Zacks Small-Cap Research

July 27, 2011
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InVivo Therapeutics, Hdls Corp. (NVIV-OTC)

NVIV: Novel Device For Spinal Cord Injury Has Big Potential. Initiating With Outperform Rating and $4.50 Target.

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	07/26/2011
Current Price (07/27/11)	$0.96
Target Price	**$4.50**

INITIATION

We are initiating coverage of InVivo Therapeutics with an Outperform rating and $4.50 price target. We are excited about the opportunity that InVivo presents to investors. There are currently no significant treatment options for patients with spinal cord injury (SCI). Although many companies are currently working on pharmaceutical treatment options, we like InVivo's approach with their biopolymer scaffold device (BSD) for several reasons. These include speed to market, simplicity of the idea, intellectual property protection, and strong animal model data.

We arrive at our $4.50 price target through DCF, which incorporates an aggressive discount rate. Over the long-term, we see significant upside in shares of NVIV through commercialization partnerships or a take-over.

SUMMARY DATA

52-Week High	**$1.20**
52-Week Low	**$0.66**
One-Year Return (%)	**N/A**
Beta	**0.00**
Average Daily Volume (sh)	**10,885**
Shares Outstanding (mil)	**52**
Market Capitalization ($mil)	**$49**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**35**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2011 Estimate	**N/A**
P/E using 2012 Estimate	**N/A**
Zacks Rank	**2**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	0 A	0 A	0 A	0 A	0 A
2011	0 A	0 E	0 E	0 E	0 E
2012					0 E
2013					0 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$0.02 A				-$0.24 A
2011	-$0.02 A	-$0.03 E	-$0.03 E	-$0.03 E	-$0.11 E
2012					-$0.14 E
2013					-$0.21 E

Zacks Projected EPS Growth Rate - Next 4 Years % **N/A**

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WHAT'S NEW

Initiating Coverage

We are initiating coverage of InVivo Therapeutics with an Outperform rating and $4.50 price target. We are excited about the opportunity that InVivo presents to investors. There are currently no significant treatment options for patients with spinal cord injury (SCI). Although many companies are currently working on pharmaceutical treatment options, we like InVivo's approach with their biopolymer scaffold device (BSD) for several reasons. These include speed to market, simplicity of the idea, intellectual property protection, and strong animal model data.

InVivo is taking a different approach to SCI, focusing on protection of the spinal cord and prevention of secondary injury rather than regeneration. It is often this secondary immune response and inflammation that does the majority of the tissue damage sustained following an acute injury. The company's technology focuses on minimizing tissue damage sustained following acute injury and promoting neural plasticity of the spared healthy tissue, which may result in full or partial functional recovery. In fact, management believes that if as little as 10% of the healthy tissue can be spared, local reorganization can occur that adds meaningfully to functional recovery. We think this is a model that lends itself well to clinical trials. Regulation of BSD will be as a medical device, not a biologic or a pharmaceutical product, which should allow management to move quickly through clinical development. The IDE was filed in July 2011, with human subject trials planned for later in the year.

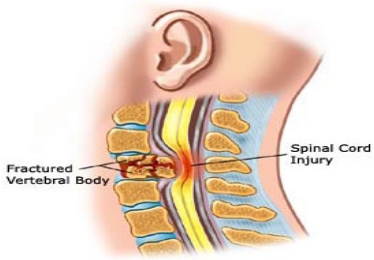
Longer-term, upside to the story comes from gaining approval for the injectable Hydrogel formulation, which can be used with pharmaceutical products like methylprednisolone sodium succinate (MPSS). This will then be followed by applications for use of BSD in-combination with stem cells. We think this has the potential to turn BSD into a potential blockbuster for the treatment of SCI because it opens up the opportunity to heal stalled SCI wounds in the 250,000 to 300,000 patients in the U.S. currently living with SCI. If we look outside the U.S., and include Canada and Western Europe, and the number grows to 400,000 chronic SCI patients in these markets. Including Asia, Australia, and Latin America, and the number of chronic SCI patients is around 2.0 million worldwide.

We have performed a discounted cash flow (DCF) analysis to value the shares. We assume that InVivo looks to launch BSD in 2014 at a price of $60,000. We assume 90% gross margin, a sales force of 25 full-time representatives, and ongoing R&D funding the registration programs for Hydrogel and BSD + cells. We model approval of the Hydrogel in 2015 and the combination therapy in 2016. We think management can slowly raise the price towards $100,000, and capture 10% of the 100,000 to 150,000 chronic and acute SCI patients in the U.S. We have used an extremely aggressive discount rate of 50% to account for the early-stage nature of the product. We arrive at a market value of approximately $360 million, or $4.50 per share based on roughly 65 million shares currently outstanding, 6.4 million unregistered shares, and a future dilution of 10 million shares to fund operations in 2012 (adjusted fully diluted share count of 81.6 million). Our DCF model can be found at the back of this report.

OVERVIEW

InVivo Therapeutics Corporation is a Cambridge, MA based medical device company founded to develop and commercialize groundbreaking technologies for the treatment of spinal cord injuries (SCI). InVivo intends to create a new paradigm of care by taking a novel approach to SCI. Instead of focusing exclusively on regeneration, InVivo concentrates on neuroprotection. The company's products are intended to protect the spinal cord after primary injury by mitigating the bleeding, inflammation, and further cell death that result from the body's immune response to SCI. By minimizing these secondary injury processes, and by supporting subsequent repair and recovery, the body can locally reorganize toward functional recovery through the spared healthy tissue. This process, known as neuroplasticity, may result in partial functional recovery. InVivo has an unmatched development portfolio composed of platform technologies for the treatment of both spinal cord injury and other application. These technologies encompass multiple strategies involving biomaterials, U.S. Food & Drug Administration (FDA) approved drugs, growth factors, and human neural stem cells (hNSCs).

Spinal Cord Injury



Spinal Cord Injury (SCI) refers to an injury to the spinal cord that is caused by direct trauma or a secondary damage to the surrounding bone, tissue, or blood vessels. Classification of the extent of the SCI is based on neurological responses, touch and pinprick sensations tested in each dermatome (an area of the skin supplied by a single spinal nerve), and strength of ten key muscles on each side of the body, including the hip flexion (L2), shoulder shrug (C4), elbow flexion (C5), wrist extension (C6), and elbow extension (C7). The four categories of SCI classification and their respective percent of the market are:

Classification of SCI	Percent
Complete Tetraplegia	22%
Incomplete Tetraplegia	34%
Complete Paraplegia	25%
Incomplete Paraplegia	19%

Source: National Spinal Cord Injury Statistical Center

…Epidemiology…

Incidence of spinal cord injury (SCI) occurs at about 40 cases per 1 million persons. In the U.S., we estimate there are approximately 12,500 new cases per year. Including Canada and Western Europe, and the total number of new cases per year is around 20,000. Adding in India, China, Australia, and Latin America, and Japan and the total grows to over 100,000 new (acute) cases of SCI worldwide per year. We estimate that 75% of these patients would benefit from a new treatment paradigm.

Prevalence of SCI in the U.S. is around 300,000 individuals. Including Canada and Western Europe, the number grows to 400,000 chronic SCI patients. Including Asia, Australia, and Latin America, the number of chronic SCI patients is around 2.0 million worldwide. We estimate that 50% of these patients would benefit from a new treatment paradigm.

According to the National Spinal Cord Injury Center, the mean age of a SCI patient is 38 (median 34), although most injuries occur between the ages of 16 and 30. About three-fourths of the patients are male, and about two-thirds are employed at the time of their injury. Less than half of those two-thirds will still be employed in ten years. Life expectancy (for persons that survive the first 24 hours) decreases with the severity of the injury. Below are statistics from the National Spinal Cord Injury Statistic Center on life expectancy vs. SCI severity:

…Life Expectancy Of SCI Patients…

Age at SCI	Normal (No Injury)	Incomplete Paraplegia	Complete Paraplegia	Incomplete Tetraplegia	Complete Tetraplegia	Ventilator Dependent
20 years	+58 years	+53 years	+46 years	+41 years	+36 years	+17 years
40 years	+39 years	+35 years	+28 years	+24 years	+21 years	+7 years
60 years	+22 years	+18 years	+13 years	+10 years	+8 years	+1 years

…Etiology…

SCI can be caused by any number of injuries to the spine. The most common is vehicular crashes, at roughly 50% of all SCI cases. Accidental falls account for another 25% of SCI cases. Violent crimes, with or without a firearm, account for another 10%. Sports related injuries account for 10% as well, with diving making up 75% of all sports-related SCI injuries, followed by snow skiing, football, and surfing.

Causes of SCI	Percent
Vehicle Accidents	50%
Accidental Falls	25%
Violence / Firearms	10%
Sports	10%
Other	5%

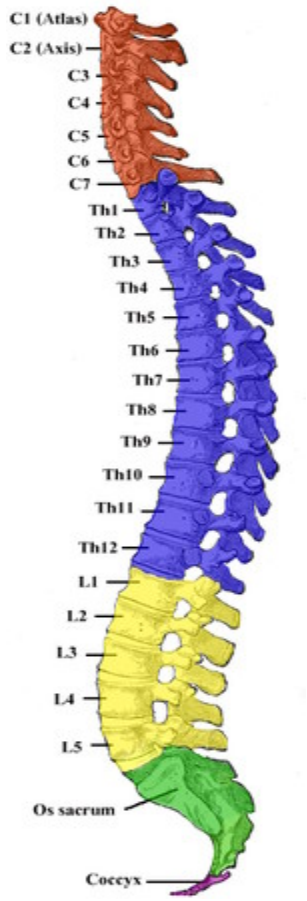
Source: National Spinal Cord Injury Statistical Center

Injuries from vehicle accidents usually occur through direct trauma, or through cuts or protruding fragments of metal. Direct damage can also occur if the spinal cord is pulled, pressed sideways, or compressed. This may occur if the head, neck, or back are twisted abnormally; this is typical in sports-related injuries. Individuals prone to falls, such as patients with multiple sclerosis, epilepsy, stroke, or OA, are at high risk for SCI. Although, as noted above, most spinal cord injuries occur in young, healthy men, typically through vehicle accidents or sports-related injuries.

However, even a minor injury can cause SCI if the spine is weakened, such as from rheumatoid arthritis (RA) or osteoporosis (OA). The elderly, or those with spinal stenosis, are at increased risk of SCI if the spinal canal protecting the cord has become too narrow.

…Symptoms…

Symptoms of SCI vary greatly with the severity and location of the injury. SCI causes weakness, loss of motor function, and sensory loss at and below the point of injury. The severity of the symptoms depends on whether the entire cord is severely injured (complete) or only partially injured (incomplete).



- Complete SCI: Complete loss of all function below the injury. Complete SCI includes the inability to contract the anal sphincter or feel pinprick or touch below the injury. Complete loss of muscle function can lead to atrophy of the muscle and bone degeneration.

