Alynx, Co. Form 8-K February 08, 2008

# UNITED STATES

#### SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 8-K

# **CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act 1934

Date of Report (date of earliest event reported): February 8, 2008

# ALYNX, CO.

(Exact name of registrant as specified in charter)

Nevada (State or other jurisdiction of incorporation) 000-52491 (Commission File Number) 90-0300868 (IRS Employer Identification No.)

1234 Airport Road, Suite 105

**Destin, Florida** (Address of principal executive offices) **32541** (Zip Code)

(850) 269-0000

(Issuer s Telephone Number)

706 Rildah Circle, Kaysville, Utah 84037

(Former name or former address, if changed since last report)

# Edgar Filing: Alynx, Co. - Form 8-K

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the following provisions:

- " Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- " Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- " Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- " Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### CAUTIONARY NOTICE REGARDING FORWARD LOOKING STATEMENTS

This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements reflect the current view about future events. When used in the filings the words anticipate, believe, estimate, expect, future, intend, plan or the negative of these terms and similar expressions as they relate to Registrant or Registrant s management identify forward looking statements. Such statements reflect the current view of Registrant with respect to future events and are subject to risks, uncertainties, assumptions and other factors (including the risks contained in the section of this report entitled Risk Factors ) relating to Registrant s industry, Registrant s operations and results of operations and any businesses that may be acquired by Registrant. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended or planned.

Although Registrant believes that the expectations reflected in the forward looking statements are reasonable, Registrant cannot guarantee future results, levels of activity, performance or achievements. Except as required by applicable law, including the securities laws of the United States, Registrant does not intend to update any of the forward-looking statements to conform these statements to actual results. The following discussion should be read in conjunction with Registrant s pro forma financial statements and the related notes that will be filed herein.

In this Form 8-K, references to we, our, us, the Company, our company, the combined companies refer to Alynx, Co., a Nevada corporation (Alynx), MiMedx, Inc., a Florida corporation (MiMedx), a wholly-owned subsidiary of Alynx, and SpineMedica, LLC, a Florida limited liability company (SpineMedica), a wholly-owned subsidiary of MiMedx.

#### Item 1.01 Entry into a Material Definitive Agreement.

As previously reported by Alynx in its Form 8-K filed January 29, 2008, Alynx Co., MMX Acquisition Corp., a Florida corporation wholly-owned by Alynx, and MiMedx, Inc., a Florida-based, privately-held, development-stage medical device company (MiMedx), executed an Agreement and Plan of Merger on January 29, 2008 (the Merger Agreement).

Pursuant to the terms of the Merger Agreement, and upon satisfaction of specified conditions, including approval by MiMedx shareholders on February 8, 2008, MMX Acquisition Corp. merged into MiMedx.

On the closing date, pursuant to the terms of the Merger Agreement, former MiMedx shareholders received approximately 52,283,090 shares of Alynx Common Stock and 3,684,040 shares of Alynx Series A Preferred Stock (the Preferred Stock ) (convertible into 56,944,572 shares of Common Stock), for an aggregate of 109,227,662 shares of Common Stock (as converted), or approximately 97.25% of the post-merger company s outstanding shares (as converted). In addition, certain persons received 636,376 shares of Alynx Common Stock as compensation for finder s services in connection with the Merger. The shares of Alynx Stock were issued pursuant to Rule 506 of Regulation D and Section 4(2) of the Securities Act of 1933. The shares are unregistered, restricted stock bearing a restrictive legend. See Alynx Shares Eligible for Future Sale at Item 2.01 of this Form 8-K.

The material terms of the Merger Agreement are described more fully in Item 2.01 of this Current Report on Form 8-K. The information therein is hereby incorporated into this Item 1.01 by reference.

#### Item 2.01 Completion of Acquisition or Disposition of Assets. Closing of Merger Agreement

As described in Item 1.01 above, on February 8, 2008, Alynx acquired MiMedx, a Florida-based development-stage medical device company in a merger (Merger). MMX Acquisition Corp. merged with and into MiMedx. The outstanding MiMedx capital stock was converted into approximately 52,283,090 shares of Alynx Common Stock and 3,684,040 shares of Alynx Preferred Stock (convertible into 56,944,572 shares of Common

Stock), for an aggregate of 109,227,662 shares of Common Stock (as converted), or approximately 97.25% of the post-merger company s outstanding shares (as converted). See Alynx Shares Eligible for Future Sale below.

Pursuant to the Merger Agreement the sole director and executive officer of Alynx, Ken Edwards, resigned from his positions with Alynx at the closing of the Merger. The directors and executive officers of MiMedx became the directors and executive officers of Alynx. See Management below.

