

Spinal Surgery – New Technologies

Sector: Medical Devices & Procedures

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Sector Report

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Company Name	Ticker	Stock Price	P/BV	Debt / Equity	P / Rev. TTM	P / EBITDA TTM	TTM	P / E 2004 E	2005 E
Public Companies									
Johnson & Johnson, Inc.	JNJ	\$ 55.74	12.5x	0.60x	3.8x	12.0x	18.9x	18.4x	16.9x
Biomet, Inc.	BMET	\$ 42.32	7.7x	0.09x	7.0x	19.6x	33.3x	27.1x	23.5x
NuVasive, Inc.	NUVA	\$ 10.27	n.m.	0.74x	10.5x	n.m.	n.m.	n.m.	n.m.
CryoLife, Inc.	CRY	\$ 4.64	1.8x	0.04x	1.8x	n.m.	n.m.	n.m.	n.m.
Protein Polymer Technologies, Inc.	PPTI	\$ 0.31	n.m.	0.00x	8.5x	n.m.	n.m.	NA	NA
Average - Public Companies			7.3x	0.3x	6.3x	15.8x	26.1x	22.8x	20.2x
Private Companies									
Disc Dynamics, Inc.				TranS1, Inc.			Spinecore, Inc.		
RayMedica, Inc.				Endius, Inc.			HydroCision, Inc.		

Sources: SEC Filings, Bloomberg, Multex, First Call and Yahoo-Finance Stock Prices as of July 23, 2004 TTM – Trailing Twelve Months and E – Estimates

According to the National Institute of Health (NIH), back pain is one of the most prevalent medical conditions among Americans. Estimates indicate that between 30 to 60 million Americans suffer from back pain in any given year and it is expected that they will spend over \$100 billion annually in treating back problems. The bulk of this money goes into pharmacology and physical therapy. Nevertheless, spinal implants and instrumentation utilized in spine surgery is one of the fastest growing segments in orthopedics with an expected annual growth rate of between 20.0% and 30.0% through the end of the decade. In 2002, the U.S. spinal implants and instrumentation market reached approximately \$1.6 billion by far the largest in the world representing well over 65% of the total global market according to Knowledge Enterprises. Of the millions of Americans that suffer from back pain there are only approximately 900,000 spinal surgeries performed every year, however, this figure is expected to increase significantly as new less invasive technologies make this treatment option more attractive. Two factors will drive the growth of this market over the next several years: the aging of the population and the development of new innovative technologies. In this report we will focus on three innovative technologies in spinal surgery: **artificial discs**, **prosthetic nucleuses** and **minimally invasive surgery systems**.

These new technologies, once approved by the FDA, will offer several benefits including reducing the length of hospital stays and the time of recovery; thus, lowering cost. In addition, artificial disc and prosthetic nucleuses technologies will provide a more natural mobility of the spine. The benefits of these less invasive options are expected to lead to an increase in the overall number of surgical candidates, many of whom are currently treated for degenerative disc disease (DDD) using an invasive and risky procedure called spinal fusion. As a result, the prospective market size for artificial discs and prosthetic nucleuses could reach over \$2.2 billion, larger than the expected size of the fusion market by 2005.

The impressive growth and future prospects of the spine implants and instrumentation market has attracted the attention of companies and investors. Large corporations such as Johnson & Johnson, Inc. (NYSE:JNJ) and Abbot Laboratories (NYSE:ABT) have shown great interest in the business through a number of acquisitions in the past couple of years. The venture capital community has also indicated a strong interest in the space. In 2003, spine related companies received \$177.2 million in funding from venture capital firms, a 99.3% increase over the \$88.9 million invested in 2002. Lastly, our Entrepreneurial Confidence Index (ECI) indicated continued strong interest in the medical device sector.

Of the three technologies discussed in this report, only minimally invasive surgery products have received FDA clearance and are being actively marketed. **Artificial discs are expected to be approved for marketing in the US in late 2004 or early 2005**, while prosthetic nucleuses have a longer road ahead as the more advanced programs are just beginning clinical trials. Although these technologies are already being used in Europe, there is no guarantee that the FDA will approve these technologies, which is a risk investors should consider.

In this report, we have identified 38 companies that have product portfolios that encompass at least one of the technologies featured. Of this list of companies, we have profiled 10, five public and five private companies. We believe that the spine surgery space offers a unique and viable opportunity for investors looking to participate in an emerging and high-growth sector.

FOR FULL DISCLOSURE INFORMATION REFER TO THE LAST PAGE OF THIS REPORT

Entrepreneurs and Venture Capitalists

Towards the end of 2003, we saw continued strength in funding for medical device companies by the Venture Capital (VC) community. During the fourth quarter medical device companies received \$505.2 million in venture capital, according to the National Venture Capital Association (NVCA), a 55.1% increase from the \$325.6 million in the third quarter of 2003 and 3.2% above the \$489.6 million for the same quarter in 2002. The \$505.2 million was the second largest amount of venture capital funding for the sector in almost three years and is well above the average dollars invested per quarter since Q1 of 1995 (\$359.4 million). Companies with products relating to spine surgery or spine injury received \$177.2 million during all of calendar year 2003 a 99.3% increase over the \$88.9 million invested by venture capitalists in 2002. Medical device and equipment companies received \$1.5 billion during this time period, the majority of which went to vascular or heart disease related companies (see March 10, 2003 report on Drug-Eluting Stents). Venture Capitalist interest in spinal surgery is warranted as this is considered a high-growth niche. Moreover, back pain is among the most prevalent medical conditions for Americans, second only to the common cold. Small start-up medical device and biotechnology companies developing products have recently received large investments of capital. For example, Endius, closed a \$26.5 million financing on March 2003 from 11 VC firms; RayMedica, which is developing a hydrogel-filled polyethylene capsule utilized to replace a disc's nucleus, received \$12 million from investors. The influx of capital will make it possible for the continued development of emerging technologies such as artificial discs, prosthetic nucleus replacement devices and minimally invasive spine surgery devices, which are the focus of this report. Moreover, the significant funding of spine related companies by "smart money" investors (i.e. venture capitalists) indicates that the sector may provide an opportunity for investors to participate at an early stage in an emerging technology.

Medical Appliances and Equipment ranked 71st of a possible 289 sub-sectors in our Q2 2004 Entrepreneurial Confidence Index (ECI). Although entrepreneurial interest in this industry has decreased slightly this year, it still generates a significant level of interest as the sub-sector was still in the upper echelon of the second quartile in our study; thus indicating a strong interest among entrepreneurs.

The Spine and Spine Fusion Market

Back pain or discomfort is the second most cited reason for a person to visit his or her primary care physician (PCP). According to the Center for Disease Control (CDC) and the National Institute of Health (NIH) these are some statistics about the prevalence of back pain:

- Chronic back pain affects 15.0% to 45.0% of the U.S. population each year;
- It is the most common cause of limited activity for Americans under the age of 45;
- It is the fifth most cited reason for hospitalization;
- And it is the third most common reason for surgery.

Many postulate that 4 in 5 or some 80% of Americans will suffer some sort of back discomfort in their lifetime. There are numerous causes of back pain. Some common causes include disc herniation, degenerated disc(s) or compression fractures either from trauma or osteoporosis in elderly people. Of these, degenerated disc disease (DDD) has come to the forefront of the medical device industry as new technologies such as artificial discs (AD), prosthetic disc nucleuses (PDN) and minimal invasive surgery (MIS) systems are expected to greatly improve the quality of life for patients, reduce hospital stays, recovery time and more importantly attract new patients who were not candidates for spine surgery previously.

According to Knowledge Enterprises, an industry research and consulting firm, the global market for spinal implants and instrumentation was \$2.4 billion in 2002 of which the U.S. accounted for 67.9% or some \$1.6 billion. The industry is dominated by Medtronic, Inc. (NYSE:MDT), which had 36.9% global market share; Johnson & Johnson (NYSE:JNJ), which had 19.8% market share; and Synthes-Stratec, which did \$312 million in spinal implant sales or some 13.2% market share. Spine surgery is thus a sizable business and represents the fastest growing segment in orthopedics according to analysts. Estimates call for 20.0% to 30.0% per year growth through the end of the decade. Driven by the core growth factors of the entire healthcare sector including the growing and aging population and rapid technological advancements that provide less invasive treatment options, the number of surgery candidates is expected to show substantial growth.