- Incomplete SCI: Some of all function below the injury is unaffected, including the ability to control the anal sphincter or feel pinprick or touch around the anus. The nerves in this area are connected to the very lowest region of the spine, the sacral region, and retaining sensation and function in these parts of the body indicates that the spinal cord is only partially damaged.

A complete injury frequently means that the patient has little hope of functional recovery. The relative incidence of incomplete injuries compared to complete spinal cord injury has improved over the past half century, due mainly to the emphasis on better initial care and stabilization of spinal cord injury patients. Incomplete SCI accounts for approximately 53% of all SCI cases, up from below 45% in 1970. Most patients with incomplete injuries recover at least some function.

In addition to sensation and muscle control, the loss of connection between the brain and the rest of the body can have specific effects depending on the location of the injury. Patients with SCI can experience pain, weakness, spasticity, loss of bowel and bladder control, sensory changes, numbness, loss of sexual function, and difficulty breathing. Other complications include blood pressure changes, chronic kidney disease, deep vein thrombosis, contractures, pulmonary infections, skin infections, urinary tract infections, and pressure ulcers.

Nearly half of all spinal cord injuries are associated with the C4, C5, C6, and C7 vertebrae. Determining the exact level of injury is critical in determining treatment and rehabilitation options, as well as making predictions of the outcome. The extent of the injury is usually determined initially by a physical examination, followed by neurological exams that include a CT scan or MRI of the spine, a myelogram (x-ray), or a somatosensory evoked potential (SSEP) testing (nerve testing).

…Current Treatment Options…

The time between the injury and treatment is a critical factor affecting prognosis. Spinal cord trauma is a medical emergency and requires immediate surgical attention. The primary objective is to remove fluid or tissue pressing on the spinal cord (decompression laminectomy), remove bone fragments, disk fragments, or other foreign objects that could do further damage, and then stabilize the cord by fusing bone or implanting spinal braces. In some cases, if spinal cord compression is caused by a mass, such as a hematoma or bone fragment, removal may improve the paralysis. Surgery is often followed by use of corticosteroids, such as dexamethasone or methylprednisolone, to reduce secondary swelling that may damage the spinal cord. Corticosteroids should begin as soon as possible after the injury because it is often this secondary inflammation and immune response that does the long-term damage to the spinal cord. Ideally, patients with SCI should be on bedrest to allow the bones in the spin to heal. Spinal traction or a neck brace may be useful in aiding in reducing secondary damage to the weakened bone.

Following a SCI, the nerve cells below the level of injury become disconnected from the brain. This is due to scar tissue which forms in the structure of the damaged area of the spinal cord, blocking messages from below the level of injury reaching the brain. This can cause muscle spasticity. However, spasticity may not occur immediately following an injury. Often the body is in shock following SCI; this may last several weeks. During this time changes take place to the nerve cells which control muscle activity. Once spinal shock wears off, the natural reflex reappears, which may be followed by spasticity if there is structural damage in the cord. Spasticity may also cause pain, loss of range of motion, contractures, sleep disorders and impair ambulation in patients with an incomplete lesion. Medications like Botox, baclofen, dantrolene, and tizanidine may be used to control spasticity. We note that none of these above pharmaceutical options, either corticosteroids, anti-inflammatory drugs, or anti-spasticity drugs, are designed to treat paralysis.

Extensive physical therapy, occupational therapy, and other intense rehabilitation therapies are often required after the acute injury has healed. Much of the rehabilitation takes place in a hospital or acute care setting. The average hospital stay for someone with SCI is two weeks. However, the average stay in the rehabilitation unit is five weeks. We note the trend over the past decade has been to shorter inpatient rehabilitation and longer post discharge therapy. Roughly 88% of all SCI patients live in private residence. Only 5% reside in nursing homes and 7% in long-term care facilities. Key to the rehabilitation phase is training the SCI patient to use assistive devices such as wheelchairs, treadmills, and sliding boards. The more independence the SCI patient gains, the greater the likelihood of continued rehabilitation progress and life expectancy.

Historically, the leading cause of death among persons with SCI has been renal failure. However, today, the leading causes of death are pneumonia, pulmonary emboli, and septicemia. In addition, pain resulting from SCI can be debilitating. Immobility can lead to muscle atrophy and pressure ulcers. Infections are a major life-threatening side-effect of paralysis. Besides corticosteroids, spasticity medications, and pain medications, SCI patients may find themselves on and off antibiotics and antifungal agents to combat infections.

…Market Opportunity…

The acute care market for SCI is significant. Below are estimates of what it costs, per year, to treat and care for an SCI patient by severity, and what lifetime costs are for SCI patients ages 25 and 50.

…Healthcare Costs of SCI…

Cost By Severity of SCI	First Year	Subsequent Years
Complete Tetraplegia	~$680K	~$125K
Incomplete Tetraplegia	~$440K	~$50K
Complete Paraplegia	~$250K	~$25K
Incomplete Paraplegia	~$200K	~$15K

Combining our stats from above, we calculate that each year, in the U.S., nearly $18 billion is spent for the care of patients with SCI. It's an enormous market opportunity and one where significant new medical breakthroughs are necessary.

…The Acute SCI Market…

SCI Injury	Number of New Patients	Cost of Care Year-1	Subsequent Care	Life Expectancy	Total Spent on Care
Complete Tetra	3,300	~$680K	~$125K	+21 years	$6.2B
Incomplete Tetra	5,100	~$440K	~$50K	+24 years	$7.0B
Complete Para	3,750	~$250K	~$25K	+28 years	$3.0B
Incomplete Para	2,850	~$200K	~$15K	+35 years	$1.7B
					$17.9B

Besides the estimated $18 billion being spent for acute SCI patients each year. We estimate another $20 billion is being spent each year on chronic care for patients. These costs include hospitalizations, nursing homes, new catheters, rehabilitation, wheel chairs, etc. Yet, even with this significant amount of money being spent, there are no approved pharmaceutical or medical device treatments to cure paralysis.

InVivo Therapeutics

InVivo was founded in Cambridge, MA, in 2005 to develop and commercialize new technologies for the treatment of spinal cord injuries (SCI). The company's proprietary technology was co-invented by Robert S. Langer, ScD, Professor at Massachusetts Institute of Technology (MIT) and Joseph P. Vacanti, MD, affiliated with Massachusetts General Hospital. These intellectual property (IP) rights, which we discuss in greater detail below, are the basis for the company's products licensed under an exclusive, worldwide agreement from Children's Medical Center Corporation (CMCC) and MIT.

InVivo Therapeutics is developing a medical device that could be a breakthrough for the treatment of spinal cord injury. Currently, there are no successful spinal cord injury treatment options for spinal cord injury patients. While numerous companies are working on therapeutic or cell therapy compounds, InVivo is taking a different approach to SCI by focusing on protection of the spinal cord and prevention of secondary injury rather than regeneration. As discussed above, it is the secondary immune response and inflammation that does the majority of the tissue damage sustained following an acute injury. The company's technology focuses on minimizing this tissue damage sustained following acute injury and promoting neural plasticity of the spared healthy tissue, which may result in full or partial functional recovery. In fact, data shows that if as little as 10% of the healthy tissue can be spared, local reorganization can occur that adds meaningfully to functional recovery.

Biopolymer Scaffolding Device



InVivo is developing a customizable biodegradable (biopolymer) scaffolding designed to protect the injured spinal cord and prevent secondary damage from the body's cascading inflammatory and immune responses. It is this additional damage that dramatically reduces patient quality of life post-injury. We estimate that 90% of SCI patients experience some degree of paralysis due to this secondary injury, not the initial primary trauma.

The biopolymer scaffolding device (BSD) is surgically implanted into the lesion following the acute injury. The device is designed to protect what healthy tissue may remain in the cord and promote neuroplasticity, a process where functional recovery (the recovery of motor movement or sensation) may occur through the rerouting of signaling pathways to healthy tissue. Achieving these results is essential to the recovery process, as secondary injury can significantly worsen the immediate damage sustained during trauma.

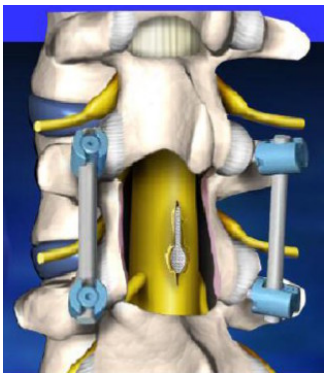
BSD consists of polylactic-co-glycolic acid (PLGA) and polylysine (PLL). PLGA is a biodegradable and biocompatible polymer, FDA approved for application such as surgical sutures (Dolphin sutures and Ethicon sutures), drug delivery (Lupron Depot and Sandostatin LAR Depot), and tissue engineering (Dermagraft). The PLGA-PLL scaffolding degrades naturally inside the body without requiring subsequent removal. The device is customized to fit inside a patient-specific lesion. InVivo can tailor the degree and speed of degradation from as quickly as 24 hours to as long as 1.5 years. The current device is designed to biodegrade in about 12 weeks. BSD is regulated by the U.S. FDA as a Class 3 medical device. A Class III medical device requires FDA approval of a Pre-Market Approval Application (PMA) before the company can start selling the product in the U.S. However, this is a significant time and cost advantage over a traditional new drug application (NDA) or biologic licenses application (BLA) required for pharmaceutical or biotechnology products.

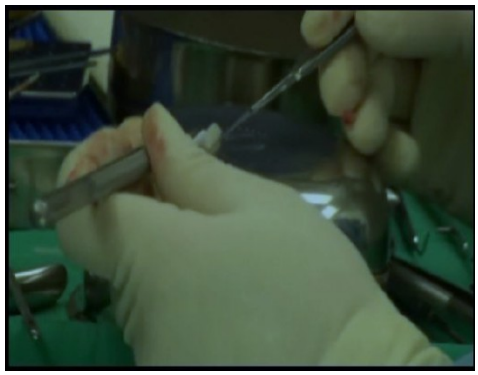
…Version 1 – BSD Alone…

InVivo plans to introduce its first version of the biopolymer scaffolding device without any other FDA regulated drugs for spinal cord injury treatment. As noted above, this allows management to proceed as a Class 3 medical device without conducting lengthy drug or drug/device combination studies. BSD alone is designed to:

- Fill the necrotic lesion to minimize secondary injury, which may occur by inhibiting cell-cell signaling via inflammatory cytokines. This process may occur up to three weeks following the acute trauma.
- Bridge the gap formed by the lesion, providing a matrix designed to promote regrowth and reorganization of neural elements (neurons and neuritis).
- Act as a synthetic extracellular matrix, with the goal of promoting neuroplasticity and the survival of surrounding neurons. Management believes that if just 10% of healthy tissue can be spared, paralysis can be reduced.
- Reduce scar formation (astrogliosis).

