CLICKNSETTLE COM INC
Form 8-K
September 09, 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 of 1934
Date of Report (Date of earliest event reported): August 29, 2008
clickNsettle.com, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**0-21419**	**23-2753988**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

8899 Beverly Boulevard, Suite 619 Los Angeles, California	**90048**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: **(310) 274-2036**
4400 Biscayne Boulevard, Suite 950, Miami, Florida 33137
(Former name or former address, if changed since last report.)

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

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

Item 1.01. Entry into a Material Definitive Agreement.

The disclosure set forth under Item 2.01 to this Current Report on Form 8-K is incorporated by reference.

Item 2.01. Completion of Acquisition or Disposition of Assets.

On August 29, 2008, clickNsettle.com, Inc. (CKST) completed an acquisition of Cardo Medical, LLC, a privately held California limited liability company (Cardo), and its subsidiaries pursuant to a Merger Agreement and Plan of Reorganization, dated as of June 18, 2008, as amended, by and among CKST, Cardo and Cardo Acquisition, LLC, a California limited liability company and wholly-owned subsidiary of CKST.

The Merger Agreement provides for the merger of Cardo with and into Cardo Acquisition, LLC, with Cardo continuing as the surviving entity in the merger and a wholly-owned subsidiary of CKST (referred to as the Merger). As previously disclosed in the Current Report on Form 8-K filed with the Securities and Exchange Commission on June 23, 2008, on or about the signing of the Merger Agreement, Frost Gamma Investments Trust and other investors invested $12.975 million in Cardo in exchange for units of Cardo s membership interests. Dr. Phillip Frost, Chairman and Chief Executive Officer of Opko Health, Inc. (formerly known as eXegenics Inc.), is the trustee and beneficiary of Frost Gamma Investments Trust. Cardo used approximately $9.7 million of the proceeds from these investments to close on the acquisition of the outstanding equity interests of three partially owned subsidiaries of Cardo (Accelerated Innovation, LLC, Cervical Xpand, LLC and Uni-Knee, LLC), to repay an existing member loan (in the amount of $1.2 million) and for transaction expenses, and expects to use the remaining funds to accelerate its research and product development.

Under the terms of the Merger Agreement, at the closing of the Merger, each Cardo unit issued and outstanding was converted into and exchanged for the right to receive 667,204.70995 shares of common stock of CKST. As a result of the Merger, CKST s shareholders and optionholders own approximately 5.5% of the combined company on a fully diluted basis (or 11,298,979 shares of common stock outstanding and underlying options), the members of Cardo, excluding the new investors, own approximately 64.8% of the combined company on a fully diluted basis (or 133,440,942 shares of common stock), the new investors own approximately 28.5% of the combined company on a fully diluted basis (or 58,641,701 shares of common stock), and optionholders of Cardo own approximately 1.2% of the combined company on a fully diluted basis (or 2,398,400 shares of common stock underlying those options).

In connection with the consummation of the Merger, CKST will propose to its shareholders an amendment to its Certificate of Incorporation to change its name from clickNsettle.com, Inc. to Cardo Medical, Inc. CKST s trading symbol is CKST.OB, which we expect to change in connection with the name change. CKST intends to apply to have its shares listed on the American Stock Exchange. We cannot ensure that we will be able to satisfy the listing standards of the American Stock Exchange or that our common stock will be accepted for listing.

In addition, 10 days after filing and transmitting an Information Statement to CKST s shareholders (approximately September 19, 2008) pursuant to Section 14(f) of the Securities

Exchange Act of 1934, as amended, and Rule 14f-1 thereunder (the Information Statement), the Board of Directors of Cardo initially will consist of five directors to be appointed by Dr. Andrew Brooks and two directors to be appointed by Dr. Frost. Dr. Brooks, an orthopedic surgeon, will serve as Chief Executive Officer of the combined company and as its Chairman of the Board 10 days after we file the Information Statement and transmit it to CKST s shareholders. The company will be headquartered in Los Angeles, California.

Escrow Agreement

As security for the customary indemnification obligations of Cardo to CKST, 10.0% of CKST s shares issued in connection with the Merger to the historical members of Cardo (*i.e.*, the members of Cardo prior to the admission of the new investors) will be held in escrow by a third-party escrow agent until August 28, 2009, which shares will thereafter be released except with respect to a number of escrowed shares as determined by the Board of Directors to be necessary to satisfy any unresolved claim until the claim is fully and finally resolved.

Lockup Agreements

In connection with the Merger, the officers and directors of the combined company and certain of their family members, as well as each Cardo member owning 5% or more of the outstanding capital stock of CKST, entered into lockup agreements. Each lockup agreement provides that the shares of CKST issued in the Merger may not be, directly or indirectly, sold for a period of two years following completion of the Merger.

* * *

The summary discussion of material terms of the Merger Agreement set forth above is qualified by reference to the Merger Agreement and its amendment, copies of which are attached as Exhibits 2.1 and 2.2 to the Current Report on Form 8-K filed on June 23, 2008 and are incorporated herein by reference. The summary discussion of material terms of the Escrow Agreement and the Lockup Agreements set forth above is qualified by reference to those agreements, copies of which are attached as Exhibits 10.1 and 10.2 to this report, respectively, and are incorporated herein by reference.

On September 2, 2008, we issued a press release announcing the closing of the Merger Agreement and the related transactions described herein, which press release is attached as Exhibit 99.1 to this report.

FORM 10 DISCLOSURES

As disclosed under Item 2.01 of this Current Report on Form 8-K, on August 29, 2008, clickNsettle.com, Inc. acquired Cardo Medical, LLC and its subsidiaries 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, then the registrant must disclose the information that would be required if the registrant were filing a general form for registration of securities on Form 10 under the Securities Exchange Act of 1934, as amended.

Accordingly, we provide below the information that would be included in Form 10. Please note that the information provided below relates to the combined company after the completion of the Merger, except that information relating to periods before the date of the Merger only relates to clickNsettle.com, Inc., unless otherwise specifically indicated.

EXPLANATORY NOTE REGARDING DISCLOSURES ABOUT DIRECTORS AND EXECUTIVE OFFICERS

Except where the context otherwise requires, disclosures presented in this Current Report on Form 8-K, including the disclosures in accordance with Form 10, regarding the directors and executive officers of clickNsettle.com, Inc. are as of the tenth day following the filing and transmission to shareholders of the Information Statement (approximately September 19, 2008). Prior to that date, the directors and executive officers are the following: Glenn L. Halpryn, Chairman of the Board, Chief Executive Officer and President; Noah M. Silver, Vice President, Secretary, Treasurer and director; Alan Jay Weisberg, Chief Financial and Accounting Officer and director; and Curtis Lockshin, director. Information regarding these directors and executive officers can be found in the following filings of clickNsettle.com, Inc., which are incorporated by reference: Information Statement Pursuant to Section 14(c) of the Securities Exchange Act of 1934, as amended, filed on February 20, 2008; Current Report on Form 8-K filed on March 18, 2008; and Information Statement Pursuant to Section 14(f) of the Exchange Act and Rule 14f-1 thereunder, filed on September 9, 2008.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Current Report on Form 8-K, including the disclosures in accordance with Form 10, contain forward-looking statements, as that term is defined under the Private Securities Litigation Reform Act of 1995, or the PSLRA. Forward-looking statements include statements about our expectations, beliefs or intentions regarding our product development efforts, business, financial condition, results of operations, strategies or prospects. You can identify forward-looking statements by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Without limiting the foregoing, the words believes, anticipates, plans, expects and similar expressio are intended to identify forward-looking statements.

Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described under the caption Risk Factors in Item 1A of these Form 10 disclosures, some of which are briefly listed below. Other factors besides those listed there also could adversely affect us.

Any or all of our forward-looking statements in this Current Report on Form 8-K may turn out to be wrong. They can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. Many factors mentioned in our discussion in this Current Report on Form 8-K will be important in determining future results. Consequently, no forward-looking statement can be guaranteed. Actual future results may vary materially. While we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so to reflect actual results, changes in assumptions or changes in other factors affecting forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance.

Risks and uncertainties, the occurrence of which could adversely affect our business, include the following:

- our ability to market, commercialize and achieve market acceptance of any of our products or any product candidates that we are developing or may develop in the future, and the acceptance of those products;

- our ability to maintain an adequate sales network for our products, including our ability to attract and retain independent distributors;

- our ability to obtain regulatory approval for our products and our ability to comply with ongoing regulation of our products;

- the effect on Medicare prescription drug coverage legislation and future legislative or regulatory reform of the health care system and its effect on our ability to sell our products profitably;

- our business strategy and our underlying assumptions about market data, demographic trends, reimbursement trends, pricing trends, and trends in the treatment of spine, hip and knee disorders;

- our estimates regarding anticipated operating losses, future revenue, expenses, capital requirements, liquidity and our potential need to raise additional financing;

- our ability to comply with industry standards in regulatory compliance matters;

- our ability to control our costs and achieve profitability;

- our ability to market and sell our products in any international market that we attempt to enter;

our ability to attract and retain a qualified management team, as well as other qualified personnel and advisors;

our ability to enter into licensing and business combination agreements with third parties and to successfully integrate the acquired technology and/or businesses;

our management team s ability to accommodate growth and manage a larger organization;

our ability to protect our intellectual property, and to not infringe upon the intellectual property of third parties;

because our common stock may be a penny stock, it may be more difficult for investors to sell shares of our common stock, and the market price of our common stock may be adversely affected;

our ability to conclude that we have effective disclosure controls and procedures; and

our ability to comply with corporate governance programs and with changing regulations concerning corporate governance and public disclosure.

Except where the context otherwise requires, the term we, us, our, the company or CKST refers to the business o clickNsettle.com, Inc. and its consolidated subsidiaries as follows: the term Cardo or Cardo Medical, LLC refers to the business of Cardo Medical, LLC, our wholly-owned subsidiary, prior to the consummation of the Merger; the term Accelerated or Accelerated Innovation, LLC refers to the business of Accelerated Innovation, LLC, the wholly-owned subsidiary of Cardo; the term Cervical Xpand or Cervical Xpand, LLC refers to the business of Cervical Xpand, LLC, a subsidiary owned by Cardo directly and indirectly through Accelerated; and the term Uni-Knee or Uni-Knee, LLC refers to the business of Uni-Knee, LLC, a subsidiary owned by Cardo directly and indirectly through Accelerated. Cardo, Accelerated, Cervical Xpand and Uni-Knee are CKST s operating subsidiaries and comprise all of the operations of the combined company as of the date of this Current Report on Form 8-K.

Item 1. Business.

Information about clickNsettle.com, Inc. Before the Merger

clickNsettle.com, Inc., or CKST, was incorporated in the State of Delaware on January 12, 1994. CKST previously was involved in the business of providing alternative dispute resolution, or ADR, services. On October 31, 1994, CKST acquired all of the outstanding common stock of its predecessor operating company, which was formed on February 6, 1992, and was primarily owned by its former Chief Executive Officer and President. CKST s predecessor began operations in March 1992 as a provider of ADR services. CKST s predecessor was merged into CKST as of the end of June 1999. In June 2000, CKST s name was changed from NAM Corporation to clickNsettle.com, Inc. CKST ceased all operations relating to its historical ADR business in January 2005 when it sold that business to National Arbitration and Mediation, Inc., a company owned by CKST s former Chief Executive Officer. From the consummation of the sale of the ADR business and until the closing of the Merger, CKST had no operating business. As such, prior to the Merger, CKST was a publicly traded shell company actively searching for a new operating business to acquire or to enter into a merger transaction. Upon consummation of the Merger, CKST adopted Cardo s business plan, which is now CKST s wholly-owned subsidiary. You should read the discussion below in conjunction with CKST s consolidated financial statements and the related notes and the pro forma financial statements contained in this Current Report on Form 8-K.

Information about Cardo Medical, LLC and Its Subsidiaries

Overview

Cardo Medical, LLC is an early-stage orthopedic medical device company specializing in designing, developing and marketing reconstructive joint devices and spinal surgical devices. Reconstructive joint devices are used to replace knee, hip and other joints that have deteriorated through disease or injury. Spinal surgical devices involve products to stabilize the spine for fusion and reconstructive procedures. Within these areas, Cardo intends to focus on the higher-growth sectors of the orthopedic industry, such as advanced minimally invasive instrumentation and bone-conserving high-performance implants. Cardo is focused on developing surgical devices that will enable surgeons to bridge the gap between soft tissue-driven sports medicine techniques and classical reconstructive surgical procedures. Cardo commercializes its reconstructive joint devices through its Cardo Orthopedics division and its spine devices through its Cardo Spine division.

In December 2006, Cardo initiated sales of the Align 360 unicompartmental knee device, a partial knee resurfacing device for the medial or lateral part of the knee. Cardo has received approval under Section 510(k) of the Federal Food, Drug and Cosmetic Act (Section 510(k)) for its uniquely instrumented patello-femoral arthroplasty, a resurfacing device for the back of the kneecap, as well as for its total hip replacement system and its monopolar and bipolar hip systems. Cardo also have received Section 510(k) approvals for its spinal lumbar fusion system and its cervical plate and screw systems. Cardo is actively engaged in a number of research and development projects for total knee arthroplasty, spinal motion preservation, fusion devices and minimally invasive approaches for treating an array of spinal disorders.

Recent Transactions

Cardo Medical, LLC was formed on April 6, 2007 as a California limited liability company for the purpose of acquiring an interest in the medical device business conducted by Accin Corporation directly and through Accin s interests in Cervical Xpand, LLC and Uni-Knee, LLC. Following Cardo s organization:

Cardo and Accin formed a Delaware limited liability company on April 20, 2007 under the name Accelerated Innovation, LLC;

On May 21, 2007, Accin contributed substantially all of its business, properties and assets, including its majority interests in Cervical Xpand and Uni-Knee, to Accelerated in exchange for a 62.5% interest in Accelerated and the distribution referenced below in the amount of $3.75 million;

Concurrently with the above, on May 21, 2007, Cardo contributed $3.75 million to Accelerated in exchange for a 37.5% interest in Accelerated; and

the amount of $3.75 million was distributed by Accelerated to Accin.

Under the terms of Accelerated s Limited Liability Company Agreement, Cardo was granted an option to purchase the 62.5% interest in Accelerated held by Accin for a purchase price of $6.25 million. Following the exercise of that option in June 2008, Cardo acquired all of the interests in Accelerated held by Accin, and Accelerated became a wholly-owned subsidiary of Cardo.

