MiMedx, Inc. dated June 20, 2008   |
| 10.58 *#              | Assignment and Assumption of Employment Agreement of Thomas W. D. Alonzo between               |
|                       | MiMedx Group, Inc. and MiMedx, Inc. dated June 21, 2008  |
| 10.59 *#              | Assignment and Assumption of Employment Agreement of John C. Thomas, Jr. between               |
|                       | MiMedx Group, Inc. and MiMedx, Inc. dated June 24, 2008  |
| 10.60 *#              | Assignment and Assumption of Employment Agreement of Matthew J. Miller between                 |
|                       | MiMedx Group, Inc. and MiMedx, Inc. dated June 23, 2008  |
| 10.61 *#              | Assignment and Assumption of Employment Agreement of Brian J. Splan between MiMedx,            |
|                       | Inc. and MiMedx Group, Inc. dated June 20, 2008  |
| 10.62 *#              | Consulting Agreement between SpineMedica Corp. and Randal Betz, M.D.                           |
| 10.63 *#              | Consulting Agreement between SpineMedica Corp. and Ronald DeWald, M.D.                         |
| 10.64 *#              | Form of SpineMedica Corp. Physician Advisory Board Consulting Agreement                        |
| 14.1 <sup>(7)</sup>   | Code of Business Conduct and Ethics  |
| 16.1 <sup>(8)</sup>   | Letter From Aidman Piser Dated June 12, 2008   |
| $21.1^{(1)}$          | Subsidiaries of MiMedx Group, Inc.   |
| 31.1#                 | Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Acts of |
| "                     | 2002   |
| 31.2#                 | Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Acts of |
| !!                    | 2002   |
| 32.1#                 | Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of  |
| 22.2#                 | 2002   |
| 32.2#                 | Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of  |
|                       | 2002   |

## **Notes**

\* Indicates a management contract or compensatory plan or arrangement

#### # Filed herewith

All other footnotes indicate a document previously filed as an exhibit to and incorporated by reference from the following:

(1) Form 8-K filed February 8, 2008

- (2) Schedule 14A filed March 10, 2008
- (3) Form 8-K filed April 2, 2008
- (4) Form 8-K filed February 25, 2008
- (5) Form 8-K filed April 4, 2008
- (6) Form 8-K filed May 29, 2008
- (7) Form 8-K filed May 1, 2008
- (8) Form 8-K filed June 13, 2008

70