One of the most common procedures to treat DDD is spinal fusion. However, it is a very invasive procedure, which makes it appropriate only for a relatively small number of potential candidates. Minimally invasive surgical (MIS) systems and tools is a technology targeted on improving on traditional spinal fusion by reducing the amount of tissue damage during surgery. According to Enterprise Knowledge, there were 391,050 fusions performed in the U.S. in 2002 and the number of fusions is expected to grow to 488,750 by 2005, an increase of 24.6%. Furthermore, the average price of implants and instruments utilized in spinal fusions ranges between \$3,500 and \$4,500, which translates to a \$1.4 to \$1.8 billion market size in 2002 growing to almost \$2.2 billion by 2005. This is the minimal applicable market for MIS system manufacturers and developers.

Proponents of artificial disc and prosthetic nucleus technologies look to replace fusion with a more naturally functioning prosthetic option. Offering a slightly less invasive procedure, according to some of the more recent studies release by market participants, the added benefits of these two technologies are quicker recovery time and the increased and more natural motion of the spine after surgery. While many of these technologies have been around in Europe for several years, the very first artificial disc is expected to be introduced in the U.S. market in late 2004 or early 2005. These technologies will probably replace some, but not all of the spinal fusion or MIS market. They will also help to broaden the potential spinal surgery market by making treatment available to a larger candidate pool. We assume a 25% penetration rate for these technologies in the fusion market, and calculate the expected market size for these prosthetics for 2005 at approximately \$500 million, in the U.S. alone.

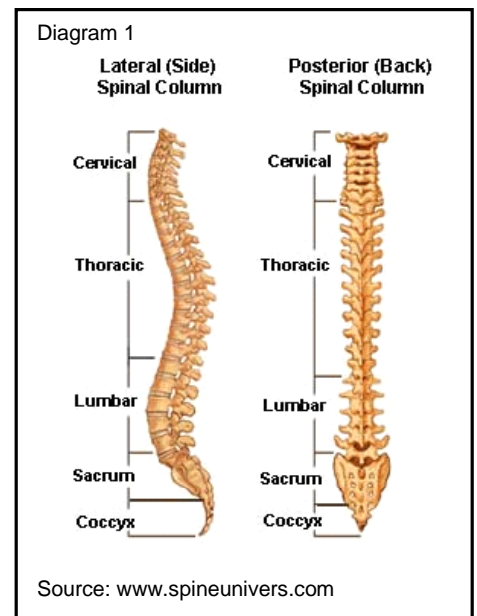
Over the next couple of pages we discuss in some detail the causes DDD and anatomy of the spine, current treatment options and the three aforementioned technologies targeted on improving patients' quality of life.

Degenerative Disc Disease (DDD)

Degenerative Disc Disease (DDD) is a prominent cause of back pain and a reason for spinal surgery. The name is somewhat of a misnomer as it is really not a disease but much like "heart disease" is a condition. To better understand the affects of degenerative disc disease first we must understand the make up of the human spine and more specifically the cervical and lumbar discs. For the purpose of this report, the anatomy of the human spine can be divided up into three major sections: Cervical, Thoracic and Lumbar spine. Below the lumbar spine is a bone called the Sacrum followed by the Coccyx. Each spinal section is made up of individual bones called vertebrae. There are seven cervical vertebrae, 12 Thoracic vertebrae, and five Lumbar vertebrae (see Diagram 1). The 24 vertebrae are separated by spinal discs. A spinal disc serves three purposes. It is a spacer, maintaining separation between the vertebrae allowing multidirectional motion. It is also a shock absorber allowing the spine to compress when loaded during activities such as running or jumping. Finally, a motion unit, the elastic attributes of the disc allow for motion coupling meaning the spine may flex, rotate and bend all at the same time.

Each disc is made up of two parts. The hard, tough outer layer called the annulus fibrosis, which surrounds a mushy, moist center, termed the nucleus pulposus. One could equate a spinal disc to a jelly-filled donut. At birth, the nucleus is highly-hydrated consisting of approximately 80.0% to 90.0% water. Over time, the disc's nucleus dehydrates and loses height and motion. This is a natural aging process. Sometimes a twisting injury damages the disc and starts a cascade of events that leads to degeneration. The condition can be progressive although most healthcare practitioners would agree that pain does not necessarily increase over time. The disc itself has few nerve endings and no blood supply; therefore, without a blood supply the disc does not have the ability to regenerate itself. The damaged disc can cause relative discomfort and can be more susceptible to tears and disc herniations in the annulus. Some surgeons believe the proteins found in the soft inner core of the disc can leak out of the tear in the disc and inflame the neural anatomy in proximity to the disc.

MRI scans have documented that approximately 30.0% of 30 year olds have signs of disc degeneration even though they have no symptoms. Most believe that the demographic most affected by DDD are adults between the ages of 30 and 60. According to the Census 2000, this demographic represented 41.5% of the U.S. population or some 116.8 million



Americans. These numbers suggest a sizable applicable target market for surgical products discussed in this report. For some, the pain is so intense that they are forced to deal with it by undergoing several treatments (i.e. Pharmacology, physical therapy or surgery). Unfortunately, many of these treatments are not effective as they only alleviate the symptoms but do not treat the condition. In this report, we focus on alternative surgical treatments of degenerative disc disease. The following section discusses the current methodologies utilized and some emerging technologies.

Surgical Treatments for DDD – Spinal Fusion and New Alternatives

Currently, degenerative disc disease is often surgically treated with an interbody spinal fusion or fixation procedure, which is designed to alleviate pain and stabilize the spine. Spinal fusion often requires a three to six inch incision and can involve the removal of the degenerated tissue and packing the space using bone graft material to essentially restore disc space height. The bone graft grows into the existing bone and fuses two vertebrae together to form one long fused segment. This procedure has been used by orthopedic and neurological surgeons since the 1930s and is currently the “gold standard” and the most successful procedure for the treatment of advanced degenerative disc disease. Moreover, the fusion rate for spinal fusions is approaching 90.0% and with new bone-morphic agents that increase the growth and fusion of the bone graft, experts expect even higher fusion rates in the near future. Fusion is successful in reducing pain in about 75% of cases.

Despite these high fusion rates, spinal fusion has many drawbacks especially when the fusions involve multiple levels meaning more than two vertebrae are fused. The fixation of the vertebrae obviously restricts any and all natural lateral movement of the fused segment. As such, the restrictions can put added pressure on the adjacent vertebrae, which may eventually require surgery as well. A recent study reported in *The Spine Journal*, which studied the likelihood of additional surgery for adjacent degeneration 10 years after the original fusion surgery revealed that 18% of 178 patients who underwent lumbar fusion required additional surgery. New less invasive procedures, implants and instrumentation are being developed, which allow for more natural movement of the spine as well as quicker recovery times and overall improvement in quality of life for the patients. The technologies provide an alternative to traditional spinal fusion. This report speaks on two technologies artificial disc and prosthetic nucleuses, which are at different levels of development and regulatory clearance. Additionally we speak about minimally invasive surgery a third adjunct technology currently being utilized with spinal fusion to lessen the recovery time by reducing the size of access incisions and damage to tissue.

Artificial Disc - AD

One of the current procedures being tested for the treatment of degenerative disc disease is total disc replacement (TDR), which utilizes an artificial disc (AD). Artificial disc technology replaces a degenerated disc with a prosthetic, which will have all the biomechanical attributes with regards to stiffness and flexibility as the original disc allowing for a more natural movement of the spine, which is restricted in fusion. The technology was originally introduced in the 1980's by Dr. Buttner-Janz and colleagues with the first evolution of the artificial disc being the LINK SB Charite. The products have never been cleared for use in the U.S. Over time developers have significantly improved upon the original designs. Patients receiving the artificial disc returned to work after three months according to some of Medtronic's clinical trial results. A typical traditional fusion patient returns to work after three to six months.

An artificial disc has four attributes to which one can compare and contrast between different products and spinal fusion: flexibility, durability, fixation and size (bulkiness).

- **Flexibility** – The artificial disc must provide segmental motion of a normal spine. Different developers have attacked this through different design and materials, both of which we will discuss further.
- **Durability** – As we previously mentioned, degenerative disc disease primarily affects adults between the ages of 30 and 60; therefore, the prosthesis ideally should last at least 40 years. The compressive load supported by the artificial disc will cause wear and tear of the prosthetic. One of the biggest concerns about this technology is the amount of debris released by the artificial disc over time. Developers have tested a number of different materials and have run the devices through thousands of cycles simulating the wear and tear experienced by the prosthesis during its life cycle.
- **Fixation** – The prosthesis must be fixed to vertebrae. To improve the physical interfacing of the prosthesis with the bone vertebrae, most artificial discs' endplates have a porous surface. Some even

coat the surface with bone growth promoting chemicals to insure better fusion with the vertebrae and improve the success rate of the implant.