Prior to that, in February 2008, Cardo entered into Membership Interest Purchase Agreements with the holders of the minority membership interests in Cervical Xpand and Uni-Knee. Cervical Xpand and Uni-Knee were formed as New Jersey limited liability companies on July 12, 2005 and May 10, 2006, respectively, for the purpose of conducting research and development activities. Prior to the closing of the transactions contemplated by the Membership Interest Purchase Agreements, Accelerated, as the assignee of Accin s assets, owned 52.083% of the membership interests in Cervical Xpand and 51.21% of the membership interests in Uni-Knee, and the minority holders held the remaining outstanding interests. Upon the closing of the transactions contemplated by the Membership Interest Purchase Agreements, in June 2008, Cardo acquired the outstanding membership interests from the minority holders for an aggregate purchase price of $1,437,510 for the Cervical Xpand interests and $2,049,180 for the Uni-Knee interests. As a result, Cardo now owns all of the interests in Cervical Xpand and Uni-Knee directly and indirectly through its ownership of Accelerated.

On June 18, 2008, Cardo entered into a Merger Agreement and Plan of Reorganization with CKST and Cardo Acquisition, LLC, a California limited liability company and wholly-owned subsidiary of CKST. Upon the consummation of the transactions contemplated by the Merger Agreement, CKST acquired Cardo through a merger of Cardo with Cardo Acquisition, with Cardo continuing as the surviving entity in the Merger and a wholly-owned subsidiary of CKST. Pursuant to the Merger Agreement, all of the issued and outstanding units of Cardo s membership interests were converted into the right to receive shares of the common stock of CKST.

On or about the signing of the Merger Agreement, Frost Gamma Investments Trust and other investors invested $12.975 million in Cardo in exchange for units of Cardo s membership interests. Dr. Phillip Frost, Chairman and Chief Executive Officer of Opko Health, Inc. (formerly known as eXegenics Inc.), is the trustee and beneficiary of Frost Gamma Investments Trust. Cardo used approximately $9.7 million of the proceeds from these investments to close on the acquisition of the outstanding equity interests of three partially owned subsidiaries of Cardo (Accelerated Innovation, LLC, Cervical Xpand, LLC and Uni-Knee, LLC), to repay an existing member loan (in the amount of $1.2 million) and for transaction expenses, and expects to use the remaining funds to accelerate its research and product development.

In addition, as of the closing of the Merger, CKST had cash and cash equivalents in the approximate amount of $2.5 million held in money market accounts and certificates of deposit, which is now available for use in our business due to the Merger. In total, following the Merger, the combined company currently has $4.7 million in cash and cash equivalents.

Under the terms of the Merger Agreement, at the closing of the Merger, each Cardo unit issued and outstanding was converted into and exchanged for the right to receive 667,204.70995 shares of common stock of CKST. As a result of the Merger, CKST s shareholders and optionholders own approximately 5.5% of the combined company on a fully diluted basis (or 11,298,979 shares of common stock outstanding and underlying options), the members of Cardo, excluding the new investors, own approximately 64.8% of the combined company on a fully diluted basis (or 133,440,942 shares of common stock), the new investors own approximately 28.5% of the combined company on a fully diluted basis (or 58,641,701 shares of common stock), and optionholders of Cardo own approximately 1.2% of the combined company on a fully diluted basis (or 2,398,400 shares of common stock underlying those options).

Ten days following the filing and transmission to shareholders of the Information Statement (approximately September 19, 2008), our Board of Directors will consist of five directors originally designated by Andrew A. Brooks, M.D. and two directors originally designated by Phillip Frost, M.D. Dr. Brooks, an orthopedic surgeon, will serve as the Chairman of the Board and Chief Executive Officer of the combined company on the tenth day after we file and transmit the Information Statement. In the future, our directors will be designated by our shareholders. However, given that a few shareholders together own a majority of our common stock, they will be able to elect a majority of the directors of CKST.

We are headquartered in Los Angeles, California. In connection with the consummation of the Merger, CKST will propose to its shareholders an amendment to its Amended and Restated Certificate of Incorporation to change its name from clickNsettle.com, Inc. to Cardo Medical, Inc. CKST s trading symbol is CKST.OB, which we expect to change connection with the name change. CKST s common stock is quoted on the National Association of Securities Dealers, Inc. s, Over-the-Counter Bulletin Board, or the OTC Bulletin Board.

We intend to apply to have our shares listed on the American Stock Exchange. We cannot ensure that we will be able to satisfy the listing standards of the American Stock Exchange or that our common stock will be accepted for listing.

As soon as practicable after the closing of the Merger, we will merge Accelerated with and into Cardo, with Cardo as the surviving entity in that merger, and then convert Cardo into a Delaware

limited liability company. In addition, following Cardo s conversion, we will merge each of Cervical Xpand and Uni-Knee with a Cardo wholly-owned subsidiary formed in Delaware, with each Delaware entity as the surviving entity in those mergers.

Products

Following is a listing of our current products:

Knee Portfolio

Align 360 Unicompartmental Knee System - A uniquely instrumented partial knee replacement that allows resurfacing of either the medial or lateral compartments of the knee. This product promotes the consistent balancing of the flexion and extension gaps for unicompartmental knee surgery.

Align 360 Patellofemoral System - A uniquely instrumented and novel patellofemoral system that allows resurfacing of the patellofemoral joint. This product is an anatomic system that addresses the disease of the patellofemoral joint.

Hip Portfolio

Accin Total Hip System - A taperloc type of hip system that allows replacement of the ball and socket of the hip joint. This product offers a dual taper hip design for total hip arthroplasty complemented by the Accin Bipolar and Monopolar Hip Systems for hip fracture applications.

Accin Bipolar Hip System - A bipolar hip that allows replacement of the ball of the hip for either fracture, tumors or reconstruction from some other type of pathology.

Accin Monopolar Hip System - A monopolar hip that allows replacement of the ball of the hip from either fracture, tumors or reconstruction from some other type of pathology.

Spinal Product Line

Accin Lumbar Pedicle Screw/Rod System- A pedicle screw and rod system for instrumentation of lumbar spine fusion incorporating an evolutionary locking mechanism allowing for high screw angulation.

Accin Cervical Plate/Screw System- An innovative low-profile system for cervical spine fusion incorporating an integrated, floating tapered-ring locking mechanism to simplify surgical procedure.

Our products listed above have received Section 510(k) approval. In addition, we have submitted Section 510(k) applications for our Helibone VBR System, a novel device with potentially larger applications in spine surgery, and our Accin Total Knee System, a uniquely instrumented high-performance total knee device, which are currently being reviewed by the FDA. We have a number of earlier stage research and development projects underway, some of which we may submit for regulatory approval in the future.

Orthopedic Industry

According to the 2007-2008 Orthopaedic Industry Annual Report published by Knowledge Enterprises, Inc., which we refer to herein as the Industry Annual Report, the worldwide market for orthopedic products in 2007 was estimated to be $32.5 billion, representing an 11.8% increase from the previous year. According to this report, bone and joint diseases account for half of all the chronic conditions in people over 50 years of age. With the predicted doubling of the aged population by the year 2020, the report suggests that demographics alone will drive growth in the global orthopedic industry. We also believe that the orthopedic industry will continue to grow due to an increasingly older population and extended life spans in the Unites States and other developed countries worldwide.

According to the Industry Annual Report, the world s six largest replacement companies Zimmer, Johnson & Johnson, Stryker, Smith & Nephew, Biomet and Wright Medical generated 89% of joint product sales in 2007. We believe that the size of these companies often leads them to concentrate their marketing and research and development efforts on products that they believe will have a relatively high minimum threshold level of sales. As a result, there is an opportunity for a smaller orthopedic company, such as us, to focus on smaller, higher-growth sectors of the orthopedic market, while still offering a comprehensive product line to address the needs of its customers in a customized and interactive fashion.

Orthopedic devices are commonly divided into several primary sectors corresponding to the major subspecialties within the orthopedic field: reconstruction, trauma, arthroscopy, spine and biologics. Management s initial focus is on innovation related to reconstructive joint devices and spinal products, as discussed below.