The first version of BSD is designed to treat new (acute) SCI patients. Implanting the device requires only a short medical procedure (60 seconds) and can be accomplished by the neurosurgeon. The implantation of the BSD takes place during the surgery (adjunctive) to remove fluid or tissue that presses on the spinal cord, and while the surgeon is removing bone or other fragments and stabilizing the cord with rods and Screws. The device itself is about the size of a stent, and is easily customized to fit into the spinal cord injury.

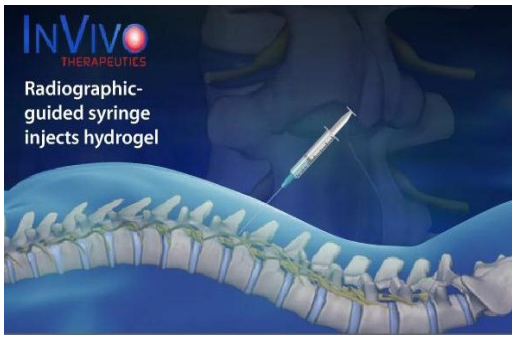




IDE Filed: On July 7, 2011, InVivo submitted an Investigational Device Exemption (IDE) to the U.S. FDA for the biopolymer scaffolding device. The proposed indication is to protect and support spinal tissue and prevent secondary injury, including inflammation and glial scarring, following traumatic spinal cord injury. In the submission, InVivo requested permission to initiate an open-label study of 10 patients with acute spinal cord injuries within several days of injury. As currently planned, patients will be enrolled in the pilot trial at sites in Boston and Washington, D.C. under Principal Investigators Eric Woodard, M.D., InVivo's Chief Medical Officer and Chief of Neurosurgery at New England Baptist Hospital, and Jonathan Slotkin, M.D., neurosurgeon at Washington Brain & Spine Institute. Patients will subsequently be transferred to a rehabilitation center and will be followed for one year.

The trial will evaluate safety data as the primary endpoint. Motor and sensory recovery, as determined by the American Spinal Injury Association (ASIA) Impairment Score, will also be assessed as secondary endpoints. We view this as a major step forward for the company. The animal data presented to date has been outstanding.

…Version 2 – Injectable Hydrogel…



The second product management intends to develop is an injectable hydrogel designed to counteract the inflammatory environment that results during a secondary injury from a closed-wound spinal cord injury. The hydrogel is designed to release drugs over a specific duration in order to synchronize the rate of delivery to match the period in which the inflammatory response peaks during secondary injury. While the hydrogel could incorporate other hydrophilic drugs or therapeutic agents that counteract secondary injury, promote neuroplasticity or support endogenous repair mechanisms, management is currently focusing on delivering an anti-inflammatory steroid, methylprednisolone sodium succinate (MPSS).

MPSS is FDA-approved, and is currently a treatment option used by neurosurgeons for SCI. However, high-dose intravenous administration of MPSS can result in harmful systemic side effects, including increased risks of pneumonia and sepsis. This is a major issue for patients with SCI. As noted above, two of the leading causes of mortality for SCI patients are pneumonia and septicemia. By precisely controlling the release of methylprednisolone at the site of injury, we expect that therapeutically effective doses can be delivered to the point of inflammation while mitigating the risk of harmful systemic side effects.

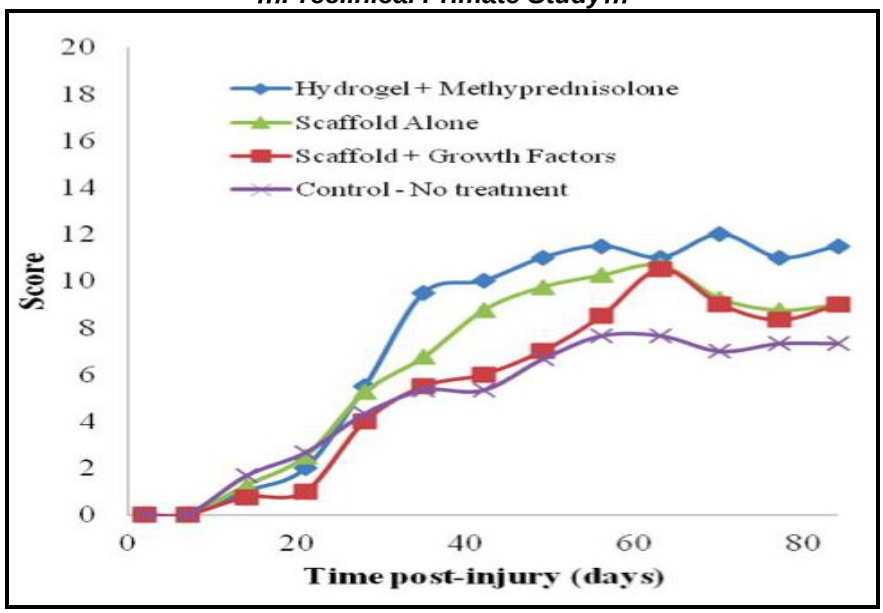
Management has conducted some *in vitro* and initial animal studies with its MPSS-Hydrogel. Data from the *in vitro* studies was published in Biomaterials, *An injectable thiol-acrylate poly(ethylene glycol) hydrogel for sustained release of methylprednisolone sodium succinate* (32(2011)587-597). Results not only show feasibility of the application, but potential synergies between the mechanism of the injectable hydrogel and the anti-inflammatory characteristics of MPSS.

In 2010, management conducted a primate study evaluating 16 African Green monkeys with surgically-induced spinal cord injury through T9-T10 thoracic lateral hemisections. The trial tested the implantation of:

- BSD (PLGA-polylysine scaffold) (n=4),
- BSD (PLGA-polylysine scaffold) soaked in growth factors (EGF, bFGF, 15 µg each) (n=5),
- Hydrogel (thiol-acrylate polyethylene glycol) containing 150 µg MPSS (n=4),
- No treatment for control (n=4).

Implants were administered at the time of lesioning. The objective was to determine the feasibility and reliability of this pre-clinical model of spinal cord injury, the safety and efficacy of the implants in a non-human primate model, as well as the establishment of assessment measures. Analysis of functional neuromotor improvements was performed by statistical evaluation of 3D kinematic and electromyographic (EMG) recordings, InVivo's neuromotor scoring system (scale 0 to 20) and histological and immuno-histochemical stains on post-mortem spinal cord thoracic and lumbar cross-sections. The neuromotor assessment by a blinded trained neuroscientist for each group over the 12-week period for the left hind limb was charted (below).

…Preclinical Primate Study…



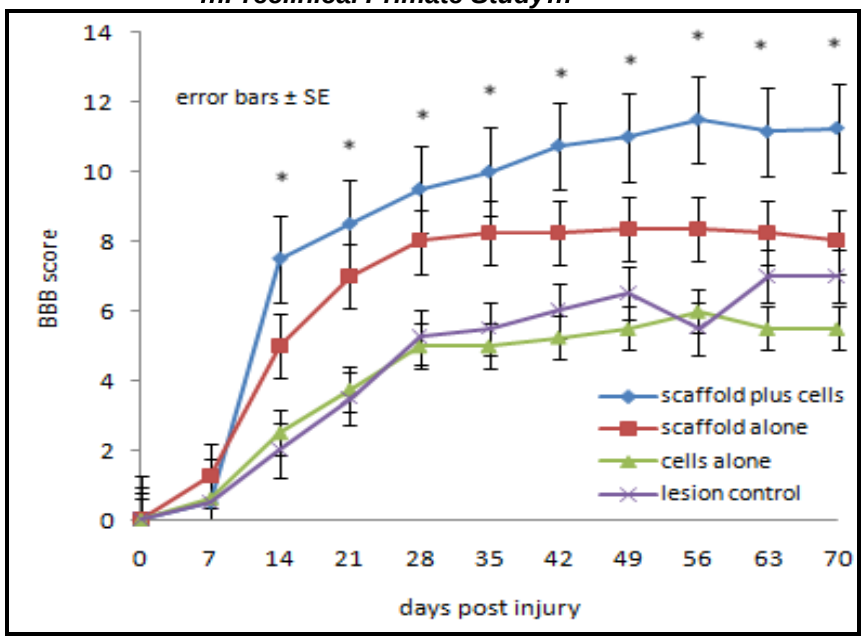
All groups show an initial paralysis two days post-injury. The treatment groups exhibited an improved recovery compared to untreated injured controls on average. Kinematic and EMG analyses exhibited the same trend, although with only 16 primates evaluated, no statistical power tests were performed. However, we are highly encouraged by the fact that trends of the Hydrogel + MPSS looked clearly superior to the other groups, especially the control. The company plans to accumulate additional animal data in the future, and then advance into human clinical studies. Our best guess is that this will take place in 2013. Neurosurgeons are already using MPSS in patients with SCI. The switch to a controlled-release MPSS-hydrogel that adds synergistic benefits to the recovery process should be a blockbuster opportunity for InVivo.

…Version 3 – BSD + Stem Cells…

InVivo's technology encompass multiple strategies involving biomaterials, U.S. FDA approved drugs, growth factors, and human neural stem cells. This approach could become a standard treatment for both acute and chronic spinal cord injuries.

In 2002, InVivo conducted its first animal (rodent, n=12) study performed by academic researchers at MIT and Harvard Medical School. Results were published in the *Proceedings of the National Academy of Sciences* (PNAS, 2002, vol.99, no.5, 3024-9). The implemented scaffold was designed to mimic the cellular architecture of the inner 'grey' matter and outer 'white' matter of the spinal cord. The study demonstrated the impact of BSD alone, along with BSD with human neural stem cells (hNSC) in treating spinal cord injury. The trial had two controls, which included no treatment and human neural stem cells alone. The data can be seen in the chart (below).

…Preclinical Primate Study…



Results show that BSD + hNSC achieved the best outcome based on the Basso-Beattie-Bresnahan (BBB) scoring scale used to evaluate neuromotor improvement at one day post-surgery and weekly time points over the course of six weeks post-injury.

The study also demonstrated that stem cells injected into the lesion without an extracellular matrix offered little therapeutic effect. In fact, BSD alone was superior to hNSC alone. We believe this is clear evidence that a scaffolding device is necessary for the human neural stem cells to survive and function following transplantation. What we also find highly encouraging is the timeframe in which treatment effect becomes evident. For both BSD and BSD + hNSC, separation becomes evident is as little as two weeks post-surgery.