- **Size (Bulkiness)** – Some of the artificial discs are relatively large especially when one is speaking about ADs utilized to replace lumbar discs, which by nature are larger than cervical discs. The disc's large size require a larger incisions and/or anterior (from the front of the body) approach often requiring a vascular or general surgeon to open a pathway to the spine. This procedure can increase the risk of complications. Some developers have designed an artificial disc that comes in parts and can be put together during the operation; thus requiring less distraction of the vertebrae.

There are a number of products in clinical trials to prove efficacy and safety in order to attain FDA clearance. The following are summary descriptions of two such devices, the SB Charite III (Depuy Spine a subsidiary of Johnson & Johnson) and ProDisc (Spine Solutions, Inc. part of Synthes-Stratec).

SB Charite III™

SB Charite III



Source: www.spine-health.com

The third iteration of the Charite prosthetic disc, the SB Charite III is a total disc replacement technology that uses two cobalt chromium alloy endplates. The endplates are coated with titanium and hydroxyapatite porous coating (available in 2006) to enhance bone fixation. The disc is able to remain stationary through the anchoring teeth along the edges of the endplates. The movement of the disc is made possible through the utilization of the ultra high molecular weight polyethylene (UHMWPE) sliding core placed between the endplates. Theoretically, the implant offers the advantage of allowing the spacer to shift dynamically within the disc space and provide spinal motion similar to that of an original disc.

The SB Charite disc is by far the most utilized and widely studied artificial disc with over 7,000 patients receiving the implants around the world, predominantly in Europe. As such, the disc received unanimous

endorsement from the FDA Orthopedic Advisory Panel in early June 2004. The recommendation from the FDA advisory panel does not guarantee FDA clearance but it gives a good indication. The SB Charite III disc is expected to hit the U.S. market in late 2004 or early 2005; thus, giving JNJ a solid first mover advantage over the competition and 100% market share until Synthes-Stratec introduces its artificial disc, ProDisc, in late 2005 or early 2006.

ProDisc® II

The ProDisc, designed in the late 1980's by Thierry Marnay, a French Orthopedic surgeon, constitutes two alloy endplates and a polyethylene core. Unlike its counterpart, the ProDisc comes in three separate pieces that are attached through a large central keel. Moreover, each endplate has two spikes to anchor the implant to the vertebrae. The ProDisc matches the range of motion as a normal spine. The device is modular, so the surgeon can customize the device to each patient. The endplates are inserted in a collapsed form as to not require over-distraction (excessive spreading) of the vertebral bodies. Only after the metal endplates are seated are the vertebral bodies fully distracted. The surgeon can then insert a polyethylene core between the endplates to complete the assembly process.

An 11-year follow-up study cited in *BioMechanics Magazine* this past May showed that 93% of patients (60 patients included in study) were satisfied with the procedure. Furthermore, the study revealed that the all the original implants were intact and functioning. There had been no implant migration or failures within the study group. The ProDisc has been implanted in over 5,000 patients around the world. Much like Charite, it has been well studied and the FDA is likely to make a final clearance decision in the next 18 months.

ProDisc Artificial Disc



Source: www.spine-health.com

The impending introduction of artificial discs in the United States has created significant interest amongst healthcare practitioners. The adoption is expected to be quick and predominantly driven by patient demand. Already many surgeons have waiting lists of patients that are looking to become surgical candidates. As we discussed earlier, utilization of

artificial disc may have a slight cannibalizing affect on spinal fusions, but will also allow for new patients that are currently being treated with non-surgical methods and may be more willing to undergo the procedure. The clearance process has been long and complicated and those companies with initial first products will benefit from the initial quick adoption. After the first discs are cleared by the FDA, the clearance process will become significantly shorter and less costly. As such, there is a growing number companies touting to have or are developing an artificial disc program. It is also important to point out that the two preceding descriptions are for lumbar artificial disc, but there are several companies working on cervical artificial discs. Medtronic is taking a multiple platform approach with its Prestige™ and Bryan® cervical disc. The Prestige disc is expected to be first to market with an expected launch in 2007. Synthes-Stratec with its cervical artificial disc is about 12 months behind Medtronic.

Prosthetic Disc Nucleus - PDN

A second technology touted to cause a paradigm change in the treatment of degenerative disc disease is the use of a prosthetic disc nucleus (PDN) to replace the existing nucleus of the degenerated disc. This technology is very similar to that of total disc replacement, but centers on replacing just the inner nucleus portion of the disc with a synthetic thus retaining the original annulus fibrosis (the hard, tough outer layer of a disc). Technically speaking the objective of the prosthetic nucleus is to re-inflate the annulus and relieve the compressive load of the disc by sharing a significant portion of said load and restore height. Much like Total Disc Replacement (TDR), nucleus replacement was first attempted back in the 1950's utilizing metal balls. Advances in biochemicals have introduced a variety of synthetic polymers and hydrogels currently being test for efficacy and safety. One of the main advantages of the PDN procedure is that it is a less invasive surgical procedure requiring less tissue trauma and no fixation component is required as compared to fusion. As such, surgical and recovery time could be shorter in comparison to both fusion and TDR. Moreover, unlike fusion, the procedure is reversible. Should the prosthetic offer no real benefit, it can be removed and the surgeon can then offer a more permanent solution (i.e. fusion). The PDN technology still has several years of testing before the product is introduced into the U.S. market. Several are currently in pre-clinical trials and some have begun clinical trials. This is a summary of one of the more developed products being tested.

PDN-SOLO™

The PDN-SOLO and PDN-SOLO XL prosthetic disc nucleus devices, developed by privately held RayMedica, are the first commercially available prosthetic disc nucleus implants in the world. RayMedica's PDN device aims to relieve back pain by restoring disc height as well as retaining range of motion, reducing the risk of accelerated degeneration in the treated disc or adjacent discs. The device is implanted in a dehydrated state and has the ability to restore disc height as it expands with hydration. The polyethylene jacket is critical because it keeps the hydrogel from becoming too flat, thus not functioning as intended. Few materials are strong enough to perform this function properly and be biocompatible.

Latest clinical data released by the Company showed significant improvement in patient low back pain based on the Oswestry Disability Index (ODI), which is the standard pain measurement survey used to indicate the level of disability with lower back pain, after 12 months.

RayMedica's PDN device is by far the most studied and implanted prosthetic nucleus. There are several other companies working on comparable technologies at different stages of development. Table 1 illustrates a couple of these new technologies.

Table 1

Product	Company	Device Description	Stage
• PDN-SOLO	RayMedica	Hydrogel in Polyurethane Jacket	IDE Began Late 2003
• BioDisc	CryoLife	Hydrogel	Pre-Clinical approved; awaiting IDE meeting with FDA
• Dascor	DiscDynamics	Polyurethane Balloon	Clinical Trials in Europe
• NeuDisc	Replication Medical	3 layers of hydrogel with Dacron mesh jacket	Pre-Clinical testing



Minimally Invasive Surgery - MIS

Another recent technological breakthrough that will have an impressive impact on spinal surgery is the process of minimally invasive surgery, which utilizes special instruments that make smaller incisions thus creating less tissue damage as well as special imaging or optics technologies allowing for more precise percutaneous (through the skin) approach to spinal surgery. The end result of these new techniques and methodologies are shorter hospital stays and quicker recovery times post operations reducing costs and improving patient satisfaction.

Much like the artificial disc, the different minimally invasive surgery systems may be compared based on predominantly three criteria focusing on the advantages and disadvantages of said systems. Such criteria include:

- **Ease of Use:** As with any medical instrumentation, surgeon adoption success centers on the efficiency, predictability and repetitiveness of a particular procedure utilizing said medical instrumentation.
- **Incisions:** The size of the incisions are obviously directly correlated to the time of recovery and the general satisfaction of the patient measured either by pain Post-Op or physical appearance.
- **Surgeon Learning Curve:** Related to our first bullet point, MIS systems may require surgeons to learn new skills and some represent very steep learning curves. The easier system with the flatter learning curve will probably be the one to have superior adoption rate holding everything else equal.

Minimally invasive surgery (MIS) of the spine has come a long way and has begun to receive a significant attention from the medical device community. Over the past several years, the larger medical device companies have either initiated internal development programs or went out and acquired a program. One such example is Johnson & Johnson, which acquired certain assets of The Bright Group, a start-up MIS development company based in Boca Raton, Florida. There are a great number of MIS systems currently in the market and more are expected to come. Unlike the artificial disc and nucleus replacement technologies the clearance process for MIS systems goes through the 510(k) process in the FDA, which significantly reduces the time and capital needed to bring a product to market. The following are short descriptions of some of the different minimal invasive surgery systems that are already in the market.