### **Change in Corporate Headquarters**

In connection with the closing of the Merger, Alynx relocated its corporate headquarters from 706 Rildah Circle, Kaysville, Utah 84037 to 1234 Airport Road, Suite 105, Destin, Florida 32541.

#### **Accounting Treatment**

For accounting purposes, the Merger is being accounted for as a reverse merger, which means MiMedx will be deemed to have acquired Alynx. This accounting treatment was required since the shareholders of MiMedx now own a substantial majority of the issued and outstanding shares of common stock of the Registrant, and certain of the directors and executive officers named by MiMedx became the directors and executive officers of the Registrant at the closing, replacing the prior directors and executive officers. No agreements exist among present or former controlling stockholders of the Registrant or present or former officers and directors of MiMedx with respect to the future election of the members of the Registrant s Board of Directors, and to the Registrant s knowledge, no other agreements exist which might result in a change of control of the Registrant. See the pro forma financial information at Exhibit 99.3 to this Form 8-K for further details.

#### **Treatment of Options and Warrants**

Alynx assumed each stock option to purchase shares of MiMedx s common stock that was outstanding immediately prior to the Merger, whether or not then vested or exercisable (each, an Assumed MiMedx Option ). Each Assumed MiMedx Option was converted into an option to acquire that number of shares of Alynx Common Stock equal to the number of shares of MiMedx capital stock subject to such option, multiplied by 3.091421. The exercise price per share for the Assumed MiMedx Options was adjusted by dividing the exercise price for the MiMedx Assumed Option by 3.091421, rounded up to the nearest whole cent. At closing, Alynx assumed options representing rights to purchase up to approximately 12,238,170 shares of Alynx Common Stock at a weighted average exercise price of \$0.56 per share of Alynx Common Stock. All other terms and conditions of the options remained the same.

Further, Alynx assumed each warrant to purchase, acquire or otherwise receive MiMedx shares, exclusive of Assumed MiMedx Options outstanding immediately prior to the Merger, whether or not then vested or exercisable (each, an Assumed MiMedx Warrant ). Each Assumed Warrant was converted into a warrant to acquire that number of our shares equal to the number of shares of MiMedx capital stock subject to such warrant, multiplied by 3.091421. The purchase price per share for the Assumed MiMedx Warrant was adjusted by dividing the exercise price for each Assumed MiMedx Warrant by 3.091421, rounded up to the nearest whole cent. At closing, Alynx assumed warrants representing rights to purchase up to approximately 2,192,840 shares of Alynx Common Stock at a weighted average exercise price of \$0.46 per share of Alynx Common Stock. All other terms and conditions of the warrants remained the same.

#### FORM 10-SB DISCLOSURES

Prior to the Merger, Alynx was a shell company as defined in Rule 12b-2 promulgated by the SEC under the Securities Exchange Act of 1934, because it had no or nominal operations, and assets consisting of cash, cash equivalents and nominal other assets. As disclosed elsewhere in this report, on February 8, 2008, we acquired MiMedx in the Merger. Item 2.01(f) of Form 8-K states that if the registrant was a shell company, as we were immediately before the Merger disclosed under Item 2.01, then the Registrant must disclose the information that would be required if the Registrant were filing a general form for registration of securities under the Securities Act of 1934, as amended.

Alynx ceased to be a shell company upon consummation of the Merger. Accordingly, we are providing the required information. The information provided below relates to the combined company after the Merger.

# **DESCRIPTION OF BUSINESS**

# **BACKGROUND: ALYNX BEFORE THE MERGER**

Alynx was originally formed as a Utah corporation on July 30, 1985 under the name Leibra, Inc. On October 1, 1986, the stockholders approved a merger with Leitech, Inc., a newly formed Nevada corporation, to change the domicile of Leitech, Inc. from Utah to Nevada. Alynx had several name changes in connection with various business acquisitions, all of which have been discontinued or rescinded. For the past several years the Company has had no active business operations, and has been seeking to acquire an interest in a business with long-term growth potential. It has been an inactive shell corporation for at least the past 10 years.

# **Historical Activities**

Ken Edwards, the sole officer and director of Alynx, was appointed as a director, President, Secretary and Treasurer on October 15, 2000. Since that date Mr. Edwards has managed the company solely in preparation for locating and consummating a transaction whereby the company could recommence business operations. In April 2006 he purchased 20,000,000 shares of common stock of Alynx for \$20,000. Through his company, Booder Corp., Mr. Edwards receives compensation of \$1,000 per month for the services performed by him for Alynx. Alynx raised an additional \$10,000 in May 2006 thorough the sale of convertible promissory notes in the principal amount of \$2,500 each to four persons. On May 25, 2006, Alynx effected a 10-for-1 forward stock split of its outstanding common stock. In May 2007 Alynx borrowed \$15,000 from Mr. Edwards and in October 2007 Mr. Edwards agreed to loan up to an additional \$25,000 to Alynx. Alynx s Form 10-KSB, filed January 23, 2008, is incorporated herein by reference.