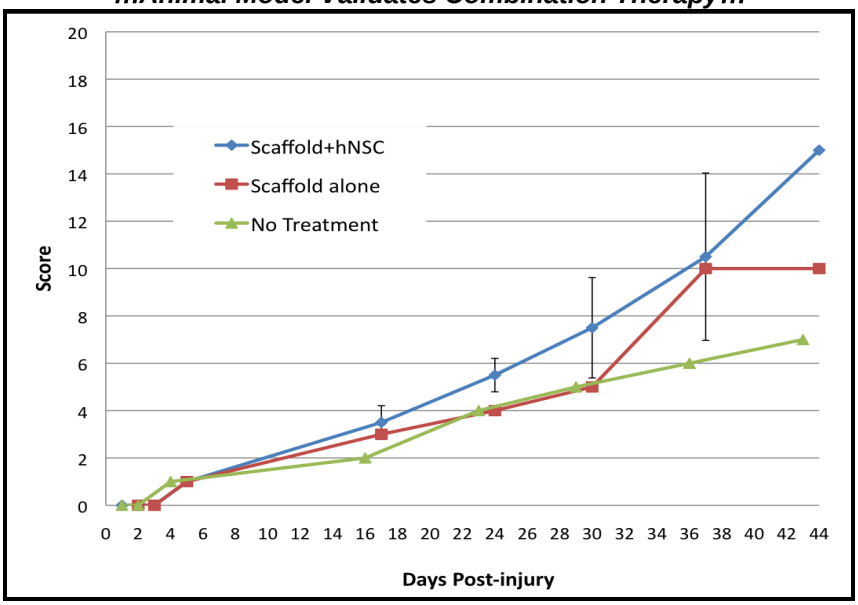
In 2008, InVivo moved from a rodent model to a primate model. This was the first of two primate studies to date, the second of which we discuss above. The first study involved four African Green monkeys with an induced spinal cord injury model and was published in the Journal of Neuroscience Methods, and focused mainly on neuromotor assessment criteria following the model spinal cord injury. The study was designed as a pilot study to test the model injury in assessing the potential therapeutic efficacy of the company's technologies. The study was conducted at the St. Kitts Biomedical Research Foundation in St. Kitts and Nevis and employed a lateral hemisection spinal cord injury model in which the left-half segment of the spinal cord between T9 and T10 was surgically removed.

Immediately following tissue removal, InVivo's BSD was inserted into the resulting lesion. The injury model resulted in paralysis of the animals' left hind limb and loss of sensory function in the animals' right hind limb. The injury model was successful in preserving bowel and bladder function in all animals.

Animals were monitored for six weeks post-injury, and behavioral scoring was performed to measure functional recovery by a neuroscientist blinded to the injury model or treatments performed on each subject. Preliminary video data of the primates was reviewed and rated by a blinded reviewer not involved in the conduct of the study based on a 20 point neuromotor observational scale developed by InVivo that is analogous to the BBB 20 point neuromotor scale for rodents. InVivo's 20 point scale assesses the degree of neuromotor recovery in the hind-limbs of primates after the lateral hemisection injury model. For example, a score of zero means the primate has no voluntary muscle function after injury, a score of 20 means a completely recovery after injury. Any score greater than 8 indicates the subject has regained the ability to bear weight and perform deliberate stepping.

The chart below shows Left Hindlimb Neuromotor Performance on InVivo's modified BBB 20 point scale. The African Green monkeys (n=2) that received scaffolds seeded with human neural stem cells (BSD + hNSC) demonstrated an improved level of functional recovery compared to the control animal (n=1). The data was published in the Journal of Neuroscience Methods, (188(2010)258-269). We encourage investor to view the videos on the company's website – they are impressive.

…Animal Model Validates Combination Therapy…



These results mirrored the behavioral observations obtained in the rodent study presented above. Furthermore, implantation of the biopolymer scaffold device (BSD) alone demonstrated improved efficacy in promoting functional recovery compared to the control in both primate and rodent studies.

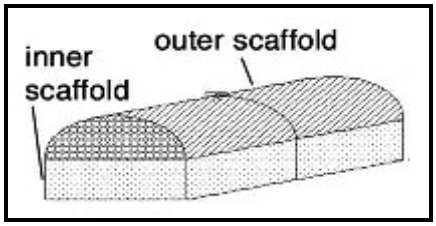
Chronic SCI

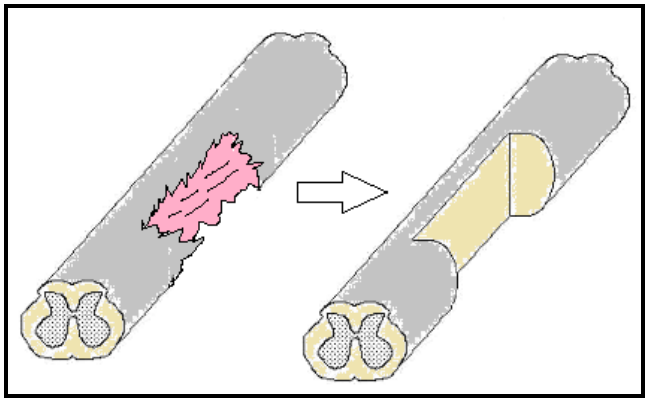
The data we've discussed above has been in the acute SCI setting. From the primate studies, paralysis was confirmed following surgical lesioning. The implants were administered at the time of or shortly after lesioning. The animal model data certainly shows promise, and warrants moving BSD into human clinical studies. However, there are only an estimated 13,000 to 15,000 new (incidence) spinal cord injuries per year in the U.S. We estimate approximately 75% of these may be eligible for treatment. The larger opportunity for InVivo is the 250,000 to 300,000 persons in the U.S. (prevalence) currently living with SCI. The post-acute market is 20x the size of the acute market. And even if only 50% of these SCI patients are eligible for treatment with BSD, Hydrogel, or BSD + cells, we are still talking about a market of over 100,000 patients desperate for a new breakthrough technology.

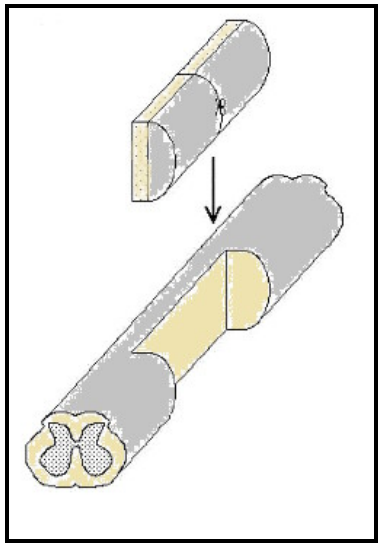
For patients living with chronic SCI, post-acute, there is a disruption of the signal from the brain to the spinal cord at and below the injury. However, the cord and the nerve cells below the injury remain healthy, as long as they are receiving adequate blood supply. In the simplest analogy, spinal cord injury can be thought of as old Christmas tree lights. The wire with the lights represents the spine, and the outlet represents the brain. When one bulb along the wire breaks, all lights after the broken bulb go out. When the broken bulb is replaced, the circuit is fixed and all of the lights come back on. For SCI, the first step is to remove the broken bulb (surgical lesion) so that a new bulb (spinal tissue) can be cleanly inserted into place. The neurosurgeon cuts out a section of cord around the damaged area, essentially creating a new, clean, acute injury. Then, the surgeon customizes the BSD + cells to fit into the new acute injury. Because the cut area is a new injury, cleanly cut by the neurosurgeon, the body responds to heal the damaged area. BSD protects the spinal cord from secondary inflammation and this immune response, and the cells work to facilitate reorganization and neuroplasticity.

…Model For Chronic SCI Repair…

The damaged cord is cleaned to remove scar tissue, and then surgically cut (hemi-sectioned) to create a new acute injury. The acute injury assures adequate blood supply and a clean fit for the scaffolding. BSD + cells are then customized to fit into the new surgically created hemi-section. From there, the healing process becomes analogous to healing for an acute spinal cord injury.





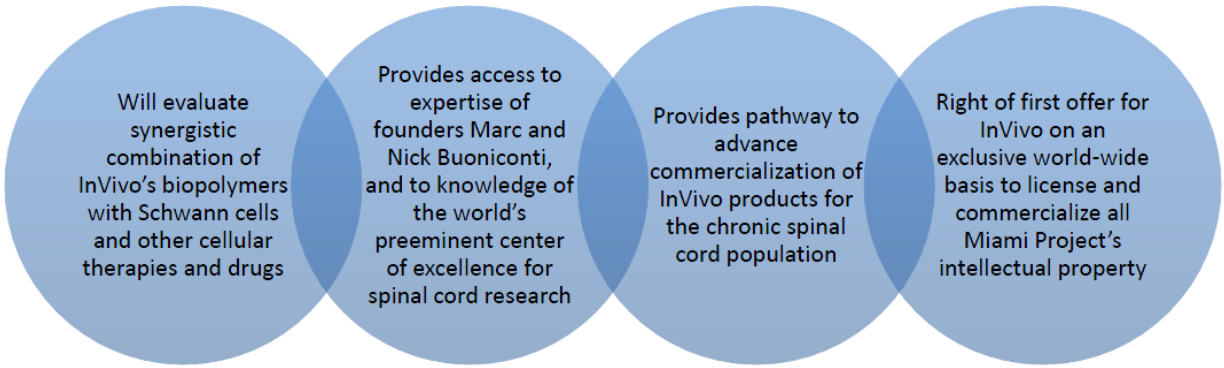


Source: InVivo Therapeutics & Zacks Investment Research, Inc.

Strategic Relationships

On April 27, 2011, InVivo entered into a Collaborative Research and License Agreement (CRLA) with The University of Miami, on behalf of The Miami Project to Cure Paralysis at the University of Miami Miller School of Medicine. Under the agreement, InVivo and The Miami Project will collaborate on the development of novel spinal cord injury treatments. The University of Miami Miller School of Medicines Miami Project to Cure Paralysis is one of the world's most comprehensive spinal cord injury research centers.

The parties will evaluate and pursue the combination of InVivo's biopolymer scaffolding technology and The Miami Project's Schwann cells and other cellular therapies. Intellectual property created under the agreement will be jointly owned by both parties. The initial term of the agreement is five years. Pursuant to the CRLA, The Miami Project agreed to grant InVivo a right of first offer to an exclusive worldwide license to develop and further commercialize any technology developed by the Miami Project.



Besides The Miami Project to Cure Paralysis, InVivo has strategic relationships or affiliation with The Massachusetts Institute of Technology (MIT), Harvard Medical School, Children's Hospital Boston, New England Baptist Hospital, Washington Brain and Spine Institute, The Adaptive Sailing Program at Piers Park Sailing Center, Boston Bruins Foundation, and the University of California, Los Angles.

We expect InVivo to look to strike several more strategic relationships over the next several quarters. The primary focus is to secure neural stem cells designed to work along with the BSD device. We believe BSD is highly attractive to stem cell companies like Geron and Neuralstem, currently working on spinal stem cells for SCI.

A Platform For Growth

What we find exciting about InVivo's technology is that it creates a platform for future products and label expansion. Several companies are working on treatments for SCI. At this point in the game, it is too early to tell who the big pharmaceutical winners in SCI will be.