Pathfinder™

The Pathfinder system, introduced in 2003, was developed by Spinal Concepts, a private medical device company based in Austin, Texas recently acquired by Abbott Labs. The Pathfinder system requires only one 3 centimeter (cm) incision, no muscle retraction and only minimal stripping of the muscles. Utilizing guide wires and specialized instruments allow for posterolateral (from the back) fusion to be performed with traditional instruments.

Atavi™

Developed by Endius, a private company based in Plainville, Massachusetts, the Atavi system also requires minimal muscle stripping and a small access incision. Approved in October 2000, it has undergone several iterations and product improvements. The Atavi systems integrates access technology with visualization and instrumentation into one system; thus, maximizing the access at the point of treatment with minimal trauma to the surrounding areas. More than 800 patients have been treated with the Atavi system. Most patients leave the hospital within 24 hours and in a latest comparative study to traditional open surgery 65% reported reduction in pain and use of narcotic pain medication.

MaXcess™ and NeuroVision™ Systems

NuVasive's latest iteration of its MIS access system, which received 510(k) clearance in April of this year, combines minimal access spine products (MaXcess) with neural monitoring (NeuroVision) enabling surgeons to access the spine from a lateral (from the side) approach. Implant components can be rigidly locked into a variety of different configurations to suit the individual pathology and anatomical conditions of the patient. The system enables minimally invasive disc height restoration while minimizing musculature disruption. The NeuroVision JJB System is a nerve avoidance technology, which allows the surgeon avoid critical nerves while operating. This is a novel approach to an existing neurological technology.

As indicated earlier, the MIS systems being introduced in the U.S. market look to improve upon existing methodologies and procedures. Reducing the time of recovery and operative time will undoubtedly improve on the costs associated with spinal surgery. Moreover, the ability for 510(k) clearance makes this niche much more attractive to smaller companies as the capital requirements are less intense. As a result, there are a much larger number of companies with relatively much smaller size to those involved in the artificial disc niche. The companies in the space have been well capitalized over the past twelve months and most of those dollars are earmarked for marketing and sales development purposes. Nevertheless, the niche presents an area of opportunity with one caveat. As we will learn later in the report, the intellectual property (IP) of medical device companies is very important. Medical device companies spend millions on defending their IP.

Intellectual Property (IP) is Everything!

As with any business as competitive and dynamic as the spinal implant industry, ownership and control of intellectual property (IP) is paramount. The defensibility of the IP is almost as important as its viability. Market participants are constantly looking to improve on current technologies and at times there have been accusations of patent infringement. Since the early 1990s, the spinal implant industry has been peppered with intellectual property lawsuits. These lawsuits often take years to resolve and require substantial amounts of resources both human and financial. IP disputes can cause significant loss of sales. For example, the case of Dr. Gary Michelson, inventor of threaded implants among other items, vs. Medtronic Sofamor Danek has caused over \$1.1 billion in lost sales for Medtronic, according to the company. Another example of patent litigation is the Interpore Cross International, Inc. vs. Medtronic case filed February of last year. The California court hearing this case ruled in favor of Interpore Cross stating that Medtronic was infringing on Interpore's patents. The courts must still determine whether or not the patent in question covering polyaxial screws is valid. No remedy may be considered until this ruling is made.

These examples indicate the highly litigious environment that exists in the medical device arena especially with regard to spine related devices. In our opinion, this may be a significant road block for many up and coming companies in the space. While companies like Medtronic and Johnson & Johnson can cope with product litigation as sales from any one product or products represent a small percentage of total sales, for smaller companies like Endius and NuVasive, both private companies with innovative minimally invasive surgery technologies, the costs of a patent litigation could be catastrophic.

Regulatory and Reimbursement Explained

The Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) are the two most important federal agencies for medical device companies. The FDA is the federal agency responsible for clearing medical devices for effectiveness and safety before they are introduced in the U.S. market. The CMS is the federal agency responsible for setting reimbursement rates for the over 500 diagnosis related group codes (DRGs) used by Medicare and Medicaid for the processing of medical expenses and as such plays a key role in the adoption of a particular medical device.

Clearance criteria in the United States are by far the most stringent in the world. The E.U. has its own criteria and procedures, which are less stringent as reflected by the fact that most of the products discussed in this report are already being marketed in Europe.

In the United States, the clearance process for medical devices is much simpler than that of pharmaceuticals by all accounts. Regulated by the Center for Devices and Radiological Health (CDRH), a division of the FDA, the Office of Device Evaluation with the CDRH is responsible for the clearance of medical device applications. There are three main steps in the clearance process under current FDA regulations:

Classification of product as a medical device. This would seem as a simple enough task, but it is paramount and at times very complex, especially with the advent of new combination of drugs with devices such as the drug-eluting stents. Different attributes of the devices may place it under the jurisdiction of another department of the FDA or require additional clearance criteria as is the case if the device emits electronic radiation as in the case of Computed Tomography (CT) machines.

Risk classification of medical device. The CDRH has three classes (see Table A on the next page) for medical devices each one implying a higher level of risk associated with; therefore, requiring more stringent testing for safety.

Preparation of data and information required for marketing clearance. The PMA submission includes an exorbitant amount of technical data, which includes non-clinical laboratory studies discussing the toxicology, biocompatibility and shelf life of a product based on laboratory and animal testing as well as clinical investigations. Manufacturers are allowed to market medical devices after applying for an Investigational Device Exemption (IDE). As the name suggests the devices can be introduced into the market for investigational purposes in clinical trials utilized to gather data for the eventual PMA application.

Table 2

	Types of Products in Class	Device Sophistication / Patient Risk	Company Notification and Clearance Requirements
• Class I	Conventional commodity-type devices such as stethoscopes and surgical scalpels.	Low/Low	Most devices are exempted but some require 510(k) submission also known as a Premarket Notification application 90 days prior to release.
• Class II	X-ray machines, endoscope and surgical lasers.	Slightly higher risk and sophistication as Class I.	Devices are approved via a 510(k), Premarket Approval application, to show "substantially equivalent" to existing like products.
• Class III	Implanted pacemakers, drug-eluting stents and artificial discs.	High level of sophistication that entails a much higher degree of risk.	Premarket Approval application includes non-clinical laboratory studies discussing animal testing as well as clinical investigations.

Source: vFinance Investments, Inc. Research and FDA

The reimbursement of a medical procedure is paramount in the eventual adoption and success of a medical device(s) involved in that procedure. Medical device manufacturers put forth great effort in convincing payers that their product(s) are safe, effective and should be reimbursed. Determining the safety and efficacy of products is delegated to the FDA. The CMS will then determine whether or not to reimburse a procedure utilizing a new product or not. Spinal surgery reimbursements rates overall did received a healthy increase among most of the DRGs relating to spinal surgery including an 11.0% increase in combine anterior/posterior spinal fusion (DRG 496) from \$27,511 to \$30,524. This is good for minimally invasive surgery system developers, whose products are utilized in fusion and the increase in reimbursement rates more than covers the costs; therefore, will not deter the adoption of the products for a lack of reimbursement.

No specific reimbursement was proposed for procedures utilizing artificial discs or prosthetic nucleuses. The only time CMS approved reimbursement before FDA clearance of a particular product was JNJ's Cypher stent back in 2003. Originally we had thought this might set a precedent, but this will not be the case for artificial discs. The CMS did create 11 new procedures codes specifically covering the implanting and removing of spinal disc prosthesis. This is a positive because the creation of the procedural codes allows the CMS to gather cost data on the procedures and be able to adequately increase the DRG reimbursement rates if warranted by higher costs of the new technologies. As a result of the lack of reimbursement in 2005, it is possible that JNJ's anticipated roll out of their Charite disc in late 2004 or early 2005 may be slower than expected. It is fair to say that the product rollout without a reimbursement agreement will be slower than the rollout had the Company been able to have the CMS agree to increased reimbursement for spinal disc replacement surgery. Nevertheless, we expect the CMS, with the data gathered over the next several months after the new procedure codes go into effect (October 1, 2004), will create new DRGs covering these new technologies.

Conclusion

This report should show investors the vast opportunity currently in spine surgery. As expansive and prevalent as back pain and related conditions are among Americans only a small fraction receive surgical treatment. In particular, degenerative disc disease has come to the attention of many in the medical device and investment communities. The invasiveness of current spinal fusion procedure has been a deterrent for many patients and surgeons forcing them to alleviate not treat the symptoms with physical therapy or pharmacology. The introduction of new minimally invasive surgical systems and tools will have a positive affect on the market by expanding the universe of surgery candidates. Moreover, the new artificial disc and prosthetic nucleus technologies will also be a positive for the overall market as the number of surgeries performed increases. Those companies involved in providing successful products in any of the three aforementioned technologies are expected to participate in the expansion of the overall market and should see very positive top line results.