On March 6, 2007, Alynx filed a registration statement with the Securities and Exchange Commission on Form 10-SB to register the company s common stock under the Securities Exchange Act of 1934. Alynx has filed periodic reports with the Commission since that time.

#### INFORMATION ABOUT MIMEDX

#### Overview

Our business is now the business conducted by our principal subsidiary, MiMedx. MiMedx is a development-stage company, incorporated in Florida in November 2006, that is currently developing products primarily for use by musculoskeletal specialists in both surgical and non-surgical therapy. 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.

#### **Our Strategy**

Our business strategy is to identify, acquire, reduce-to-practice, 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 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

Dr. Thomas Koob s discovery of a unique polymerization chemistry led directly to the development of the nordihydroguaiaretic acid (NDGA) cross-linking process under exclusive license to us. Dr. Koob and his team devised a strategy to use NDGA as a collagen cross-linking agent in which Dr. Koob s initial bench testing shows may produce 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.

The core technology licensed to us is embodied in two of Dr. Koob s 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 such as glutaraldehyde, which is toxic to cells and may create scar-tissue; but nonetheless is currently marketed and used to treat biologic applications, including soft tissue. Initial biocompatibility tests conducted to date show NDGA cross-linked biomaterials may not be cytotoxic and have shown 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 the Company has identified several potential 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 preliminarily suggest results that the materials are biocompatible and biodegradable, with a tunable rate of resorption *in-vivo*;

Biocompatibilization (make 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 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. We are planning to initially pursue linear arrays and braided constructs for ligament 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. The total United States spinal implant market in 2006 was approximately \$3.75 billion, approximately a 15% increase over 2005, and is expected to grow to \$4.3 billion in 2007.

Our wholly-owned subsidiary, SpineMedica, is currently developing two products, a cervical total disc replacement and a posterior interbody fusion device for this market. Salubria® biomaterial, a poly-vinyl alcohol and water-based biomaterial that SpineMedica owns specific rights to, can be manufactured with a wide range of mechanical properties, including those that appear to closely mimic the mechanical and physical properties of a natural, healthy spinal disc. We believe the intervertebral disc space and the normal mobility of the spine can be preserved using a biomimetic material like Salubria® biomaterial. Salubria® biomaterial 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, the 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 Salubria® biomaterial 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.

SpineMedica has recently begun developing a third product for the spine, a vessel guard made of Salubria® biomaterial material. This vessel guard, which would 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*, www.ryortho.com. 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.

The Ortho FactBook (2006), published by Knowledge Enterprises, Inc, an orthopedic industry analysis organization, 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. Whereas competitive implants are not intended to replace normal body structure or provide the full mechanical strength to the repair site, initial testing indicates that our licensed technology may be able to provide full mechanical strength and potentially surpass the original mechanical strength of adjacent, native tissues.

Though not yet in development, other possible non-orthopedic products are related to the use of our technology as general soft-tissue patches and slings, including general surgical reconstruction.

The market for general soft-tissue patches and slings is not heavily populated because so few products work 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 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 medical 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. Also, our products could potentially be used in other orthopedic categories.

#### Salubria® Biomaterial

Salubria® biomaterial is a unique poly-vinyl alcohol (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 use of Salubria® biomaterial from SaluMedica, LLC, for certain applications within the body (see Collaborations and License Agreements). The material has been sold in Europe for certain applications for over five years. Salubria® biomaterial 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 s strength and compliance. For certain applications, the material 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 Salubria® biomaterial 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 Salubria® biomaterial for use in the spine, hand, and rotator cuff. Development of applications for use in the spine 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 back 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. In our experience, 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 and the pain patients are experiencing, approximately 227,000 cervical and 295,000 lumbar procedures were performed in 2006, 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* (www.ryortho.com).

In Europe, there are several artificial 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. over one million patients undergo spine surgery each year in the United States, and the number of spine surgery procedures grew to over 1.2 million per year in 2005. 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.

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 Salubria® biomaterial,

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 competitor s 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 and replacement with a mechanical or polymer artificial disc	Maintain disc height and restore motion of spinal segment.
Nucleus Replacement	Replacement of the disc s <i>nucleus pulposus</i> , 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 the disc and allows a range of motion using a variety of implants or flexible materials.	Reduce loads on the disc and correct the spinal balance and alignment.

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 metallic, 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. Salubria® biomaterial 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 Charite® 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 sandwiched between them. 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 our Series B Convertible Preferred Stock and a warrant for one share of our 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.