Reconstructive Joint Device Market

Most reconstructive joint devices are used to replace or repair joints that have deteriorated as a result of disease or injury. Despite the availability of non-surgical treatment alternatives such as oral medications, injections and joint fluid supplementation of the knee, severe cases of disease or injury often require reconstructive joint surgery. Reconstructive joint surgery involves modifying the bone area surrounding the affected joint and inserting one or more manufactured components, and also may involve using bone cement.

The reconstructive joint device market is generally divided into the areas of hips, knees and extremities. According to the Industry Annual Report, it is estimated that the worldwide reconstructive joint device market had sales of approximately $11.6 billion in 2007, with hip reconstruction and knee reconstruction representing the largest sectors.

Knee Reconstruction. The knee joint involves the surfaces of three distinct bones: the lower end of the femur, or thigh bone, the upper end of the tibia, or shin bone, and the patella, or kneecap. Cartilage on any of these surfaces can be damaged due to disease or injury, leading to pain and inflammation requiring knee reconstruction. According to the Industry Annual Report, knee reconstruction was the largest sector of the reconstructive joint device market in 2007, with estimated sales of approximately $5.9 billion worldwide.

One of the major trends in knee reconstruction includes the use of minimally invasive techniques to accomplish reconstructive goals with less damage to surrounding soft tissues. Our unicompartmental device has been designed to be inserted through small incision surgery with an innovative instrumentation approach. Our design approach was to develop an innovative instrumentation system to improve and simplify surgical technique for a clinically proven implant concept. We believe that our system allows the surgeon to simply and reproducibly balance both flexion and extension gaps. This is a general approach we plan to continue with our other products.

Hip Reconstruction. The hip joint is a ball-and-socket joint that enables the large range of motion that the hip performs in daily life. The hip joint is most commonly replaced due to degeneration of the cartilage between the head of the femur (the ball) and the acetabulum or hollow portion of the pelvis (the socket). This degeneration causes pain, stiffness and a reduction in hip mobility. According to the Industry Annual Report, it is estimated that the worldwide hip reconstruction market had sales of approximately $5.1 billion in 2007.

Similar to the knee reconstruction market, major trends in hip replacement procedures and implants are to extend implant life and to preserve bone stock for possible future procedures. New products have been developed that incorporate advances in bearing surfaces from the traditional polyethylene surface. These alternative bearing surfaces include metal-on-metal, cross-linked polyethylene and ceramic-on-ceramic combinations, which exhibit improved wear characteristics and lead to longer implant life. In addition to advances in bearing surfaces, implants that preserve more natural bone have been developed in order to minimize surgical trauma and recovery time for patients. These implants, known as bone-conserving implants, leave more of the hip bones intact, which may be beneficial given the likelihood of future revision replacement procedures as the average patient s lifetime increases. Bone-conserving procedures are intended to enable patients to delay their first total hip procedure and may significantly increase the time from the first procedure to the time when a revision replacement implant is required. Our hip product portfolio, currently consisting of three products, is focused on improving the surgical techniques for bone-conservative procedures. These products integrate implant designs that are based on predicate devices (*i.e.*, a device with a similar design that has already received clearance) with successful long-term clinical histories. We are actively engaged in several research and development efforts to develop better instrumentation for less traumatic surgeries, improved component designs and bearing surfaces to increase longevity of our devices.

Spine Market

Back and neck pain is one of the leading causes of healthcare expenditures in the United States, with a direct cost of approximately $86 billion annually for diagnosis, treatment and rehabilitation, according to an article published in *The Journal of the American Medical Association* (published February 13, 2008). According to the Industry Annual Report, the U.S. market for lumbar and cervical spine fusion, which is the focus of our spinal business, was estimated to be over $3 billion in 2006 and over $3.6 billion in 2007, and is estimated to grow to more than $4.2 billion in 2008.

The spine consists of vertebrae, which are 29 separate bones connecting the skull to the pelvis. The vertebrae are joined together by soft tissue structures that provide the core of the human skeleton. Within the spinal column, the spinal cord, which is the body s central nerve pathway, is protected by the bony parts of the vertebrae. Nerves contained in the spinal column exit through the foramen openings to the rest of the body. Vertebrae are joined to each other in pairs which are often referred to as motion segments. These motion segments move by means of three joints: two facet joints and one spine disc. The facet joints provide stability and enable the spine to bend and twist while the discs absorb pressures and shocks to the vertebrae.

The four major categories of spine disorders are degenerative conditions, deformities, trauma and tumors. The largest market, and the focus of our spinal research and development business, is degenerative conditions of the facet joints and disc space. These conditions can result in instability and pressure on the nerve roots as they exit the spinal column, causing back pain or radiating pain in the arms or legs.

The recommended treatments for spine disorders depend on the severity and duration of the disorder. Initially, physicians will prescribe non-operative procedures, including bed rest, bracing, medication, lifestyle modification, exercise, physical therapy, chiropractic care and steroid injections. In most cases, non-surgical treatment options are effective; however, many patients do not respond to non-operative treatments and require spine surgery to alleviate their symptoms.

It is estimated that in excess of one million patients undergo spine surgery each year in the United States. The most common spine surgery procedures are: discectomy, which consists of 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. All three of these procedures require access to the spine through either a traditional open approach or through smaller, less invasive methods using various types of retractors or other percutaneous techniques.

We believe that the implant market for spine surgery procedures will continue to grow because of the following market dynamics:

Demographics. The population cohort most likely to experience back pain is likely to grow as a result of our aging baby boomer population. The first baby boomers turned 62 in 2008, and over the next two decades we will see a substantial increase in our aging population. We believe that this generation of older people is less willing to compromise on reducing activity levels and is more interested in treatments that will allow a more rapid return to activities with shorter periods of disability.

Increased Acceptance of Implants. The implementation of implants for use in spine surgery has become the standard of care over the past decade. In the last five years, there has been a substantial and significant increase in the percentage of spinal fusion surgeries using implants. According to Millennium Research Group, an estimated 85% or more of all spinal fusion procedures involve an implant. The current generation of modern trained spine surgeons has accepted usage of implants as the gold standard for achieving optimal results.

Increased Demand for Newer Technologies. Because of the ubiquitous nature of back pain, the market is interested in newer technologies, such as motion preservation, and novel minimally invasive techniques which would potentially allow earlier intervention in the degenerative process of the spine for many patients.

Government Regulation

United States

Our products are regulated by the U.S. Food and Drug Administration, or the FDA, under the Federal Food, Drug, and Cosmetic Act. Some of our products also are regulated by state agencies. FDA regulations and the requirements of the Federal Food, Drug, and Cosmetic Act affect the pre-clinical and clinical testing, design, manufacture, safety, efficacy, labeling, storage, recordkeeping, advertising and promotion of our medical device products. FDA regulations govern, among other things, the following activities that we or our partners perform and will continue to perform:

- product design and development;
- product testing;
- product manufacturing;
- product labeling;
- product storage;
- premarket clearance or approval;
- advertising and promotion; and
- product sales and distribution.

Generally, before we can market a new medical device, marketing clearance from the FDA must be obtained through either a premarket notification under Section 510(k) or the approval of a premarket approval, or PMA, application. The FDA typically grants a Section 510(k) clearance if the applicant can establish that the device is substantially equivalent to a predicate device (*i.e.*, a device with a similar design that has already received clearance). It generally takes approximately three months from the date of a Section 510(k) submission to obtain clearance, but it may take longer, particularly if a clinical trial is required. The FDA may find that a Section 510(k) clearance is not appropriate or that substantial equivalence has not been shown and, as a result, will require a PMA application.