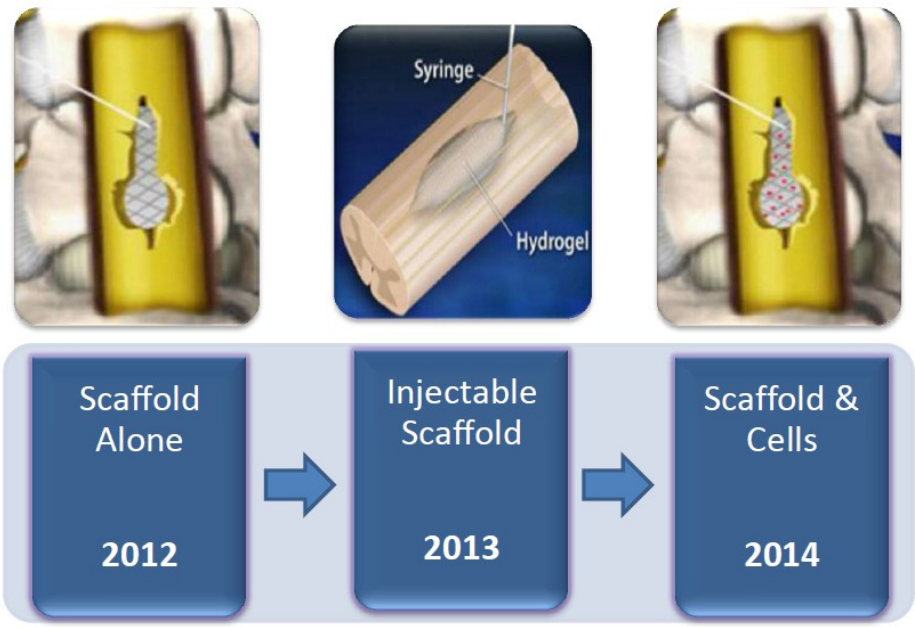
- Geron is working on a glial cell therapy derived from human embryonic stem cells (hESC). Geron has been able to show that its (hESC)-derived oligodendrocyte progenitor cells, GRNOPC1, turn into new glial progenitor cells that work to improve transmission of nerve impulses along the injury. The company initiated a phase 1 study with GRNOPC1 in October 2010.

- Acorda Therapeutics has completed phase 1 trial with AC105, a proprietary magnesium formulation that has demonstrated neuroprotective properties leading to improvement of locomotor function in SCI and cognitive function in traumatic brain injury (TBI) when therapy was initiated within four hours of injury. We note the FDA has granted Acorda 'Fast Track' designation on AC105 to improve functional recovery following treatment of acute SCI patients.

- Cytori Therapeutics has presented preclinical data demonstrating the potential benefit of adipose-derived regenerative cells (ADRC) for the treatment of damaged intervertebral discs. The data show a significant increase in disc tissue density and disc-specific extracellular matrix components such as aggrecan and type II collagen at 12-months post treatment (animal model). The ADSC were administered in a hyaluronic acid (HA) carrier compared to HA alone as the control.

- BioAxone, a privately held biotech company, is developing Cethrin, a recombinant fusion protein designed to promote neuroregeneration in the central nervous system. BioAxone has completed phase 2a clinical studies with Cethrin, and recently licensed the product to Boston Life Sciences for future development and commercialization.

Whether the ideal pharmaceutical product for SCI is an embryonic stem cell, an adult stem cell, a small molecule formulation, or a biologic fusion protein, we believe having InVivo's biopolymer scaffolding matrix will be part of the standard of care. Given the complex nature of SCI, combination therapy makes the most sense to attack the problem from multiple angles: glucocorticoid or corticosteroid molecules to reduce inflammation, cells to encourage reorganization and neuroplasticity, and extracellular scaffolds to protect from immune response, provide support for the cells, and act as a vehicle for controlled drug release. Results from InVivo's rodent models shows that cells alone and MPSS alone are not an effective treatment option. In our view, the BSD that functions as the extracellular matrix similar to the grey and white matter of the spinal cord is a key missing piece of the puzzle, and InVivo is uniquely positioned to benefit from advancing therapies in the near future.



Intellectual Property

When we started our due diligence on InVivo Therapeutics, we found a company with a potentially revolutionary breakthrough for SCI, but questioned whether bigger players in the medical device industry would come in, copy the technology, work around the patents, and develop alternative products. We envisioned a market similar to the drug-eluting stent industry over a decade ago, where J&J initially dominated, but then lost significant market share when superior technology became available and companies like Abbott Labs and Medtronic entered. Prices declined and profits became thin.

However, we've found that InVivo has strong intellectual property. The company has an exclusive world-wide license to broad suite of patents that are co-owned by the Children's Medical Center Corporation (CMCC) and Massachusetts Institute of Technology (MIT) that we believe effectively block any competing biomaterial products for SCI. The licensed patents cover the use of any biomaterials as an extracellular matrix for treating spinal cord injury by itself or in combination with drugs, growth factors and human stem cells. The patents also cover the use of biomaterials to promote the survival and proliferation of human stem cells in the spinal cord. These patents also protect the use of time-release drugs and cells that can range from one day to 1.5 years based on formulation. Patents also cover the design and manufacture of materials for use in SCI. Additional fields of use include parts of the peripheral nervous system, the brain, retina and cranial nerve, and the cavernous nerve surrounding the prostate. The CMCC License has a 15-year term, or as long as the life of the last expiring patent right, whichever is longer, unless terminated earlier by party. In total, InVivo has 10 issued and 3 pending U.S. patents, plus 67 issued and 34 international pending patents.

InVivo's rodent studies have shown that human stem cells cannot proliferate and survive without the addition of the biopolymer scaffolding that serves as an extracellular matrix replacement and acts similarly to the natural cellular architecture of the inner grey and outer white matter of the spinal cord. The patents are the results of over a decade of research by Dr. Robert S. Langer, Professor of Chemical and Biomedical Engineering at MIT and his research teams at MIT's Langer Lab. We believe that any company developing a biomaterial for spinal cord injury used alone or in combination with stem cells or drugs will infringe on these patents. The potential licensing rights alone to this technology make InVivo an attractive investment opportunity in our view.

…Sublicense Payments…

In connection with the CMCC License, InVivo paid an initial $75,000 licensing fee and is required to pay certain annual maintenance fees, milestone payments and royalties. Specifically, the company is required to pay a license amendment fee as consideration for the expansion of the field of use and to make milestone payments upon completing various phases of product development. These include:

(a) Filing the first Investigational New Drug (IND), Investigation Device Exemption (IDE), or comparable application, for each licensed use, with the U.S. FDA → $50,000
(b) Enrollment of the first patient in Phase 2 testing, for each licensed use → $75,000.
(c) Enrollment of the first patient in Phase 3 testing, for each licensed use → $100,000.
(d) Filing the first New Drug Application (NDA), 510(k) application, Pre-Market Approval (PMA) application, or Biologic License Application (BLA), or comparable application, for each licensed use → $250,000.
(e) Upon approval by the FDA of the first NDA, 510(k), PMA, BLA, or comparable application within the U.S., with respect to any licensed product → $500,000
(f) Upon first marketing approval in the first country outside of the U.S. → $500,000.

InVivo is also required to be a yearly maintenance fee of $10,000. If InVivo grants a sub-license on the technology for manufacturing or commercialization, it is obligated to pay CMCC 25% of the sublicense revenues. These exclude reimbursement for expenses and funded R&D programs. We note that InVivo is also required to pay a 3% royalty on net sales of each licensed product following commercialization to CMCC, or 12.5% of their royalty payment from a partner if InVivo chooses to out-license the commercialization of BSD, etc… to a third party. We note in the past, InVivo has reported being in talks with Johnson & Johnson, Medtronic, Stryker, Synthes Spine, and Abbott Labs on developmental partnerships. We do not know if any of these talks remain ongoing.

Financial Position

InVivo Therapeutics exited the first quarter 2011 with $6.9 million in cash and equivalents, along with $0.1 million in restricted cash. Cash burn for the first quarter totaled $2.1 million. We estimate the company will need to raise as much as $20 million over the next two years prior to the launch of its biopolymer scaffolding device in 2014. We remind investors that there are currently 13+ million outstanding warrants exercisable at $1.40 per share. If these warrants can get in the money, it could generate an additional $18 million in cash to InVivo. We note these 13 million warrants are already factored into our DCF Model.

If the stock fails to break above the $1.40 exercise price, we believe the company may need to raise cash through a secondary offering later this year. We estimate the current cash balance runs out in the Q2 2012. We estimate that $5 to $10 million will be sufficient to fund operations through the results of the planned IDE study. Following data from the IDE study, we expect rapid re-valuation to higher levels, which should allow for another wave of capital inflow through the warrants.

Risk

The biggest risk we see right now with investing in InVivo Therapeutics is the early-stage nature of the data. So far both rodent and primate studies have been impressive. However, the transition from primates to humans is a major leap forward. We note the physiological similarities between primates and humans are clearly enough to warrant excitement, humans are primates after all, but the FDA needs to see human studies prior to approval. The second risk we see is financing. We believe the InVivo story is dramatically undervalued today, and if the stock can get above $1.40 per share there are 13+ million warrants outstanding that could provide an additional $18 million in funds to the company. However, if the stock remains below the $1.40 exercise price, InVivo may need to raise as much as $10 million later in the year or in 2012 to fund operations. This dilution could create downward pressure on the stock.

VALUATION & RECOMMENDATION

Initiating Coverage

We are initiating coverage of InVivo Therapeutics with an Outperform rating and $4.50 price target. We are excited about the opportunity that InVivo presents to investors. There are currently no significant treatment options for patients with SCI. Although many companies are currently working on pharmaceutical treatment options, we like InVivo's approach with their biopolymer scaffold device (BSD) for several reasons:

- ✓ BSD will be regulated as a medical device. Management filed the Investigational Device Exemption (IDE) to the U.S. FDA in July 2011. The proposed indication is to protect and support spinal tissue and prevent secondary injury, including inflammation and glial scarring, following traumatic spinal cord injury. We think this initial, simpler approach to treating SCI provides investors with a quicker and lower risk path to market than the traditional pharmaceutical or biologic pathway.

- ✓ Strong scientific rationale. InVivo's technology for the BSD was born out of the labs of Robert S. Langer, ScD, Professor at Massachusetts Institute of Technology and Joseph P. Vacanti, MD, affiliated with Massachusetts General Hospital. Dr. Langer has written over 1,100 articles, holds approximately 760 issued and pending patents worldwide that have been licensed or sublicensed to over 220 pharmaceutical, chemical, biotechnology and medical device companies. InVivo's CEO, Frank Reynolds, having suffered a paralyzing injury to his spine in December 1992, has spent years gaining subject matter expertise on the spine and spinal cord.

- ✓ Intellectual property protection is strong. Ultimately, we believe combination therapy will become the standard of care for SCI. InVivo's owns the patent rights to use of all biopolymer scaffolding products which serve as an extracellular matrix for cell therapy, or in in combination with pharmaceutical products or biologic growth factors. These patents also protect the use of time-release drugs, design and manufacture of materials for use in SCI that mimics the natural cellular architecture of the inner grey and outer white matter of the spinal cord. We believe this creates significant barriers to entry for competitors and provides for meaningful licensing and partnering opportunities in the future for InVivo.