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

#### **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 31 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 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 a stock option grant for the purchase of up to 309,142 shares of Alynx Common Stock at \$0.32 per share (as adjusted to reflect the Merger), 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 us on March 8, 2007. Under his agreement, Dr. Graham receives compensation of \$125,000 per year and received a stock option grant for the purchase of shares of MiMedx Common Stock equal to up to 154,571 shares of Alynx Common Stock at \$0.32 per share (as adjusted to reflect the Merger), one-third of which vested upon grant and one-third of which will vest on each of the next two annual anniversaries of grant. Dr. Graham also received stock option grant, in connection with the transfer of certain technologies, for the purchase of up to 618,284 shares of Alynx Common Stock at \$0.78 per share (as adjusted to reflect the Merger), one-third of the next two annual anniversaries of grant.

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 PABs members, we have agreed to compensate each of them with a stock option grant for the purchase of up to 92,743 shares of Alynx Common Stock at \$0.32 per share (as adjusted to reflect the Merger), one-third of which vests upon grant and one-third of which will vest on each of the next two anniversaries of grant. All PAB members will be compensated \$200 per conference call. Hand Committee members will receive \$2,000 in per diem compensation, and Sports Committee members will receive \$2,500 in per diem compensation. The maximum amounts allowed to be paid to PABs members are regulated by the Health Insurance Portability and Accountability Act.

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. They are compensated per the same PAB contracts that are being employed for the sports medicine and hand advisory boards. The Chairman of the Spine PAB is Randal Betz. 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.

### **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 development; product testing; product labeling; product storage; premarket clearance or approval; advertising and promotion; and product sales and distribution.

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.

#### 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 last longer.

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, typically a panel of clinicians, likely will 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 distribution. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval. Even after approval of a PMA, a new PMA or PMA supplement is required in the event of a modification to the device, its labeling or its manufacturing process.

# **Clinical Trials**

A clinical trial is generally required to support a PMA 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 may begin once the IDE application is approved by the FDA and the appropriate institutional review boards at the clinical trial sites.

# 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 s general prohibition against promoting products for unapproved or off-label uses; and the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device 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 its 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.

# **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 constructed into digital flexor tendon implants and the vessel guard device made from Salubria® biomaterial, as well as other products which the Company believes 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.

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. <u>The Ortho FactBook</u> (2006), published by Knowledge Enterprises, Inc.

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 Sciences	Tendon/Lig Repair	Pilot (human, ACL)	
Organogenesis	Fortaflex	European Clinical (ACL)	
ReGen Biologics	Collagen matrices	Preclinical (animal)	
Biomet/Organogenesis	CuffPatch	Clinical (Rotator Cuff)	
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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, there are fewer competitors and they include:

Developer	Product	Status
DePuy CryoLife <i>SpineMedica Products</i>	BioBlanket Soft-Tiss ProPatch Soft-Tiss	Received 510(k) Oct. 2006 Received 510(k) Dec. 2006

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 products.

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

Technology	<b>Representative Product</b>	Company
Total Disc Replacement, cervical	Prestige® ProDisc-C Bryan®	Medtronic Sofamor Danek Synthes Spine Medtronic Sofamor Danek
Posterior Lumbar Interbody	PLIF Spacers Puros® Symmetry® PLIF	Synthes Zimmer
	Allograft System Trabecular Metal PLIF Device HRC Locking Cage Interbody	Zimmer Zimmer
	Fusion System VG2® PLIF Allograft SpaceVision PLIF Cage	J&J, DePuy Spine SpineVision

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Coreograft	PLIF Allograft
AlloCraft	PL

Alphatec Spine Stryker

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 3,462,392 shares of Alynx 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 Salubria® biomaterial. 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 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.

# **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	Issue Date	<b>Expiration Date</b>
6,565,960	Polymer Composite Compositions	June 1, 2001	May 20, 2003	June 1, 2021
6,821,530	Polymer Composite Compositions	May 19, 2003	November 23, 2004	June 1, 2021
Pending patent applications we have licensed include:				

Patent Application Serial Number	Title	Filing Date
U.S. 11/685,528 and corresponding	Self-Assembling, Collagen Based Material for Corneal Replacement	March 13, 2007
PCT application (US/2007/063882)		
U.S. 11/821,320 and corresponding	Collagen Scaffolds, Medical Implants With Same and Methods of Use	June 22, 2007
PCT application (US/2007/014560)		
U.S. 11/964,745 and corresponding	Woven and/or Braided Fiber Implants and Methods of Making Same	December 27, 2007
PCT application		
U.S. 11/964,756 and corresponding	Methods of Making High-Strength NDGA Polymerized Collagen Fibers and Related	December 27, 2007
PCT application	Collagen-Prep Methods, Medical Devices and Constructs	