PMA applications must be supported by valid scientific evidence to demonstrate the safety and effectiveness of the device, typically including the results of human clinical trials, bench tests and laboratory and animal studies. The PMA application also must contain a complete description of the device and its components, and a detailed description of the methods, facilities and controls used to manufacture the device. In addition, the submission must include the

proposed labeling and any training materials. The PMA application process can be expensive and generally takes significantly longer than the Section 510(k) process. Additionally, the FDA may never approve the PMA application. As part of the PMA application review process, the FDA generally will inspect the manufacturer s facilities to ensure compliance with applicable quality system regulatory requirements, which include quality control testing, control documentation and other quality assurance procedures.

If human clinical trials of a medical device are required and the device presents a significant risk, the sponsor of the trial must file an investigational device exemption, or IDE, application prior to commencing human clinical trials. The IDE application must be supported by data, typically including the results of animal and/or laboratory testing. If the IDE application is approved by the FDA and one or more institutional review boards, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a nonsignificant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more institutional review boards without separate approval from the FDA. Submission of an IDE does not give assurance that the FDA will approve the IDE and, if it is approved, we cannot assure you that the FDA will determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to and approved by the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study indication or the rights, safety or welfare of human subjects. The trial also must comply with the FDA s IDE regulations and informed consent must be obtained from each subject.

If the FDA believes we are not in compliance with the law, it can institute proceedings to detain or seize products, issue a market withdrawal, enjoin future violations and seek civil and criminal penalties against us and our officers and employees. If we fail to comply with these regulatory requirements, our business, financial condition and results of operations could be harmed.

Thus far, all of our approved products have been cleared by the FDA through the Section 510(k) premarket notification process. We have not needed to conduct any clinical trials to support some of our regulatory approvals. Regulations regarding the manufacture and sale of our products are subject to change. We cannot predict the effect, if any, that these changes might have on our business, financial condition and results of operations. In addition to granting approvals for our products, the FDA has the authority to randomly inspect us for compliance with regulatory requirements that apply to our operations. These requirements include labeling regulations, manufacturing regulations, quality system regulations, regulations governing unapproved or off-label uses and medical device regulations. Medical device regulations require a manufacturer to report to the FDA serious adverse events or certain types of malfunctions involving its products. The FDA inspects device and drug manufacturing facilities in the United States in order to assure compliance with applicable quality system regulations. As discussed in the section below titled Manufacturing and Supply, we currently outsource the manufacture of our products to third-party vendors.

Further, we are subject to various federal and state laws concerning health care fraud and abuse, including false claims laws, anti-kickback laws and physician self-referral laws. Violations of these laws can result in criminal and/or civil punishment, including fines, imprisonment and, in

the United States, exclusion from participation in government health care programs. The scope of these laws and related regulations is expanding and their interpretation is evolving. There is very little precedent related to these laws and regulations. Increased funding for enforcement of these laws and regulations has resulted in greater scrutiny of marketing practices in our industry and resulted in several investigations by various government authorities. If a governmental authority were to determine that we do not comply with these laws and regulations, then we and our officers and employees could be subject to criminal and civil sanctions, including exclusion from participation in federal health care reimbursement programs.

International

In the next few years, we plan to seek required regulatory approvals and comply with extensive regulations governing product safety, quality, manufacturing and reimbursement processes in order to market our products in some major foreign markets, which may include countries in Latin America, Europe or Asia. These regulations vary significantly from country to country and with respect to the nature of the particular medical device. The time required to obtain these foreign approvals to market our products may be longer or shorter than that required in the United States, and requirements for approval may differ from FDA requirements.

If we sell any of our products internationally, the products will be subject to certain foreign regulatory approvals. In order to market our product devices in the member countries of the European Union, we will be required to comply with the European Medical Devices Directives and obtain CE mark certification. CE mark certification is the European symbol of adherence to quality assurance standards and compliance with applicable European Medical Devices Directives. Under the European Medical Devices Directives, all medical devices including active implants must qualify for CE marking. We also would be required to comply with other foreign regulations, such as obtaining Ministry of Health Labor and Welfare approval in Japan, Health Protection Branch approval in Canada, and Therapeutic Goods Administration approval in Australia, if we market in those jurisdictions.

Research and Development

Our research and development engineering personnel have extensive experience in developing medical devices to treat joint and spine pathologies. Our engineers work closely with surgeons to design devices that are intended to improve patient care, simplify surgical techniques and reduce overall costs. In addition to constantly enhancing and improving our current product offerings, we are focusing our research and development efforts in novel approaches to total knee arthroplasty, spinal motion preservation devices and products that promote new fusion techniques and minimally invasive surgical techniques for reconstructive and spinal surgery. On a consolidated basis with Accin, we spent approximately $480,000 and $256,000 on research and development activities in the fiscal years ended December 31, 2006 and December 31, 2007, respectively.

Our research and development efforts are part of our overall business plan to become a market leader in providing solutions for the reconstructive joint and spine markets. To further promote this strategy, we are focused on converting these research and development efforts into commercially viable products that incorporate minimally invasive techniques and quick recovery

to improve patient outcomes across all of our products. Currently, our research and development staff is located in New Jersey, and we also engage the services of independent contractors in that state. However, we intend to expand this staff by hiring engineers in California as well. We expect our research and development costs to increase as we continue to expend significant resources to develop and commercialize our products and potential products.

At this time, we have no formal consulting arrangements with surgeons. However, we work with surgeons informally to obtain their feedback to enhance our products and to identify product candidates that we would like to develop. We plan to work closely with product opinion leaders to develop and enhance our product portfolio.

Manufacturing and Supply

We do not have a manufacturing facility, and we currently do not intend to build manufacturing facilities of our own in the foreseeable future. We utilize third-party vendors to manufacture all of our implants and instruments, including components of our products, while internally performing product design and quality assurance. We currently use up to seven manufacturers for each of our devices.

Our outsourced manufacturing process typically involves machining semi-completed raw materials for both our metal and polyethylene components that make up our joint replacement systems. After being machined, the parts are inspected and processed in preparation for final polishing and finishing as needed. Prior to being packaged, our parts are inspected again to ensure that they are within approved specifications. We also use components in our devices that we acquire from other companies. We distribute both sterile and non-sterile implants and instruments.

Our outsourcing strategy is targeted at companies that meet FDA Quality Standards and our internal policies and procedures. Supplier performance is maintained and managed through a corrective action program intended to ensure that all product requirements are met or exceeded. We believe these manufacturing relationships minimize our capital investment, help control costs and allow us to compete with larger volume manufacturers of spine surgery and reconstructive surgical products.

We currently utilize a small number of manufacturers for our products and rely on a limited number of sources for our product components that are manufactured by third parties. In the future, we may consider manufacturing certain products or product components internally, if and when demand or quality requirements make it appropriate to do so. Although we believe that alternative third-party manufacturers are available, we cannot assure you that we will be able to timely replace our third-party manufacturers immediately if one or more of them can no longer provide us with their manufacturing services. In addition, while we do not anticipate that we will encounter problems in obtaining adequate supplies of components, we cannot assure you that we will continue to be able to obtain components under acceptable terms and in a timely manner.

Sales and Marketing

We mostly rely on third-party independent distributors to market and sell our products. In the future, we intend to increase the number of our internal sales and marketing personnel and further build our own sales and marketing infrastructure to market some of our products targeting surgeons in certain regions. We also intend to continue collaborating with third-party independent distributors, including large regional distributors.