- ✓ Animal data has been very encouraging. Although we have only seen data in African Green monkey's, we note the physiological anatomy and neurophysiology characteristics between how the spinal cord works and functions these primates and humans is nearly identical. African Green Monkeys are an acceptable regulatory indicator of potential hazards and research supports translation to humans, Nature Medicine, Vol-13,No.5:561-566, May 2007. The genomic similarity to humans is over 98%.

…A Simple Concept…

InVivo is taking a different approach to SCI, focusing on protection of the spinal cord and prevention of secondary injury rather than regeneration. As discussed above, it is often this secondary immune response and inflammation that does the majority of the tissue damage sustained following an acute injury. The company's technology focuses on minimizing tissue damage sustained following acute injury and promoting neural plasticity of the spared healthy tissue, which may result in full or partial functional recovery. In fact, management believes that if as little as 10% of the healthy tissue can be spared, local reorganization can occur that adds meaningfully to functional recovery.



We think this is a model that lends itself well to clinical trials. As noted above, regulation as a Class 3 medical device should allow management to move quickly through clinical development. The IDE was filed in July 2011, with human subject trials planned for later in the year. We estimate that 10 patients will be enrolled in the pilot trial at sites in Boston and Washington, D.C. under Principal Investigators Eric Woodard, M.D., InVivo's Chief Medical Officer and Chief of Neurosurgery at New England Baptist Hospital, and Jonathan Slotkin, M.D., neurosurgeon at Washington Brain & Spine Institute. Patients will subsequently be transferred to a rehabilitation center and will be followed for one year. The trial will evaluate safety data as the primary endpoint. Motor and sensory recovery, as determined by the American Spinal Injury Association (ASIA) Impairment Score, will also be assessed as secondary endpoints.

The next step following this small pilot study remains to be seen. We see two potential next steps following completion of the IDE study:

1. Traditionally, the next step following the IDE is to conduct a larger Pre-Market Approval (PMA) study in approximately 30-40 patients with SCI. Assuming successfully completion of the PMA program, InVivo should be able to file for approval in the U.S. through the 510(k) pathway.

2. With "Homerun" like data from the IDE study, meaning moving patients off a ventilator or taking a complete tetraplegic and returning bowel function or more, InVivo may be able to file for approval in a narrow patient population. An option is to seek approval under the FDA's Humanitarian Device Exemption (HDE) protocol. HDE is similar in both form and content to a Pre-Market Approval (PMA) application, but is exempt from the effectiveness requirements of a PMA. An HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. The application, however, must contain sufficient information for FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use. The HDE pathway may allow approval for InVivo's BSD in an acute population or in complete tetraplegics.

Longer-term, upside to the story comes from gaining approval for the injectable Hydrogel formulation, which can be used with pharmaceutical products like methylprednisolone sodium succinate (MPSS). This will then be followed by applications for use of BSD in-combination with stem cells. We think this has the potential to turn BSD into a potential blockbuster for the treatment of SCI because it opens up the opportunity to heal chronic SCI in the 250,000 to 300,000 patients in the U.S. currently living with SCI. If we look outside the U.S., and include Canada and Western Europe, the number grows to 400,000 chronic SCI patients in these markets. Including Asia, Australia, and Latin America, the number of chronic SCI patients is around 2.0 million worldwide.

…Large Market Opportunity…

In the U.S., we estimate that 50% of SCI patients would benefit from a new treatment paradigm.

Eligible for Treatment	Percent Of SCI Patients	Eligible For BSD Treatment	Total
Complete Tetraplegia	22%	90%	20%
Incomplete Tetraplegia	34%	25%	9%
Complete Paraplegia	25%	75%	19%
Incomplete Paraplegia	19%	15%	3%
			50%

We think the initial focus will be on the acute market, with greater penetration coming as InVivo demonstrates utility with combination therapy, the Hydrogel, or with stem cells (hNSC). Given the significant unmet medical need and the lack of existing treatment options, we envision a price almost similar to an Orphan Drug. We think that $60,000 per implant is reasonable for the BSD alone, with InVivo maintaining the ability to raise the price to $75,000 and $100,000 as the Hydrogel and BSD + cells comes to market. Under this scenario, with just 10% market penetration, InVivo's device could have billion-dollar potential. We think once the next-generation products are approved, market penetration can soar to 20%, meaning peak sales for the BSD + cell is in the area of $2.5 billion.

We believe all this can be accomplished with little overhead as well. We estimate that there are only 75 Level-1 trauma centers in major cities around the U.S. with qualified neurosurgeons and the necessary equipment to perform spinal surgery. A sales force of 20 to 25 representatives can effectively target 90% of the market.

InVivo's goal is to take BSD to the market alone in an effort to build the most shareholder value possible. Ultimately, we believe this is a device that will end up in the hands of a major medical device company like Johnson & Johnson, Medtronic, Stryker, or Abbott Labs. The economics to InVivo will be higher if BSD is approved, and next-generation products like the Hydrogel and BSD + cells have advanced into registration studies.

Valuation

…On DCF…

We have performed a discounted cash flow (DCF) analysis on our sales assumptions outlined above. We assume that InVivo looks to launch BSD in 2014 at a price of $60,000. We assume 90% gross margin, a sales force of 25 full-time representatives, and ongoing R&D funding the registration programs for Hydrogel and BSD + cells. We model approval of the Hydrogel in 2015 and the combination therapy in 2016. We think management can slowly raise the price towards $100,000, and capture 10% of the 100,000 to 150,000 chronic and acute SCI patients in the U.S. We have used an extremely aggressive discount rate of 50% to account for the early-stage nature of the product. We arrive at a market value of approximately $360 million, or $4.41 per share based on roughly 65 million shares currently outstanding, 6.4 million unregistered shares, and a future dilution of 10 million shares to fund operations in 2012 (adjusted fully diluted share count of 81.6 million). Our DCF model can be found at the back of this report.

We see investment in InVivo Therapeutics as an investment in the growth of the entire SCI market. As noted above, the company's technology can be used in concert with anti-inflammatory drugs, growth factors, and stem cells. The device is designed to protect what little healthy tissue may remain in the cord, promote neuroplasticity and reorganization, and provide the extracellular matrix to hold the cells or pharmaceutical product in place. Advancing time-released technology and the liquid injection (Hydrogel) provides meaningful opportunity for partnerships and collaborations in the near future.

…On A Takeout…

As noted above, our DCF model assumes InVivo bring BSD to the market alone. However, if BSD is a success, a larger partner will surely come along and make shareholders and offer. Accordingly, we can adjust our valuation to see, "What it could be worth" to a potential larger company on a takeover. We do this so that investors can get a true sense of fair market value for the stock.

Starting with our DCF model, we've increased sales by 20% to account for "overwhelming" promotion of a massive sales force like J&J or Medtronic. We've also removed future dilution and lowered the discount rate to account for a much lower cost of capital. Finally, we've reduce the S&GA expense figuring that a larger company will use representatives already in the field promoting products for spinal surgery, biomaterials, tissue engineering, or neurology. We arrive at a "take-out" value of $525 million, or $7.25 per share. We believe this is a price that a company like J&J or Medtronic could easily pay and still see accretion.

We can also look at previous deals between larger pharmaceutical or medical device companies and see – on average – what multiple of revenue seems fair to pay. We have looked at several previous deals:

Acquirer	Target	Purchase Price	TTM Sales	Price / Sales
Abbott Labs	Spinal Concepts	$210 Million	$27 Million	7.8x
Stryker	BSI Neurovascular	$1.5 Billion	$348 Million	4.3x
Shire Pharma	Advanced Bio	$750 Million	$146 Million	5.1x
Stryker	OrthoVita	$305 Million	$95 Million	3.2x
Medtronic	Salient Surgical	$525 Million	$100 Million	5.3x
J&J	Synthes, Inc.	$19.3 Billion	$3.7 Billion	5.2x
Zimmer Holdings	Abbott Spine	$360 Million	$109 Million	3.3x
Sulzer Medica	Spine-Tech	$595 Million	$58 Million	10.1x
Integra LifeSci	Theken Spine	$75 Million	$34 Million	2.2x
Kinetic Concepts	LifeCell	$1.7 Billion	$190 Million	8.9x
Medtronic	Kyphon	$3.9 Billion	$408 Million	9.6x
"Private Equity"	Biomet	$10.9 Billion	$2.1 Billion	5.4x
Smith & Nephew	Oratec Intervent	$310 Million	$48 Million	6.5x
Smith & Nephew	Orthopaedic Bio	$28 Million	$6 Million	4.6x
Medtronic	Xomed	$800 Million	$91 Million	8.8x
Medtronic	Sofamor Danek	$3.7 Billion	$400 Million	9.2x
J&J	DePuy	$3.5 Billion	$850 Million	4.1x
DePuy	AcroMed	$325 Million	$91 Million	3.6x
Smith & Nephew	Plus Orthopedics	$899 Million	$300 Million	3.0x
			Average Deal P/S Ratio	**6.1x**

By 2015, we expect InVivo's BSD and next-generation products roughly $200 million in sales. If we apply our average P/S multiple of 6.1x, we arrive at a take-out price of $1.2 billion. Based on our fully diluted share count, we arrive at a fair price of $14.75 in 2015. Discounting that back to present day at 20%, we $7.10 per share.

…Upside To Our Target…

We are initiating coverage an establishing a near-term target of $4.50 per share based on DCF (rounding up slightly from the DCF). However, with the financing risk out of the way, perhaps later this year, and clear momentum on the clinical front, we think InVivo can trade as high as $7 per share on speculation of a take-out.