There exist a number of risks. First, of the three technologies, only minimally invasive surgery products have received FDA clearance and are being actively marketed. We expect to see the first artificial discs in the U.S. in late 2004 or early 2005. Prosthetic nucleus devices have an even longer road ahead as the more advanced programs are just beginning their clinical trials. FDA clearance is not a certainty and should be taken into consideration. Additionally, procedure

reimbursement by federal and private payers for procedures using artificial discs and prosthetic nucleuses has not been approved and is also not guaranteed. In addition, we have been unable to ascertain the expected prices of the new products and if the costs are higher than current procedures and clinical results do not show large increase in benefits to the patient, reimbursement may be denied. As we mentioned earlier this is will have an adverse affect on ADs and PDNs devices' success. Lastly, some of the smaller participants in the space will be competing against some of the largest medical device companies in the world. The litigious environment that is spine surgery may put some of the smaller companies in a cash crunch should they be force into intellectual property disputes.

We have identified 38 companies that have product portfolios encompassing one or more of the technologies mentioned in this report and may provide investors with the opportunity to take part in the expansion of the market. We have profiled 10 companies, five public and five private companies. The profiling of an individual company should not be taken as a negative or positive bias towards the individual company on the part of vFinance. Investors should perform a more thorough analysis taking into consideration their own risk/reward thresholds and investment time horizons.

Company Universe

The following table includes a list of private and public companies participating in the spinal implants market. Additionally, we have indicated each company's primary technology focus group within the three different technologies featured in this report. It is important to note that some of the companies' product portfolios may overlap and include one or more of the mentioned technologies, but our classification is intended to show each company's primary technology.

No.	Ticker/Private	Company Name	Technology Focus Group
1	JNJ	Johnson & Johnson, Inc. (DePuy Spine, Inc.)	Artificial Disc
2	MDT	Medtronic Inc (Sofamor Danek)	Artificial Disc
3	Swiss Exchange	Synthes Stratec, Inc. (Spine Solutions, Inc.)	Artificial Disc
4	Private	Vertebron, Inc.	Artificial Disc
5	Private	Axiomed Spine Corporation	Artificial Disc
6	SYK	Stryker Corp. (SpineCore, Inc.)	Artificial Disc
7	Private	Pearsalls, Ltd. (United Kingdom)	Artificial Disc
8	Private	Dynamic Spine, LLC	Artificial Disc
9	Private	Theken Disc, LLC	Artificial Disc
10	Private	Restore Therapeutics	Artificial Disc
11	Private	Tensegra, Inc.	Artificial Disc
12	Private	LDR Medical (France)	Artificial Disc
13	Private	Scient'X S.A. (France)	Artificial Disc
14	Private	Biorthex, Inc.	Artificial Disc
15	Private	Cortek, Inc.	Artificial Disc
16	ZMH	Zimmer Holdings, Inc. (Centerpulse AG)	Prosthetic Nucleus
17	BMET	Biomet, Inc.	Prosthetic Nucleus
18	PPTI.ob	Protein Polymer Technologies, Inc.	Prosthetic Nucleus
19	CRY	CryoLife, Inc.	Prosthetic Nucleus
20	Private	SpineWave, Inc.	Prosthetic Nucleus
21	Private	Replication Medical, Inc.	Prosthetic Nucleus
22	Private	RayMedica, Inc.	Prosthetic Nucleus
23	Private	Disc Dynamics, Inc.	Prosthetic Nucleus
24	ABT	Abbott Labs (Spinal Concepts, Inc.)	MIS
25	ARTC	Arthrocare Corporation	MIS
26	ISRG	Intuitive Surgical, Inc.	MIS
27	KYPH	Kyphon, Inc.	MIS
28	Private	Spineology, Inc.	MIS
29	Private	Anulex Technologies	MIS
30	Private	NuVasive, Inc.	MIS
31	Private	Innovative Spinal Technologies	MIS
32	Private	Hydrocision, Inc.	MIS
33	Private	Endius, Inc.	MIS
34	Private	Clarix Medical, Inc.	MIS
35	Private	TranS1, Inc.	MIS
36	Private	Doctors Research Group	Special Medical Devices
37	Private	Disc-O-Tech Medical Technologies, LTD	MIS
38	Private	Smith & Nephew (Oratec)	MIS

Sources: Multex.com, Crystal Research Associates, Hoovers.com and Google.com.

CryoLife, Inc.		(NYSE:CRY)				
Product Niche: Prosthetic Nucleus						
Recent Price:	\$	4.64	Financial Data:	TTM	2004 E	2005 E
52 Week Range		\$4.00 - \$8.25	Revenue (M)	\$ 58.7	\$ 66.7	\$ 77.2
Trading Data:			Diluted EPS	\$ (1.93)	\$ (1.13)	\$ (0.46)
No. Outstanding Shares (M)		23.3	P / E	n.m.	n.m.	n.m.
Estimated Float (M)		20.2	Industry P / E	29.2x		
Market Cap (M)	\$	107.9				
Average Daily Volume (10 Day)		117,000				
				Revenues	EBITDA	Earnings
Balance Sheet Data:	March 31, 2004		TTM (M)	\$ 58.7	\$ (30.1)	\$ (38.9)
Debt / Equity (Times)		0.04x	Mkt. Cap / TTM	1.8x	n.m.	n.m.
Cash (M)	\$	25.4	Insitutional Holdings	53.0%		
Total Assets (M)	\$	87.5	Insider Holdings	13.3%		
Total Liabilities (M)	\$	26.3	Fiscal Year Ends	31-Dec		

Sources: SEC Filings, Bloomberg, Multex, First Call and Yahoo-Finance Stock Price as of July 23, 2004

Overview

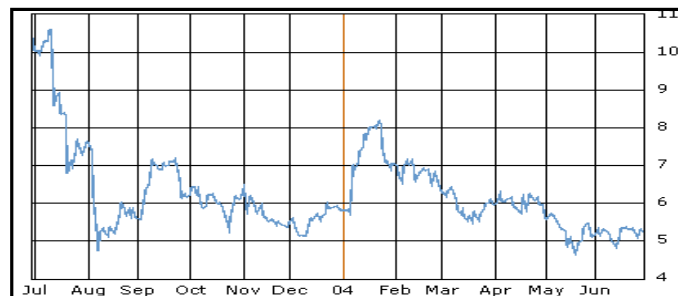
CryoLife, Inc. ("CryoLife" or "the Company"), headquartered in Kennesaw, Georgia has two businesses. Its legacy business is the low temperature preservation and distribution of human tissues for cardiovascular, vascular and orthopedic transplant applications. Its second business is the development and commercialization of implantable medical devices. The Company's most recent product is BioGlue® Surgical Adhesive. BioGlue is intended as an adjunct to traditional methods of surgical repair of large vessels (i.e. sutures and staples). Since its introduction in Europe in 1998, 225,000 units of BioGlue have been sold worldwide.

Based on the BioGlue technology, the Company began development of its own prosthetic nucleus technology marketed under the name BioDisc™.

For the three months ended March 31, 2004, revenues fell 5.0% year-over-year from \$15.9 million to \$15.1 million. Sales of BioGlue increased 33.1% and represented 75.5% of total sales or \$8.6 million for the quarter. Net loss for the quarter was \$7.0 million a significant increase over the \$434 thousand loss in Q1 of 2003. The results reflect decreased tissue preservation services as a result of the FDA restrictions on the amount of tissue derived from each donor. The restrictions resulted in lower availability of product; thus, lower revenues and higher overhead costs.

Recent Events

- On January 26th, the Company closed on a \$20 million financing and ended its first quarter of FY 2004 with \$25.4 million in cash. We expect this cash position to be enough to finance twelve months of operations as analyst estimate call for a loss \$23.5 million for the period starting Q2 '04 through Q1 '05, while it solves its cost issues with regard to the tissue preservation.
- Company completed the mechanical testing phase of its disc nucleus prosthetic and can now request for a pre-Investigational Device Exemption (IDE) meeting with the FDA. With the IDE clearance, the Company will be able to begin marketing its product for clinical trial purposes in U.S. and gather data to present to the FDA in a PMA application. The time table for product release is unknown but one would not expect a marketable product for at least two to three years.