Currently, our products are sold in California, Florida, Georgia and Pennsylvania. However, we intend to expand our sales to other states as we expand our internal sales force and relationships with third-party distributors.

Patents and Proprietary Technology; Trademarks

Patents

We have applied for U.S. and foreign patents covering several of our implant components, and some of our surgical instrumentation. As of August 29, 2008, we had 19 pending domestic and foreign patent applications covering five devices.

Patents and intellectual property will continue to be an important aspect of the orthopedic and spine industry. In this regard, we intend to defend our intellectual property rights. We believe that our patents and products do not and will not infringe patents or violate proprietary rights of others, although it is possible that our existing patent rights may not be valid or that infringement of existing or future patents or proprietary rights may occur. If some of our intellectual property and agreements relating to our products are deemed invalid, that action may have a material adverse effect on our financial condition and results of operations.

The medical device industry is characterized by patent and other intellectual property litigation, and we could become subject to litigation that could be costly, result in diverting management s time and efforts, require us to pay damages and/or prevent us from marketing our existing or future products. Patent litigation typically involves complex factual and legal questions whose outcome is uncertain. Any claim relating to infringement of patents that is successfully asserted against us may require us to pay substantial damages. 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. Our success will depend in part on our not infringing patents issued to others, including our competitors and potential competitors. If our products are found to infringe the patents of others, the development, manufacture and sale of our products or potential products could be severely restricted or prohibited. Also, our competitors may independently develop similar technologies that are not restricted by other companies patents, including ours. Due to the importance of our patents to our business, our market share can decline if we fail to protect our intellectual property rights.

A patent infringement suit brought against us or our partners may force us or our partners to halt the development, manufacture or sale of products or potential products that are claimed to be infringing, unless that party grants us or our partners rights to use its intellectual property. As a result, we may be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products, which we may not be able to do on acceptable terms, or

at all. Even if we or any partner were able to obtain rights to the third party s intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our products or potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business.

As more companies enter the orthopedic and spine market, the possibility of a patent infringement claim against us grows. While we try to ensure that our products do not infringe others patents and proprietary rights, our products, potential products and methods may be covered by patents held by our competitors.

Trademarks

As of August 29, 2008, we had one registered trademark with the U.S. Patent and Trademark Office, or USPTO, for the mark Accin, and we have applications pending for the marks Cardo Medical, Align 360 and A La Carte. On July 16, 2008, the USPTO issued a Notice of Publication dated August 5, 2008 for the mark Align 360. If no opposition is filed within 30 days of the publication date, then the mark Align 360 will be registered with the USPTO.

Competition

The orthopedic and spinal device industry is highly competitive and dominated by a number of large companies with substantially greater financial and other resources than we have. Our largest competitors in the orthopedic and spinal surgical device market are DePuy Orthopaedics, Inc. and DePuy Spine, Inc. (divisions of Johnson & Johnson Company), Zimmer, Inc. (a subsidiary of Zimmer Holdings, Inc.), Stryker Howmedica Osteonics (a subsidiary of Stryker Corporation), Smith & Nephew plc, Biomet Orthopedics, Inc. (a subsidiary of Biomet, Inc.), Medtronic Sofamor Danek, and Synthes Inc.

Companies in the industry compete on the basis of product features and design, innovation, service, the ability to maintain new product flow, relationships with key orthopedic surgeons and hospitals, the strength of their distribution network and price. While price is a key factor in the orthopedic market, other significant factors could negatively impact our results of operations and financial condition, including: technological innovation, reimbursement rates, surgeon preference, ease of use, clinical results and service provided by us and our representatives.

Our products are, and any potential products we commercialize will be, subject to intense competition. Many of our current 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. Many of these competitors also have significantly greater operating history and reputations than we do in our respective fields. We may not be able to compete successfully if we are unable 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 rapidly growing orthopedic market, we anticipate that companies will dedicate significant resources to developing competing products.

Regarding our spinal portfolio, we also face competition from a growing number of smaller companies with more limited product offerings and geographic reach than our larger competitors. These companies, who represent intense competition in specified markets, include Abbott Spine, Inc. (a division of Abbott Laboratories, Inc.), Orthofix International N.V. (parent of Blackstone Medical, Inc.), Alphatec Spine Inc. (a subsidiary of Alphatec Holdings, Inc.), Globus Medical, Inc., and Nuvasive, Inc.

Product Liability and Insurance

We are subject to potential product liability risks that are inherent in the design, marketing and sale of orthopedic implants and surgical instrumentation. We have implemented strict quality control measures and currently maintain product liability insurance in amounts that we believe are typical in the industry for companies with a comparable size to ours. Our insurance premiums are paid as a percentage of sales. We plan to evaluate our levels of product liability insurance annually, as well as the amount of retention carried compared to other comparable companies in the industry. Due to the volatility of the insurance marketplace, the value of the product liability insurance products delivered and the small number of providers of these products, there can be no guarantees as to whether we will be able to secure coverage in the future at a reasonable cost.

Third-Party Reimbursement

Sales of our products will depend on the availability of adequate reimbursement from third-party payors (such as governmental programs, for example, Medicare and Medicaid, private insurance plans and managed care programs), both in terms of the sales volumes and prices of our products. Healthcare providers, such as hospitals that purchase medical devices for treating their patients, generally rely on third-party payors to reimburse all or part of the costs and fees associated with the procedures performed with these devices. These third-party payors may deny reimbursement if they feel that a device is not the most cost-effective treatment available, or was used for an unapproved indication. As such, surgeons are unlikely to use our products if they do not receive reimbursement adequate to cover the cost of their involvement in the surgical procedures. We also believe that future reimbursement may be subject to increased restrictions both in the U.S. and internationally. If we sell our products internationally, market acceptance may depend, in part, upon the availability of reimbursement within the prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government sponsored healthcare and private insurance.

Future legislation, regulation or reimbursement policies of third-party payors may adversely affect the demand for our existing products or our products currently under development and limit our ability to sell our products on a profitable basis.

Also, third-party payors are increasingly challenging the prices charged for medical products and services. Particularly in the United States, third-party payors carefully review, and increasingly challenge, the prices charged for procedures and medical products. Also, greater numbers of insured individuals are receiving (and will continue to receive over the next decade) their medical care through managed care programs, which monitor and often require pre-approval of

the services that a member will receive. Many managed care programs are paying their providers on a capitated basis, which puts the providers at financial risk for the services provided to their patients by paying them a predetermined payment per member per month.

Legislative or administrative reforms to the U.S. or international reimbursement systems in a manner that significantly reduces reimbursement for procedures using our medical devices or denies coverage for those procedures could have a material adverse effect on our business, financial condition or results of operations. We believe that the overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry to reduce the costs of products and services. We cannot assure you that third-party reimbursement and coverage will be available or adequate, or that future legislation, regulation, or reimbursement policies of third-party payors will not adversely affect the demand for our products or our ability to sell these products on a profitable basis. We also cannot assure you that our products will be considered cost-effective by third-party payors, that reimbursement will be available or, if available, that the third-party payors reimbursement policies will not adversely affect our ability to sell our products profitably.