PROJECTED FINANCIALS

InVivo Therapeutics Holdings Corp.
Discounted Cash Flow Model

YEAR	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Americans Living with SCI	275,000	275,000	287,500	300,125	312,876	325,755	338,763	351,900	365,169	378,571	392,107
Net New Cases Per Year	12,500	12,500	12,625	12,751	12,879	13,008	13,138	13,269	13,402	13,536	13,671
Total SCI Market	287,500	287,500	300,125	312,876	325,755	338,763	351,900	365,169	378,571	392,107	405,778
Eligible SCI Patients	143,463	143,463	149,762	156,125	162,552	169,043	175,598	182,219	188,907	195,661	202,483
NVIV Market Share	*0%*	*0%*	*1.0%*	*2.0%*	*3.5%*	*5.0%*	*7.5%*	*9.0%*	*10.5%*	*11.5%*	*12.5%*
Treated Patients	0	0	1,498	3,123	5,689	8,452	13,170	16,400	19,835	22,501	25,310
Price Per Procedure	$0	$0	$60,000	$65,000	$75,000	$80,000	$85,000	$90,000	$95,000	$100,000	$100,000
NVIV Sales (in Millions)	**$0**	**$0**	**$89.9**	**$203.0**	**$426.7**	**$676.2**	**$1,119.4**	**$1,476.0**	**$1,884.3**	**$2,250.1**	**$2,531.0**
CoGS	*$0*	*$0*	*$9*	*$20*	*$43*	*$68*	*$112*	*$148*	*$188*	*$225*	*$253*
R&D	*$5*	*$10*	*$10*	*$10*	*$10*	*$10*	*$10*	*$10*	*$10*	*$10*	*$10*
SG&A	*$4*	*$5*	*$19*	*$32*	*$55*	*$81*	*$126*	*$162*	*$203*	*$239*	*$267*
Sublicense Payments	*$1*	*$1*	*$4*	*$7*	*$14*	*$21*	*$35*	*$45*	*$58*	*$69*	*$77*
EBIT	($10)	($16)	$48	$134	$305	$496	$837	$1,111	$1,426	$1,707	$1,924
Depreciation and amortization	*$0*	*$0*	*$0*	*$1*	*$1*	*$2*	*$3*	*$4*	*$5*	*$5*	*$5*
EBITDA	**($10)**	**($16)**	**$47**	**$133**	**$304**	**$494**	**$834**	**$1,107**	**$1,421**	**$1,702**	**$1,919**
EBITDA margin	-	-	*52.8%*	*65.7%*	*71.3%*	*73.1%*	*74.5%*	*75.0%*	*75.4%*	*75.7%*	*75.8%*
Cash Taxes	$0	$0	($9)	($43)	($97)	($158)	($267)	($354)	($455)	($545)	($614)
Tax Rate	-	-	*20.0%*	*32.0%*	*32.0%*	*32.0%*	*32.0%*	*32.0%*	*32.0%*	*32.0%*	*32.0%*
Balance Sheet											
Capital Expenditures	($1)	($5)	($20)	($15)	($10)	($5)	($5)	($5)	($5)	($5)	($5)
Working Capital	($1)	($2)	($19)	($37)	($71)	($109)	($177)	($231)	($294)	($350)	($394)
Interest Expense	($1)	($1)	($1)	($1)	($1)	($1)	($1)	($1)	($1)	($1)	($1)
Capital employed	**($3)**	**($8)**	**($40)**	**($53)**	**($82)**	**($115)**	**($183)**	**($237)**	**($300)**	**($356)**	**($400)**
ROIC	*-333.3%*	*-200.0%*	*118.1%*	*254.2%*	*372.9%*	*432.1%*	*457.9%*	*468.0%*	*475.0%*	*479.0%*	*481.2%*
Discounted Cash Flow											
Net Income	($10)	($16)	$57	$176	$402	$652	$1,100	$1,461	$1,875	$2,247	$2,532
Depreciation and amortization	$0	$0	$0	$1	$1	$2	$3	$4	$5	$5	$5
Net Cash Changes	($3)	($8)	($40)	($53)	($82)	($115)	($183)	($237)	($300)	($356)	($400)
Post-Tax Operating Cash Flow	**($13)**	**($24)**	**$17**	**$124**	**$321**	**$540**	**$921**	**$1,228**	**$1,580**	**$1,895**	**$2,138**
Dividends	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Free Cash Flow	**($13)**	**($24)**	**$17**	**$124**	**$321**	**$540**	**$921**	**$1,228**	**$1,580**	**$1,895**	**$2,138**

Assumptions	
Beta:	N/A
Equity Risk Premium:	20%
Risk Free Rate:	5%
Probability Adjustment:	25%
Discount Rate:	**50%**

Valuation	
10-Year Model:	$300
Terminal Growth:	6%
Terminal Value:	$60
Debt:	$0
Firm Value:	**$360**

Price Target	
Basic Outstanding:	65.2
Non-Issued:	6.4
Dilution:	10.0
Fully Diluted:	81.6
Target Price:	**$4.41**

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

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InVivo Therapeutics Holdings Corp.
Income Statement

InVivo Therapeutics	2010 E	Q1 A	Q2 E	Q3 E	Q4 E	2011 E	2012 E	2013 E	2014 E
Product Sales	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$89.9**
YOY Growth	-	-	-	-	-	-	-	-	-
Collaborative & Licensing	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0.0**	**$89.9**
YOY Growth	-	-	-	-	-	-	-	-	-
Cost of Goods / Services	$0	$0	$0	$0	$0	$0	$0	$0	$9.0
Product Gross Margin	-	-	-	-	-	-	-	-	-
R&D	$1.7	$0.6	$0.6	$0.7	$0.7	$2.6	$4.0	$5.0	$19.4
% R&D	-	-	-	-	-	-	-	-	*21.5%*
SG&A	$1.7	$0.8	$0.8	$0.9	$0.9	$3.4	$5.0	$10.0	$10.0
% SG&A	-	-	-	-	-	-	-	-	*11.1%*
Operating Income	($3.4)	($1.4)	($1.4)	($1.6)	($1.6)	($6.0)	($9.0)	($15.0)	$51.5
Operating Margin	*0.0%*	-	-	-	-	-	-	-	*57.3%*
Net Other Income	($4.5)	$0.1	$0.0	$0.0	$0.1	$0.2	$0.1	$0.1	$0.2
Pre-Tax Income	($7.9)	($1.3)	($1.4)	($1.6)	($1.5)	($5.8)	($8.9)	($14.9)	$51.7
Taxes	$0	$0	$0	$0	$0	$0	$0	$0	$9.5
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*18.3%*
Net Income	($7.9)	($1.3)	($1.4)	($1.6)	($1.5)	($5.8)	($8.9)	($14.9)	$42.2
Net Margin	*0.0%*	-	-	-	-	-	-	-	*47.0%*
Reported EPS	**($0.24)**	**($0.02)**	**($0.03)**	**($0.03)**	**($0.03)**	**($0.11)**	**($0.14)**	**($0.21)**	**$0.56**
YOY Growth	-	-	-	-	-	-	-	-	-
Wt. Ave Shares Outstanding	33.4	51.7	52.0	54.0	56.0	53.4	65.0	70.0	75.0

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

MANAGEMENT

Frank Reynolds – Chairman and CEO & CFO

Frank Reynolds founded InVivo Therapeutics in 2005 and he serves as Chairman of the Board, CEO and CFO. He is the former Director of Global Business Development at Siemens Corporation where he was responsible for new business in 132 countries. He has over 25 years of executive management experience and was the founder & CEO of Expand The Knowledge, Inc., an IT consulting company with a focus on life sciences. He is an Executive Board Member of the Irish American Business Chamber and has served on the board of the Special Olympics of Massachusetts, Philadelphia Cares, and Wharton Consulting Partners.

Mr. Reynolds suffered a paralyzing injury to his spine in December 1992. While recovering from this injury he spent years gaining subject matter expertise on the spine and spinal cord. He holds a Master of Business Administration from Sloan Fellows Program in Global Innovation and Leadership- Massachusetts Institute of Technology; a Master of Science in Engineering – University of Pennsylvania; he is an alumni of the Executive Masters of Technology Management- Wharton School of Business; a Master of Science in Management Information Systems – Temple University; a Master's of Science in Health Administration – Saint Joseph's University; and a Master's of Science in Counseling Psychology – Chestnut Hill College. He also has a Bachelor of Science in Marketing – Rider University.

Eric Woodard, MD – Chief Medical Officer

Dr. Woodard, MD is Chief, Neurosurgery at New England Baptist Hospital in Boston. Dr. Eric Woodard received his medical degree from the Pennsylvania State University and completed his residency in Neurological surgery at Emory University. Following residency, Dr. Woodard completed a fellowship in complex spinal surgery at the Medical College of Wisconsin under Dr. Sanford Larsen. He is a diplomat of the American Board of Neurological Surgeons. Dr. Woodard was formerly Chief of the Division of Spinal Surgery in the Department of Neurological Surgery at Brigham and Women's Hospital, where he held the rank of Assistant Professor in Surgery at Harvard Medical School. Since joining the medical staff in 2004, Dr. Woodard has continued to practice complex spinal surgery and has established the Neurosurgery Fellowship in spinal surgery at New England Baptist Hospital. He has been an editorial board member for The Journal of Spinal Disorders, Spine Universe.com and is an ad hoc reviewer for Neurosurgery, Journal of Neurosurgery and the New England Journal of Medicine. Dr. Woodard is a member of numerous professional societies and organizations that include the American Association of Neurological Surgeons, the Congress of Neurological Surgeons, the Joint Section of the AANS/CNS, Spine and Peripheral Nerve, AO Spine North America, the North American Spine Society, Massachusetts Medical Society, and the Racchidian Society. He is the immediate past chairman of the AO Spine North America Board and serves on the Board of AO Spine International.

Robert S. Langer, Sc.D. – Scientific Advisory Board

Robert S. Langer is the David H. Koch Institute Professor at the Massachusetts Institute of Technology (MIT). Dr. Langer has written over 1,100 articles. He also has approximately 760 issued and pending patents worldwide. Dr. Langer's patents have been licensed or sublicensed to over 220 pharmaceutical, chemical, biotechnology and medical device companies. He served as a member of the United States Food and Drug Administration's SCIENCE Board, the FDA's highest advisory board, from 1995 — 2002 and as its Chairman from 1999- 2002. Dr. Langer has received over 180 major awards including the 2006 United States National Medal of Science; the Charles Stark Draper Prize, considered the equivalent of the Nobel Prize for engineers and the 2008 Millennium Prize, the world's most prestigious technology prize. He was recently awarded the American Chemical Society's (ACS) illustrious Priestley Medal for his distinguished services to chemistry. The Priestly Medal is the highest honor bestowed by the ACS, the world's largest scientific society. He received his Bachelor's Degree from Cornell University in 1970 and his Sc.D. from the Massachusetts Institute of Technology in 1974, both in Chemical Engineering.

Sir Richard Roberts, Ph.D. – Scientific Advisory Board

Sir Richard J. Roberts is the Chief Scientific Officer at New England Biolabs, Ipswich, Massachusetts. He was educated in England, attending St. Stephen's School and the City of Bath Boys' School in Bath before moving to the University of Sheffield where he obtained a B.Sc. in Chemistry in 1965 and a Ph.D. in Organic Chemistry in 1968. His postdoctoral research was carried out in Professor J.L. Strominger's laboratory at Harvard, where he studied the tRNAs that are involved in the biosynthesis of bacterial cell walls. From 1972 to 1992, he worked at Cold Spring Harbor Laboratory, reaching the position of Assistant Director for Research under Dr. J.D. Watson. Sir Richard's current research interests focus on using bioinformatics and genomics to find new enzyme activities and to drive his experimental program. Most recently he is involved in a large community based project called COMBREX aimed at improving the functional annotation of genomes. Sir Roberts won the 1993 Nobel Prize in Medicine and Physiology

Jonathan Slotkin, MD – Scientific Advisory Board

Dr. Slotkin is a clinical neurosurgeon and research scientist. Clinically, Dr. Slotkin has expertise in complex spinal surgery, minimally invasive spinal surgery, spinal oncology surgery and brain tumor surgery. Dr. Slotkin completed residency training in neurosurgery at Harvard Medical School, Brigham and Women's Hospital. He performed a fellowship in complex spinal surgery with Dr. Eric J. Woodard. He is the co-editor of a two-volume publication on spinal surgery. Dr. Slotkin is currently a neurosurgeon with the Washington Brain and Spine Institute. Dr. Slotkin's research interests include regeneration and plasticity after spinal cord injury, and nanotechnology initiatives for cellular labeling and non-invasive cell tracking. Dr. Slotkin has authored or co-authored several peer-reviewed scientific publications in the areas of repair after spinal cord injury in animal models, and in vivo quantum dot labeling of neural stem cells. Dr. Slotkin has expertise in the application of nanotechnology research to clinical neurosurgery and neurology.