Source: Bloomberg.com

Protein Polymer Technologies, Inc.			(OTC: PPTI)			
Product Niche: Prosthetic Nucleus						
Recent Price:	\$	0.31	Financial Data:	TTM	2004 E	2005 E
52 Week Range		\$0.30 - \$0.60	Revenue (M)	\$ 1.4	n.a.	n.a.
Trading Data:			Diluted EPS	\$ (0.11)	\$ -	\$ -
No. Outstanding Shares (M)		37.1	P / E	n.m.	n.m.	n.m.
Estimated Float (M)		5.9	Industry P / E	27.5x		
Market Cap (M)	\$	11.5				
Average Daily Volume (10 Day)		7,000				
				Revenues	EBITDA	Earnings
Balance Sheet Data:	March 31, 2004		TTM (M)	\$ 1.4	\$ (2.6)	\$ (2.7)
Debt / Equity (Times)		0.00x	Mkt. Cap / TTM	8.5x	n.m.	n.m.
Cash (M)	\$	0.8	Insitutional Holdings	0.0%		
Total Assets (M)	\$	1.1	Insider Holdings	84.1%		
Total Liabilities (M)	\$	0.4	Fiscal Year Ends	31-Dec		

Sources: SEC Filings, Bloomberg, Multex, First Call and Yahoo-Finance Stock Price as of July 23, 2004

Overview

Protein Polymer Technologies, Inc. ("PPTI" or "the Company"), is a development-stage biotechnology company engaged in the development and production of synthetic protein polymers. Based in San Diego, California, the Company is focused primarily on developing materials to be used in four health treatment areas: soft tissue augmentation, tissue adhesives and sealants, wound healing and drug delivery devices. PPTI also developed a coating technology that can efficiently modify and improve the surface properties of traditional biomedical devices.

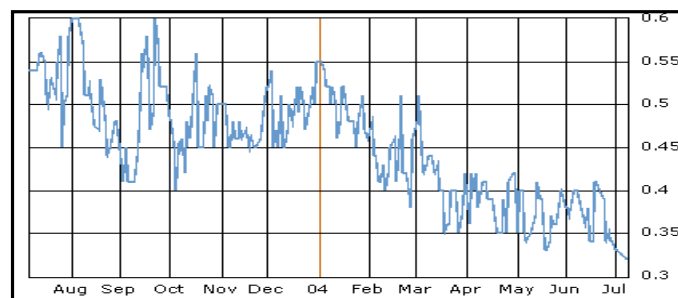
In April of 2001, PPTI entered into an agreement with Windamere Venture Partners to form, Spine Wave, Inc., which would have exclusive, worldwide license to PPTI's technology for use in developing products for spinal and orthopedic applications. In return, PPTI received equity in Spine Wave as well as royalties on the sale or sublicensing of some products. Additionally under the agreement, Spine Wave contracted PPTI for research and development services and the supply of materials for preclinical and clinical testing of its products. Spine Wave and PPTI jointly developed an injectable protein-based formulation for tissue replacement of degenerated spinal discs. Clinical trials of the implant are expected to begin in 2004 indicating a potential product release in 2008.

The Company's revenues fell 57.8% from \$452.6 thousand to \$191.0 thousand, during the first quarter of 2004 ending March 31. Additionally, net loss decreased 47.2% to \$921 thousand down from \$1.7 million in the first quarter of 2003. The decrease in revenues reflects reduced contract and licensing revenue due to the

completion of preclinical testing of the injectable prosthetic nucleus product. Lower losses reflect fewer imputed stock dividend provisions associated with the Company's 84,745 convertible preferred shares outstanding at the end of its first quarter.

Recent Events

- On December 12, 2003, Protein Polymer Technologies, Inc. and Spine Wave, Inc. extended their contractual research and development relationship. In the release, PPTI estimated it will receive approximately \$1.2 million in R&D from Spine Wave under the revised agreement.
- PPTI closed on a \$3.25 million financing on June 10, 2003. The proceeds are earmarked for Protein Polymer's research, clinical programs and for general corporate purposes. Investors in the private placement included: Johnson and Johnson Development Corporation and Taurus Advisory Group, among other, institutional and accredited investors.



Source: Bloomberg.com

Johnson & Johnson, Inc.		(NYSE:JNJ)			
Product Niche: Artificial Disc					
Recent Price:	\$	55.74			
52 Week Range		\$48.05 - \$58.14			
Trading Data:			Financial Data:	TTM	2004 E
No. Outstanding Shares (M)		2,968.6	Revenue (M)	\$ 43,600.0	\$ 46,160.0
Estimated Float (M)		2,940.0	Diluted EPS	\$ 2.95	\$ 3.03
Market Cap (M)	\$	165,469.9	P / E	18.9x	18.4x
Average Daily Volume (10 Day)		7,745,000	Industry P / E	26.2x	16.9x
Balance Sheet Data:	March 28, 2004			Revenues	EBITDA
Debt / Equity (Times)		0.60x	TTM (M)	\$ 43,600.0	\$ 13,748.0
Cash (M)	\$	10,361.0	Mkt. Cap / TTM	3.8x	12.0x
Total Assets (M)	\$	48,868.0	Insitutional Holdings	62.5%	
Total Liabilities (M)	\$	20,374.0	Insider Holdings	1.0%	
			Fiscal Year Ends	28-Dec	
				Earnings	
				\$ 7,620.0	

Sources: SEC Filings, Bloomberg, Multex, First Call and Yahoo-Finance Stock Price as of July 23, 2004

Overview

Johnson & Johnson, Inc. ("JNJ" or "the Company") is a healthcare conglomerate. With over 200 operating companies, the Company conducts business in three segments: Consumer, Pharmaceutical and Medical Devices and Diagnostics (MDD). In 2003, the three segments individually represent 17.8%, 46.6% and 35.6% of total sales, respectively. The Medical Devices and Diagnostics segment includes a range of products used in different applications including spine surgery. In May of 2003, Depuy Acromed, Inc., a subsidiary of JNJ, acquired Link Spine Group, Inc. providing the Company with the exclusive rights to the SB Charite artificial disc and placing JNJ at the lead of the artificial disc race in the United States. Moreover, the Medical Devices and Diagnostics segment grew 18.5% in 2003 outpacing both of the other two segments.

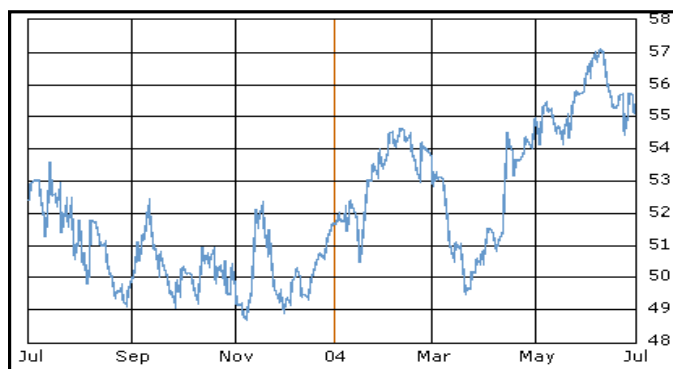
For its first quarter of 2004, JNJ reported revenues of \$11.6 billion, which was an increase of 17.7% over the same period in 2003. Furthermore, net income rose 20.4% from \$2.1 billion to \$2.5 billion. The positive results were due across the board increases in revenues and profitability in the three segments, but again the MDD segment experienced a 22.9% increase in revenues and an impressive 46.0% increase in operating profits.

Recent Events

- On June 3rd 2003, the SB Charite III artificial disc received unanimous endorsement from the Orthopedic and Rehabilitation Devices Panel indicating subsequent full clearance of the device by the FDA. As such, the device will be the first artificial disc in the U.S. market place (expected to

be released in late 2004 or early 2005) lending JNJ complete market dominance until a second disc is approved and introduced in late 2005 or early 2006.

- Through its Depuy Spine subsidiary, JNJ acquired a minimum invasive technology and patents from the Bright Group, Inc. on January 9, 2004. Bright Group developed the INSITE™ System designed to dilate the muscles in the back providing better access to the spine for surgery with the least amount of tissue damage. The acquisition of the Link Spine Group and Bright Group's patents illustrates JNJ's commitment to offer a comprehensive portfolio of minimally invasive spinal surgery products and technologies. Moreover, the Company seems well positioned to challenge Medtronic for market share in the space.