Healthcare Fraud and Abuse

Our relationship with surgeons, hospitals and the marketers of our products are subject to scrutiny under various state and federal anti-kickback, self-referral, false claims and similar laws, often referred to collectively as healthcare fraud and abuse laws. The federal anti-kickback laws prohibit unlawful inducements for the referral of business reimbursable under federally-funded health care programs, such as remuneration provided to physicians to induce them to use certain medical devices reimbursable by Medicare or Medicaid. Healthcare fraud and abuse laws are complex and subject to evolving interpretations, and even minor, inadvertent violations potentially can give rise to claims that the relevant law has been violated. Certain states in which we market our products have similar anti-kickback, anti-fee splitting and self-referral laws, imposing substantial penalties for violations. Any violations of these laws could 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. We cannot assure you that any of the healthcare fraud and abuse laws will not change or be interpreted in the future in a manner which restricts or adversely affects our business activities or relationships with surgeons, hospitals and marketers of our products. In addition, possible sanctions for violating these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare and Medicaid programs and forfeiture of amounts collected in violation of these prohibitions.

We must comply with a variety of other laws, such as laws prohibiting false claims for reimbursement under Medicare and Medicaid, which also can be triggered by violations of federal anti-kickback laws; Healthcare Insurance Portability and Accountability Act of 1996, which protects the privacy of individually identifiable healthcare information; and the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections. In certain cases, federal and state authorities pursue actions for false claims on the basis that manufacturers and distributors are promoting unapproved or off-label uses of their products.

Employees

As of August 29, 2008, we have 16 employees, all of whom were full-time. We plan to add to our headcount in key functional areas that will allow us to further develop our product candidates. In addition, we plan to hire additional qualified information technology and financial reporting personnel. None of our employees are represented by a collective bargaining agreement. We consider our relations with our employees to be satisfactory.

As of August 29, 2008, we also utilize the services of six independent contractors in the research and development of our products and product candidates.

Item 1A. Risk Factors.

An investment in our company involves a high degree of risk. You should carefully consider the risk factors described below together with the other information included in this report. If any of the risks described below occur, or if other risks not identified below occur, our business, business prospects, cash flow, financial condition, stock price and results of operations could be materially adversely affected. Under these circumstances, the trading price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our financial condition and operations.

We have identified the following categories of risk that should be considered by investors:

- Risks related to our business, industry and regulatory matters;
- Risks related to our financial results;
- Risks related to our intellectual property and potential litigation; and
- Risks related to ownership of our common stock.

Risks Related to Our Business, Industry and Regulatory Matters

We expect to incur significant losses, either directly or indirectly through the companies in which we develop our products, for at least the next several years, and we cannot assure you that we will ever be profitable.

We expect to incur significant losses over the next several years, either directly or indirectly through the companies in which we develop our products, as we expand our research and development activities, apply for regulatory approvals, develop additional technology and expand our operations. We cannot assure you that we will be successful in selling or licensing any of the products we might develop or predict the terms we may be able to obtain in any sales or licensing transaction.

We have a limited number of products currently available for sale and there is a high risk that our research and development efforts might not successfully generate any viable product candidates in the future.

We currently have seven products available for sale, all of which are in the early stages of distribution. Other than these products, we are in the preliminary stages of product identification and development, and have identified only a few potential additional products. We have not yet conducted preclinical studies or clinical testing on these additional products. It is statistically unlikely that the few products that we have identified as potential candidates will actually lead to successful development efforts, and we do not expect any additional products resulting from our research to be commercially available for several years, if at all. Our leads for potential products will be subject to the risks and failures inherent in developing medical devices and products, including, but not limited to, the unanticipated problems relating to research and development, product testing, confirming intellectual property rights and non-infringement, regulatory compliance, manufacturing, marketing and competition. Additional expenses may exceed current estimates and, therefore, adversely affect our profitability.

We may need to raise additional funds in the future to fund our operations and research, and these funds may not be available on acceptable terms, if at all.

We anticipate spending significant amounts of cash on expanding our research and development, sales and marketing efforts, and product commercialization. We believe that the proceeds from our recent transactions, together with our future sales, existing cash and cash equivalent balances and interest we earn on these balances, and the cash and cash equivalents held by CKST as of the closing of the Merger, will be sufficient to meet our anticipated cash requirements for at least the next 12 months. However, actual capital requirements may change as a result of various factors, including:

- the success of our research and development efforts, and any changes in the breadth of our research and development programs;
- results from preclinical studies and clinical trials conducted by us or our collaborative partners or licensees, if any;
- the number and timing of acquisitions and other strategic transactions;
- our ability to maintain and establish corporate relationships and research collaborations;
- our ability to manage growth and costs associated with this growth, and the costs associated with increased capital expenditures;
- the time and costs involved in filing, prosecuting, defending and enforcing patent and intellectual property claims;
- the cost and timing of obtaining and maintaining regulatory approval or clearance for our products and products in development;

the expenses we incur in manufacturing and selling our products;
the revenues generated by sales of our products; and
the costs associated with our employee retention programs and related benefits.

Our primary goal as it relates to liquidity and capital resources is to attain the appropriate level of debt and equity and the resultant cash to implement our business plan. We may need to raise additional funds, which may not be available to us on favorable terms, if at all. If we raise capital by issuing equity or debt securities, our existing shareholders may experience dilution and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing shareholders. Further, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish rights to our potential products or proprietary technologies, or to grant licenses on terms that are not favorable to us. If we are unable to raise needed capital on terms acceptable to us, we may not be able to develop new products, enhance our existing products, execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated customer requirements. Any of these events could have a material adverse effect on our business, financial condition and results of operations.

Cost containment measures, pressure from our competitors and availability of medical reimbursement may impact our ability to sell our products at prices necessary to expand our operations and reach profitability.

Healthcare costs have risen significantly over the past decade and numerous initiatives and reforms initiated by legislators, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the healthcare industry, including hospitals. This has resulted in greater pricing and other competitive pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations, independent delivery networks and large single accounts continue to consolidate purchasing decisions for some hospital customers. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to change the national and worldwide healthcare industry, resulting in further business consolidations and alliances among customers and competitors. This consolidation may reduce competition, exert downward pressure on the prices of our products and adversely impact our business, financial condition or results of operations.

Further, third-party payors in the United States and abroad continue to work to contain healthcare costs. The introduction of cost containment incentives, along with closer scrutiny of healthcare expenditures by both private health insurers and employers, has resulted in increased discounts and contractual adjustments to hospital charges for services performed and has shifted services between inpatient and outpatient settings. Hospitals or physicians may respond to these cost-containment pressures by substituting lower-cost products or other therapies for our products.

The market for orthopedic, knee and hip surgery devices is large and growing at a significant rate. Numerous new companies and technologies, as well as more established companies, have entered this market. New entrants to our markets include numerous niche companies with a

singular product focus, as well as companies owned partially by surgeons, who may have greater access than we do to the surgeons who may use our products. As a result of this intensified competition, we believe there will be increasing pressure to reduce pricing of our medical devices. If we are unable to price our products appropriately due to these competitive pressures or for other reasons, our profit margins will shrink and our ability to invest in and grow our business and achieve profitability will decrease.

In addition, sales of our products will depend on the availability of adequate reimbursement from third-party payors (such as governmental programs, for example, Medicare and Medicaid, private insurance plans and managed care programs), both in terms of the sales volumes and prices of our products. Healthcare providers, such as hospitals that purchase medical devices for treating their patients, generally rely on third-party payors to reimburse all or part of the costs and fees associated with the procedures performed with these devices. These third-party payors may deny reimbursement if they feel that a device is not the most cost-effective treatment available, or was used for an unapproved indication. As such, surgeons are unlikely to use our products if they do not receive reimbursement adequate to cover the cost of their involvement in the surgical procedures. We also believe that future reimbursement may be subject to increased restrictions both in the U.S. and international markets. If we sell our products internationally, market acceptance may depend, in part, upon the availability of reimbursement within the prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government sponsored healthcare and private insurance.