V. Reggie Edgerton, Ph.D. – Scientific Advisory Board

Dr. V. Reggie Edgerton has been the Director of UCLA's Edgerton Lab since 1968 and is a professor in the Department of Physiological Sciences at UCLA. His research is focused on neural control of movement and how this neural control adapts to altered use and after spinal cord injury. He completed his Ph.D. under the direction of Drs. Wayne Van Huss, Rex Carrow, and William Heusner at Michigan State University. Dr. Edgerton is on the Scientific Advisory Board of The Christopher Reeves Foundation (CRF) and he is one of eight labs in the world receiving funding from the CRF. In addition, he is the author of approximately 300 research papers. A key question researched in Edgerton lab is how the neural networks in the lumbar spinal cord of mammals, including humans, control stepping and locomotion after complete spinal cord injury.

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Todd Albert, MD – Scientific Advisory Board

Dr. Todd J. Albert, MD, is the James Edwards Professor and Chair of the Department of Orthopaedics at Jefferson Medical College in Philadelphia. He is also the President of the Rothman Institute in Philadelphia. Previously, he served as Co-director of Reconstructive Spine Surgery and the Spine Fellowship Program at Thomas Jefferson University. Dr. Albert graduated magna cum laude from Amherst College, received his doctor of medicine degree from the University of Virginia School of Medicine. He completed a residency in orthopaedic surgery at Thomas Jefferson University Hospital (where he was named Outstanding Chief Resident) and a fellowship in spinal surgery at the Minnesota Spine Center. Dr. Albert serves on the boards of several scholarly journals, including Spine, The Spine Journal, and The Journal of Spinal Disorders and Techniques. Dr. Albert has published over 200 scientific articles, authored over 40 book chapters, and presented his research both nationally and internationally. He has published seven textbooks on spinal surgery, including Spine Surgery: Tricks of the Trade; Surgical Approaches to the Spine; Master Cases: Spine Surgery; Physical Examination of the Spine; and Spinal Deformities, the Essentials.

George Nolen – Lead Director

George Nolen is the former President and Chief Executive Officer of Siemens Corporation, the U.S. subsidiary of Siemens, AG, a global leader in industry, energy and healthcare. George oversaw more than $17 billion in strategic acquisitions in the energy, healthcare, and industrial sectors, positioning Siemens USA as a leading U.S. and global player in these key industries. Prior to his role as Siemens USAs CEO, George served as President of Siemens Information and Communications division, overseeing this $2 billion business from 1998 to 2004. As CEO, George was active in the Business Roundtable, the Executive Committee of the U.S. Chamber of Commerce, and as a director on the Board of the New York Hall of Science. Currently, he is on the Advisory Board of Madison Capital Partners. George is also the Rector, of the Board of Visitors at Virginia Tech University, where he is an alumnus.

Christi M. Pedra – Director

Christi M. Pedra currently serves as Senior Vice President of Strategic New Business Development and Marketing in Siemens Healthcare Customer Solutions Group. Prior to joining the Customer Solutions Group, Christi Pedra was Chief Executive Officer of Siemens Hearing Instruments, Inc. where she was responsible for leading the company's sales, manufacturing, product research and development in the United States, Canada, and Latin America. Ms. Pedras career with Siemens began in 1985 in the information and communication division as part of the joint venture between IBM and Siemens. There she grew her career in various senior management roles in sales and marketing. In 2002 she helped launch Siemens One as Vice President of Executive Relations and was promoted to Vice President of Sales and Chief Operating Officer in 2004. Christi Pedra is a member of the National Collegiate Athletic Association (NCAA) Leadership Advisory Board and the National Council for Liberal Education Americas Promise.

Adam K. Stern – Director

Adam K. Stern joined the InVivo Therapeutics Board of Directors in 2010 and is the Senior Managing Director of Spencer Trask Ventures, the placement agent of InVivo Therapeutics' offering. He has over 20 years of venture capital and investment banking experience focusing primarily on the technology and life science sectors of the capital markets. He currently manages the structures finance group of Spencer Trask Ventures, Inc. Mr. Stern currently also sits on the boards of various private companies and one public company, PROLOR Biotech (NYSE/AMEX:PBTH). Mr. Stern holds a Bachelor of Arts degree with honors from the University of South Florida in Tampa.

David W. Feigal Jr, MD – Business Advisory Board

David Feigal recently served as Vice President, Global Regulatory at Amgen, Inc. Previously, Dr. Feigal was Senior Vice President, Head of Global Regulatory and Global Safety Surveillance at Elan. Prior to joining Elan in November 2006, he spent 12 years with the FDA. During his time at the FDA, he was Head of the Center for Devices and Head of the Center for Biologics for five years each. Before joining the FDA, Dr. Feigal worked for 10 years within the academic and hospital settings of the University of California in San Diego, San Francisco and Davis. He holds a BA from University of Minnesota, an MD from Stanford University and a Master of Public Health from the UC Berkeley.

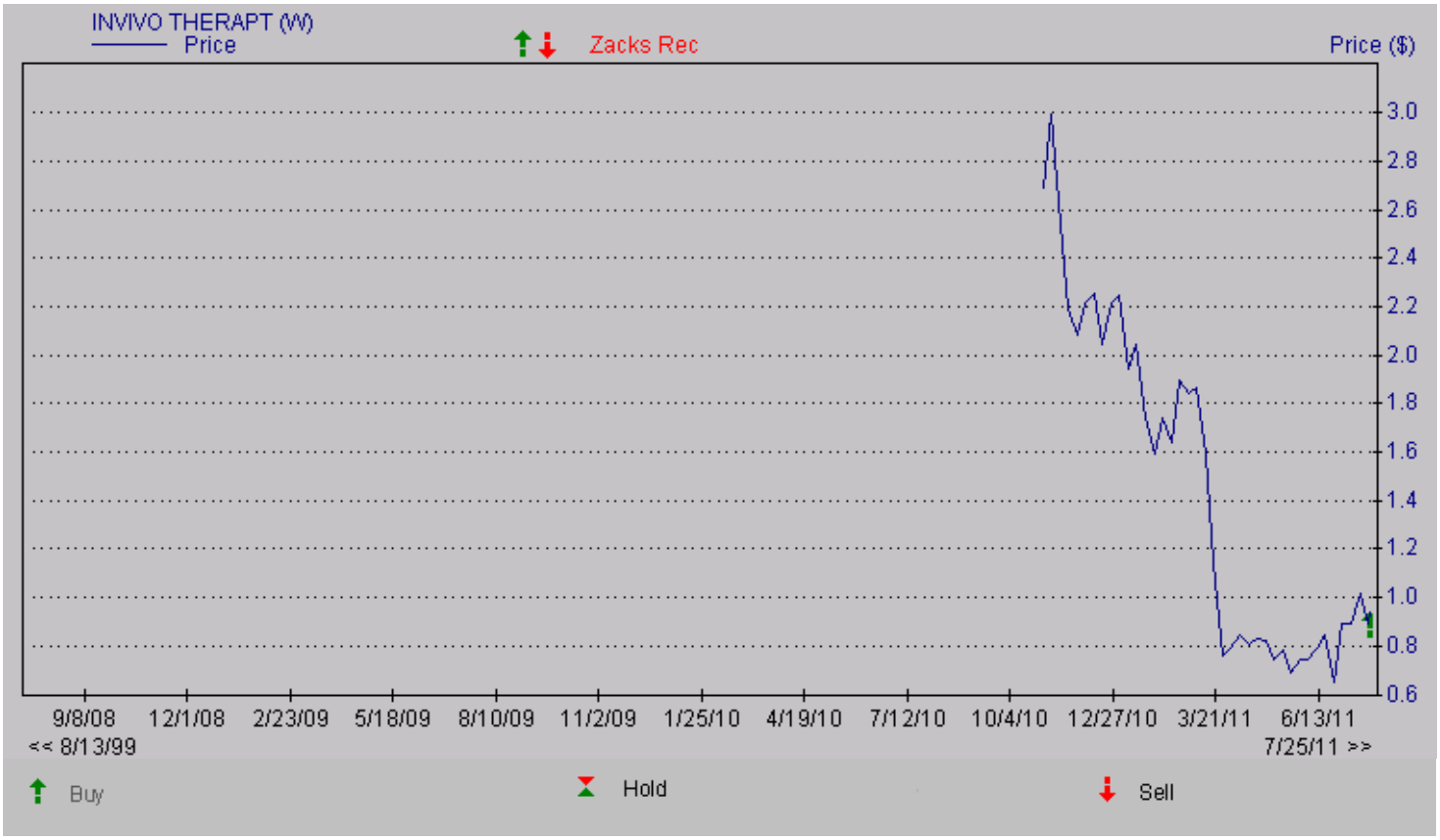
Paul Mraz – Business Advisory Board

Mr. Mraz currently serves as President and Chief Executive Officer of Cerapedics, Inc., a medical device company located outside Denver, CO. Cerapedics is developing and commercializing biologic bone grafting products for the spine, trauma and orthopaedic markets based on its proprietary small-peptide technology. To date, Cerapedics has raised $30M in venture capital financing and distributes its products in 20+ countries worldwide. Mr. Mraz most recently served as Chairman and CEO of Angstrom Medica, Inc. (acquired by Pioneer Surgical Technology), a privately funded, early-stage biomaterials and nanotechnology company engaged in the development of structural, calcium phosphate-based medical devices for the spinal, sports medicine and trauma markets.

Sean Morgan – Director of Finance

Mr. Moran joined InVivo in August 2010 and has 26 years of experience in financial management and sixteen years as a CFO for public and private companies. He has a deep background in life sciences and has served in senior financial roles for medical device, biotech and drug development companies. Mr. Moran has successfully raised capital and has extensive experience in corporate finance, mergers and acquisitions, investor and Wall Street relations and SEC reporting. Before joining InVivo, Moran served as Chief Financial Officer of four publicly traded companies, most recently at Celsion Corporation, as well as at Sontra Medical, SatCon Technology Corporation, and Anika Therapeutics. Moran was also the co-founder of Anika Therapeutics, and helped to take the company public through an IPO and guided it to profitability. Mr. Moran is a CPA and earned his M.B.A and a B.S. in Accounting from Babson College.

HISTORICAL ZACKS RECOMMENDATIONS



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