Source: Bloomberg.com

Biomet, Inc.		(Nasdaq:BMET)			
Product Niche: Artificial Disc					
Recent Price:	\$	42.32			
52 Week Range		\$28.04 - \$49.60			
Trading Data:			Financial Data:	TTM	2004 E
No. Outstanding Shares (M)		254.4	Revenue (M)	\$ 1,545.3	\$ 1,890.0
Estimated Float (M)		231.8	Diluted EPS	\$ 1.27	\$ 1.56
Market Cap (M)	\$	10,767.1	P / E	33.3x	27.1x
Average Daily Volume (10 Day)		2,929,000	Industry P / E	29.2x	23.5x
Balance Sheet Data:	February 29, 2004			Revenues	EBITDA
Debt / Equity (Times)		0.09x	TTM (M)	\$ 1,545.3	\$ 550.6
Cash (M)	\$	390.9	Mkt. Cap / TTM	7.0x	19.6x
Total Assets (M)	\$	1,817.9	Insitutional Holdings	65.5%	
Total Liabilities (M)	\$	414.2	Insider Holdings	8.9%	
			Fiscal Year Ends	31-May	
				Earnings	
					\$ 323.5
					33.3x

Sources: SEC Filings, Bloomberg, Multex, First Call and Yahoo-Finance Stock Price as of July 23, 2004

Overview

Biomet, Inc. ("BMET" or "the Company") is focused predominantly on musculoskeletal medical devices and instrumentation utilized in both surgical and non-surgical therapy. The Company's offerings are classified into four product groups: reconstructive devices, fixation products, spinal products and other products. In 2003, total sales were \$1.4 billion and spinal products represented only 10% of sales.

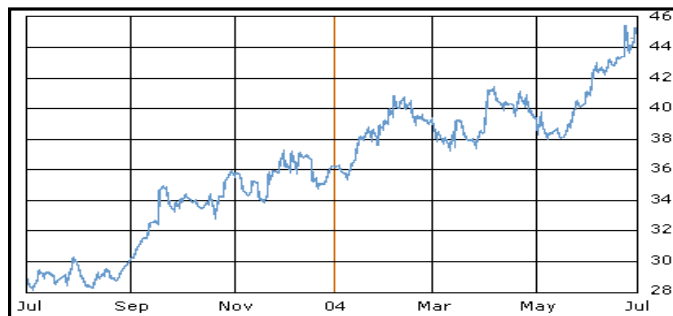
BMET's list of products includes reconstructive and fixation devices, electrical bone growth stimulators, orthopedic support devices, bone cements, spinal implants and instruments and dental reconstructive implants and associated instrumentation.

Biomet has four artificial discs in development: Lumbar Regain, Cervical Regain, and Lumbar and Cervical Rescue. The Regain product is made of pyrocarbon, which is a material used for cardiac valve prostheses. The Company has completed pre-clinical trials for its Lumbar Regain and clinical trials are expected to begin in Europe and in the U.S. for all of its products in 2005. As such, Biomet is not expected to have a commercial product until 2008.

Recent Events

- In June 2004, Biomet completed the acquisition of Interpore Cross International for an equity value of \$280 million. According to Dane Miller PhD., the deal with will expand Biomet's presence in growing spine market. Furthermore, the Company will command a number four position domestically with over 400 sales representatives servicing spinal and neurosurgeon in the United States.

- Biomet closed its FY 2004 on May 31 with sales of \$1.6 billion a 16.1% increase from the \$1.4 billion in 2003. Spinal product sales still represented less than approximately 9.9% of total sales. Additionally, the Company's earnings increased 13.5% from \$286.7 million in Q4 of 2003 to \$325.6 million in Q4 2004. The neither the year-end nor quarterly results include Interpore Cross revenues or earnings.
- Due to its strong momentum and continued strong expectation, the Company announced on July 1 that it was expanding its stock repurchase program. The program had already purchased some 20.8 million shares totaling \$609.4 million in value. The program authorizes another \$100 million or some 2.5 million shares to be repurchased. Additionally, the Company's board also approved a \$0.20 cash dividend.



Source: Bloomberg.com

NuVasive, Inc.		(NASDAQ:NUVA)				
Product Niche: Minimally Invasive Surgery						
Recent Price:	\$	10.27	Financial Data:	TTM	2004 E	2005 E
52 Week Range		\$9.49 - \$12.15	Revenue (M)	\$ 25.8	\$ 35.9	\$ 58.9
Trading Data:			Diluted EPS	\$ (0.84)	\$ (0.57)	\$ (0.21)
No. Outstanding Shares (M)		26.3	P / E	n.m.	n.m.	n.m.
Estimated Float (M)		6.5	Industry P / E	32.4x		
Market Cap (M)	\$	270.5				
Average Daily Volume (10 Day)		49,000				
				Revenues	EBITDA	Earnings
			TTM (M)	\$ 25.8	\$ (9.5)	\$ (11.7)
Balance Sheet Data:	March 31, 2004		Mkt. Cap / TTM	10.5x	n.m.	n.m.
Debt / Equity (Times)		0.74x				
Cash (M)	\$	7.5	Insitutional Holdings	0.0%		
Total Assets (M)	\$	20.8	Insider Holdings	75.3%		
Total Liabilities (M)	\$	12.2	Fiscal Year Ends	31-Dec		

Sources: SEC Filings, Bloomberg, Multex, First Call and Yahoo-Finance Stock Price as of July 23, 2004

Overview

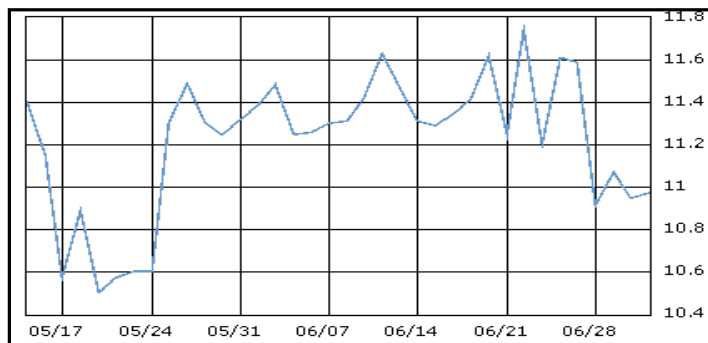
NuVasive, Inc. ("NUVA" or "the Company") is a high growth medical device company. Based in San Diego, California, the Company designs, develops and markets both traditional and minimally invasive surgical products. The Company's product offering includes a minimally invasive surgical platform, called Maximum Access Surgery (MAS) as well as traditional fusion products such as a Titanium Surgical Mesh utilized in traditional fusion procedures. The MAS combines three of the Company's product offerings: NeuroVision, a software-driven nerve avoidance system; MaXcess, a split-blade design, minimally invasive surgical system as well as specialized implants. The system like most MIS systems purports to minimize soft tissue disruption during spine surgery. NuVasive's classic fusion portfolio is comprised of a range of products including spine allografts, human bones that have been processed and precision-shaped for transplant and other spine implants such as rods, plates and screws utilized in a variety of spine surgery procedures. According to the Company, the NeuroVision visualization system has been used in over 15,000 spine surgeries and the implants have been used in over 10,000 fusions.

For its first quarter of 2004, the Company reported a 70.5% increase in revenue to \$7.6 million from \$4.4 million in the first quarter of 2003. The Company's net loss also increased 56.4% from a loss of \$2.7 million in 2003 to a loss of \$4.1 million. The increase in revenues reflects the continued market acceptance of MAS products, which more than doubled from \$2.0 million to \$4.8 million year-over-year. The Company's higher losses were predominantly due to an increase in sales and marketing expenses as well as the amortization of deferred stock based compensation expenses.

NuVasive will amortize another \$6.4 million over the next three years.

Recent Events

- NuVasive began trading on the NASDAQ after its initial public offering on May 13, 2004. The Company issued 6.8 million shares at \$11.00 thus raising \$75.4 million in proceeds before transaction costs. The funds are earmarked for the expansion of the Company's sales and marketing efforts, additional research and development and debt reduction, which was \$6.3 million as of March 31, 2004.



Source: Bloomberg.com

SpineCore, Inc.		Private
Product Niche: Artificial Disc		

Overview

SpineCore, Inc. ("SpineCore" or "the Company") is a privately-held development stage medical device company engaged in the development of implantable artificial discs for the treatment of degenerative disc disease (DDD). Based in Summit, New Jersey, the Company became the fourth company to commence clinical trials for its artificial disc in the United States, in August of 2003. Marketed under the brand name FlexiCore™, the Company's artificial disc is a metal-on-metal design. The disc was designed and developed by a group of academic physicians including Dr. Randall Chesnut, director of neurotrauma and neurosurgical critical care at Oregon Health & Science University.

According to the Company, their disc is superior to the other devices in other clinical trials because it provides for the kind of up-and-down movement of a natural disc. This is made possible via the Company's spring system at the core of their disc. Other devices such as the ProDisc and Charite models use a hard polyethylene

center to allow for natural motion and load support of a natural disc.

Recent Events

- On August 1, 2003, SpineCore, Inc. initiated a nationwide clinical trial for its FlexiCore lumbar disc. The FDA granted the device an Investigational Device Exemption allowing the Company to take part in a 21-center randomized clinical trial that will treat several hundred patients in the United States to prove the safety and effectiveness of its artificial disc compared to current standard of care.
- The trial is expected to last two years indicating that the Company will have data to present to the FDA in late 2005 and possibly get marketing clearance for the device some time in 2006, thus being the fourth company with an artificial disc in the U.S. market and the first privately held company with such a device.
- On July 21, 2004, Stryker Corporation announced that it would buy SpineCore for \$120 million in cash.