Future legislation, regulation or reimbursement policies of third-party payors may adversely affect the demand for our existing products or our products currently under development and limit our ability to sell our products on a profitable basis.

Also, third-party payors are increasingly challenging the prices charged for medical products and services. Particularly in the United States, third-party payors carefully review, and increasingly challenge, the prices charged for procedures and medical products. Also, greater numbers of insured individuals are receiving (and will continue to receive over the next decade) their medical care through managed care programs, which monitor and often require pre-approval of the services that a member will receive. Many managed care programs are paying their providers on a capitated basis, which puts the providers at financial risk for the services provided to their patients by paying them a predetermined payment per member per month.

Legislative or administrative reforms to the U.S. or international reimbursement systems in a manner that significantly reduces reimbursement for procedures using our medical devices or denies coverage for those procedures could have a material adverse effect on our business, financial condition or results of operations. We believe that the overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry to reduce the costs of products and services. We cannot assure you that third-party reimbursement and coverage will be available or adequate, or that future legislation, regulation, or reimbursement policies of third-party payors will not adversely affect the demand for our products or our ability to sell these products on a profitable basis. We also cannot assure you that our products will be considered cost-effective by third-party payors, that reimbursement

will be available or, if available, that the third-party payors reimbursement policies will not adversely affect our ability to sell our products profitably.

We must convince orthopedic and spine surgeons that our products are an attractive alternative to existing surgical treatments of orthopedic and spine disorders.

To be commercially successful, we believe that we will need surgeons to adopt our products as their preferred treatment option for their patients. Based on our experience, we believe surgeons may not widely adopt our products unless they determine, based on clinical data and published peer-reviewed journal articles, that our products provide benefits or an attractive alternative to conventional modalities of treating joint and spine disorders. Surgeons may be slow to adopt our products for the following reasons, among others:

- lack of clinical evidence;
- the time that must be dedicated for training;
- lack of experience with our products;
- perceived risks generally associated with the use of new products and procedures;
- perceived risks associated with purchasing products from an early-stage medical device company;
- costs associated with the purchase of new products and equipment; and
- limited availability of reimbursement within healthcare payment systems.

We also believe that recommendations and support of our products by influential surgeons are essential for market acceptance and adoption. If we do not receive support from these surgeons, surgeons and hospitals may not use our products. As a result, we may not achieve expected revenues and may never become profitable.

We generally do not have long-term contracts with our customers.

We anticipate that we will generally not enter into long-term contracts with our customers. As a result, we will be exposed to volatility in the market for our products and loss of our customers, and we may be unable to achieve profitability. If we are unable to market our products on terms we find acceptable, our financial condition and results of operations could suffer materially.

Our business plan relies on certain assumptions about the market for our products, which, if incorrect, may adversely affect our business and profitability.

We believe that the aging of the general population and increasingly active lifestyles will continue and that these trends will increase the need for our medical products. However, the projected demand for our products could differ materially from actual demand if our assumptions regarding these trends and acceptance of our products by the medical community prove to be

incorrect or do not materialize, or if non-surgical treatments gain more widespread acceptance as a viable alternative to our devices.

We expect to face significant competition as a result of the rapid technological changes in the medical devices industry, which could have an adverse effect on our business, financial condition or results of operations.

The medical device market is highly competitive, subject to rapid change, and significantly affected by new product introductions and other market activities of industry participants. We expect to encounter intense competition across our product lines and in each market in which our products are sold from various medical device companies, many of which are likely to have greater financial and marketing resources than us. Primary competitors are Zimmer, J&J/DePuy Orthopaedics, Stryker and Biomet in the hips and knees market, and Medtronic/Sofamor Danek, J&J/DePuy Spine and Synthes in the spine market. In addition, we will face competition from a wide range of companies that sell a single or a limited number of competitive products or which participate only in a specific market segment, as well as from non-medical device companies, including pharmaceutical companies, which may offer alternative therapies for disease states intended to be treated using our products.

Additionally, the medical device market is characterized by extensive research and development, and rapid technological change. Developments by other companies of new or improved products, processes or technologies may make our products or proposed products obsolete or less competitive and may negatively impact our revenues. We will be required to devote continued efforts and financial resources to develop or acquire scientifically advanced technologies and products, apply our technologies cost-effectively across product lines and markets, attract and retain skilled development personnel, obtain patent and other protection for our technologies and products, obtain required regulatory and reimbursement approvals and successfully manufacture and market our products consistent with our quality standards. If we fail to develop new products or enhance existing products, it could have a material adverse effect on our business, financial condition or results of operations.

Many of our larger competitors are either publicly traded or divisions or subsidiaries of publicly traded companies, and enjoy several competitive advantages over us, including:

- larger and more well-established distribution networks;
- established relationships with a greater number of surgeons, hospitals, other healthcare providers and third-party payors;
- products supported by long-term clinical data;
- greater experience in obtaining and maintaining regulatory approvals or clearances for products and product enhancements;
- greater name recognition;

- greater access to manufacturers, vendors and raw materials for manufacturing medical devices;
- more expansive portfolios of intellectual property rights; and
- greater financial and other resources for product research and development, sales and marketing, intellectual property protection and litigation.

Hospitals, surgeons, distributors and agents may have existing relationships with other medical device companies that make it difficult for us to establish new relationships with them. As a result, we may not be able to sell and market our products effectively.

We believe that to sell and market our products effectively, we must establish relationships with key surgeons and hospitals in the field of orthopedic knee, hip and spinal surgery. Many of these key surgeons and hospitals already have long-standing relationships with large, better-known companies that dominate the medical devices industry through collaborative research programs and other relationships. Because of these existing relationships, some of which may be contractually enforced, surgeons and hospitals may be reluctant to adopt our products, particularly if our products compete with or have the potential to compete with products supported through their own collaborative research programs or by these existing relationships. Even if these surgeons and hospitals purchase our products, they may be unwilling to enter into collaborative relationships with us to promote joint marketing programs or to provide us with clinical and financial data.

We work primarily with a network of independent orthopedic product agents and distributors that generate sales leads for us, in addition to working with our own internal direct sales force. If these product agents and distributors believe that their relationship with us is less beneficial than other relationships they may have with more established or well-known medical device companies, they may be unwilling to continue their relationships with us, making it more difficult for us to sell and market our products effectively.

Our manufacturers may be unsuccessful in manufacturing products at the levels required to meet future market demand.

We are seeking to rapidly grow sales of our products, and, if we are successful, our growth may strain the ability of our manufacturers to manufacture an increasingly large supply of our products. Manufacturers regularly experience difficulties in scaling up production and our manufacturers may face difficulties in increasing their production levels. Our manufacturers may not be able to manufacture our products with consistent and satisfactory quality or in sufficient quantities to meet demand, which could hurt our reputation, cause our customers to cancel orders or refrain from placing new orders for our products and reduce or slow growth of sales of our products. The increased production volume also could make it harder for us to maintain control over expenses, manage our relationships with our manufacturers, maintain good relations with our employees or otherwise manage our business.

We rely on single source manufacturers, which could impair our ability to meet demand for delivering our products in a timely manner or within our budget.

We rely on third-party manufacturers to manufacture our products. It is critical to our business that our contract manufacturers be able to provide us with products in substantial quantities, in accordance with agreed upon specifications, in compliance with regulatory requirements, at acceptable cost and on a timely basis. Our anticipated growth could strain the ability of manufacturers to deliver an increasingly large supply of products. If we are unable to obtain sufficient quantities of high quality products to meet customer demand on a timely and cost-effective basis, we could lose customers, our reputation could be harmed and our business c