TranS1, Inc.		Private
Product Niche: Minimally Invasive Surgery		

Overview

TranS1, Inc. ("TranS1" or "the Company"), founded in 2000 and based in Minneapolis, Minnesota, is an early-stage medical device company looking to gain market share in the expanding field on minimally invasive spine surgery.

Dr. Cragg, the founder, developed and patented a procedure to access the spine through the sacral bone, a triangular bone made up of five fused vertebrae just above the coccyx, for lumbar spine surgical procedures. The Company's Trans-Sacral Spinal Access and Preparation Device, received 510(k) clearance from the FDA in late September 2002. The Company was also developing adjunct implants and did not want to begin marketing their product until the FDA had approved all the components and devices.

Recent Events

- The Company's second generation of its Trans-Sacral Spinal Access and Preparation Device received marketing clearance from the FDA on January 15, 2004 via the 510(k) process. The Company is now selling this product in the U.S.
- On May 6, 2003, TranS1 Inc. closed on a \$12 million in second-round venture financing. Advanced Technology Ventures (ATV) led the round, with Delphi Ventures, Cutlass Capital and Sapient Capital also participating in the deal. The money was earmarked for development of equipment and implants. A year earlier the Company raised \$1.75 million from some of the same participants.

Disc Dynamics, Inc.		Private
Product Niche: Prosthetic Nucleus		

Overview

Disc Dynamics, Inc. ("DDI" or "the Company") is a private company based in Eden Prairie, Minnesota. Founded in 2000 as a spin-off of Advanced BioSurfaces, Inc., the Company was established to provide patients and physicians with minimally invasive surgical alternatives for treating lower back pain. DDI is developing its DASCOR™ Disc Arthroplasty System, a prosthetic nucleus technology. The DASCOR™ Disc Arthroplasty System uses a small incision to gain access to the nucleus in the disc space, remove it and replace it with an prosthetic nucleus that is designed to relieve pain and restore the disc's natural motion and function.

The DASCOR™ Disc Arthroplasty System utilizes a small incision to access the spine and remove the disc nucleus through a small hole in the annulus.

The prosthetic nucleus consists of a two-part curable polyurethane and an expandable polyurethane balloon that is inserted into the disc space after the nucleus has

been removed. The balloon is then injected with polymer gel, which creates a complete, patient specific implant that conforms to the shape and size of the disc space.

Recent Events

- On May 24, 2004, the Company raised \$24 million in a financing deal. An undisclosed strategic investor led the round but other current investors include St. Paul Venture Capital, Pequot Capital, Brightstone Capital and Affinity Capital Management. Proceeds are to be used primarily for clinical studies and continued product development.
- In June of 2002, Steve Healy, the former president of St Jude Medical Inc.'s Cardiac Surgery division, joined Disc Dynamics as CEO. The Company had just completed a financing round for \$9.3 million. The financing was led by Pequot Capital, as well as some former investors including St. Paul Venture Capital and Upper Lake Growth Capital.

RayMedica, Inc.		Private
Product Niche: Prosthetic Nucleus		

Overview

RayMedica, Inc. ("RayMedica" or "the Company") is an emerging medical device developer and manufacturer with headquarters in Minneapolis, Minnesota. Founded in 1990 by Dr. Charles Ray, the Company's goal is to develop innovative solutions for the surgical treatment of patients with lower back pain who have not responded to traditional treatments.

Currently, the Company's efforts are focused on its Prosthetic Disc Nucleus (PDN) device for the treatment of low back pain associated with degenerative disc disease by replacing the disc's nucleus with the prosthetic. The PDN device is surgically implanted into the empty nucleus cavity of the lumbar disc after the original nucleus has been extracted. Once implanted, the device is intended to increase and maintain disc height thereby restoring normal biomechanics and relieving pain. The PDN is by far the most advance disc nucleus replacement device in the world. The Company's third generation of the PDN device, the PDN-SOLO™ was introduced in September 2002, in Europe. In 2003, 1,144 PDN-SOLOs were implanted into patients. Moreover, since 1996, 2,182 of RayMedica's PDN devices have been implants into human patients.

RayMedica is expected to be first company to market with a Prosthetic Disc Nucleus in the U.S. providing a significant first mover advantage over its competitors. However, we do not expect the Company to have a marketable product in the U.S. until 2007.

In total, RayMedica owns 20 international patents for its PDN device and related technologies and has another 22 patents pending.

Recent Events

- RayMedica began enrolling patients in U.S. and Canadian clinical trials on December 10, 2003 for its PDN-SOLO. The clinical trials are being conducted Minneapolis MN, Norfolk, VA and Dallas, TX and Ontario, Canada. The data gathered in this trial will be used in support FDA Premarket Approval Application (PMAA).
- On December 22, 2003 the Company closed on \$12.0 million of venture financing led by Viscogliosi Brothers, LLC, a private equity and merchant banking firm specializing in the orthopedics and spine industries. The funding will help in concluding the clinical trials in the U.S. and Canada.
- In August 2003, the Company received final marketing clearance form the Korean Food and Drug Administration (KFDA), State Drug Administration of China (SDAC) and Australian Regulatory Agency-Department of Health and Aging for it PDN-SOLO. This allowed the Company access to three of the top five markets in the Asia/Pacific Rim markets. The other two major markets are Japan and Taiwan.
- On February 17, 2003, RayMedica received acceptance notification for its patent on its NuSeal™ nucleus closure device used in conjunction with the PDN to seal the opening created to remove the original disc nucleus. The device can also be used for discectomies or disc herniations.

Endius, Inc.		Private
Product Niche: Minimally Invasive Surgery		

Overview

Endius, Inc. ("Endius" or "the Company") was founded by Dr. Gil Aust and Timothy Taylor in 1992. Dr. Gil Aust, an orthopedic surgeon, and Timothy Taylor, an aerospace engineer formerly with NASA, were focused on developing steerable instruments for discectomies, which is the partial or full removal of the spinal disc tissue performed to relieve pain. In 1997, the Company established its headquarters in Boston, Massachusetts and changed its focus to developing and marketing devices used in minimally invasive spine (MIS) surgery. As such, Endius currently has a portfolio of products marketed under the Atavi™, TiTLE™, WAVE™ and MICOR™ brands.

The cornerstone of Endius' MIS business is the FDA-approved Atavi Atraumatic Spine Surgery System. Consisting of access, visualization and instrumentation components, the system is a single integrated system enabling surgeons to perform a full range of less invasive lumbar spine fusion procedures without changing the traditional open surgical technique. The system originally obtained FDA clearance via a 510(k) application in October of 2000. Subsequent improvements in the flexibility and visualization components received FDA clearance in October of 2002.

Recent Events

- At the 18th Annual American Spine Society Annual Meeting held on October 20, 2003, Endius unveiled its second generation Atavi Atraumatic Spine Surgery System. The significant enhancements to the original Atavi system will enable surgeons to treat nearly 80% of all patients needing a lumbar spine fusion. This increased the Company's existing applicable market opportunity four-fold.
- On March 26, 2003, Endius closed on a \$26.5 million financing earmarked for continued development of new products and marketing of the existing product lines. Additionally, the financing marked one of the largest venture capital investments amongst medical device companies in 2003.
- Michael P. McCarthy was named President and CEO on March 8, 2003. Mr. McCarthy succeeded Don Grilli, who served Endius for two years. Mr. McCarthy has more than 25 years experience in the orthopedics business predominantly in sales. He served as Sales Director for Johnson & Johnson for 20 years followed by VP of Sales and Marketing for Implex Corporation, a biotechnology company specialized in biomaterials. Mr. McCarthy's success in commercializing products will be invaluable to Endius at this time in the Company's history as it tries to expand its market share and adoption of its MIS systems and related products.

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COMPLIANCE DISCLOSURE (As July 29, 2004)

Rating	Definition	% of companies under coverage with this rating	% of ratings for which IB services² have been provided
Strong Buy	Positive return potential ¹ in excess of 20%	0%	0%
Buy	Positive return potential with moderate risk	0%	0%
Speculative Buy	Positive return potential with high risk	100%	0%
Hold / Neutral	Return potential in line with benchmark market	0%	0%
Sell	Negative return potential	0%	0%

¹ Return potential is defined as: The Target Price³ divided by the Current Price minus the return of the comparable market in which the company's stock trades (i.e. NASDAQ or AMEX).

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