InVivo Therapeutics™ Corporation

By

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Submitted to the Sloan School of Management
in Partial Fulfillment Of the Requirements for the Degree of

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Abstract

To date, the primary treatment for spinal cord injuries has been the use of spinal fixation devices to create a stable environment for the spinal cord to heal. The second treatment option is to remove soft tissue near and around the spinal cord intended to reduce pressure on the spinal cord and allow the spinal cord to heal on its own.

InVivo Therapeutics Corporation is a startup founded to commercialize novel science and technology that was developed through a collaborative effort between the Massachusetts Institute of Technology's Langer labs, and the department of Neuroscience at Harvard Medical School. Together they have created a patent pending medical device that will provide the first "Neuro-Tissue Engineered" implantable device for the immediate treatment of spinal cord injuries. We expect to have our first product on the market in 2010, and we will continue to work in our labs to develop a portfolio of three to four product categories in order to meet the systemic needs of the spinal cord injury patient.

This thesis presents the first business plan, to commercialize this innovative treatment option. It is always challenging to be first to market with such an innovative product, so we have meticulously explored all relevant strategic initiatives, and tactical tasks required to bring our products to market. As the result we have developed a comprehensive business plan to ensure InVivo's success. Key components of the plan are: Introduction to InVivo Therapeutics, InVivo's business model, critical strategic analysis, functional strategies, financial analysis, and an integrative strategic framework.

We have created a vision, mission, and strategic model that will lead to InVivo Therapeutics becoming a global leader in the treatment of neurological disease.

Thesis Supervisor: Arnoldo Hax
Title: Alfred P. Sloan Professor of Management

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Many people provided me with help and support in the completion of this thesis. Deserving of special mention is my advisor, Arnoldo Hax. Professor Hax carefully read numerous drafts of my paper, annotating them with many excellent suggestions. His advice and encouragement throughout my entire graduate education is gratefully acknowledged. I have also learned that Arnoldo is retiring from full-time teaching after a 40 year career at Harvard and MIT, and I view it as an honor to receive his guidance and support for my thesis.

Throughout my time at MIT, many MIT Sloan Fellows colleagues were an invaluable source of information and ideas. I can not list all with whom I had fruitful discussions, but I would like to mention Edward Acworth, James Skeffington, Konstantin Rozanov, Ramana Nanda, P. Bradley Rosen, James Walker, James Michael Cerda, David Lucchino, Gladys Priso, Pradeep Gupta, Steve Derezinski, who all gave generously of their time.

I would like to mention the three co-inventors of the spinal cord repair device. Two are from the MIT School of Engineering, Robert S. Langer Sc.D. of Langer Labs, as well as Langer Lab Biomedical Engineer Rajiv Saigal. The third is Yang (Ted) Teng, MD, Ph.D. a Neurosurgeon from Harvard Medical School. Their caring and commitment to the spinal cord injury patient and their contributions to my thesis can not be measured in words.

Finally, I have met and interviewed over 30 medical device industry experts and spinal cord injury patients. I received excellent support and assistance from Paul Mraz, Michael Panos, Stan Lapidus, Gloria Keehn, and Andrew Roberts.

Dedication

This is for my loving wife Robin who has been at my side for over 13 years. Robin tied my shoes, prayed at my side, and provided me with hope everyday of the 5 years it took me to recover from my paralyzing injury. Robin along with my daughter Margaret Anne both sacrificed during my time at MIT so that I could obtain the best possible education. They created an atmosphere of love in which hard work became easy.

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Introduction

Spinal cord injuries (SCI) occur unexpectedly. The normal events of life such as driving a car, diving in a lake, or walking down stairs, can suddenly result in a life-changing injury with physical and lifestyle constraints that totally reconfigure the realities of daily life. In 2005, 11,000 people suffered a spinal cord injury and 247,000 are currently living with a spinal cord injury. Globally there are 2,800,000 people living with spinal cord injuries and another 167,000 will suffer a SCI this year.[1]

For Decades, there has been significant progress in improving patient survival, emergency care, rehabilitative options, and adaptive tools for living that have improved the quality of life for the SCI survivor. During the same time the breadth and depth of neuroscience discoveries relevant to the spinal cord injury have widely expanded the horizons of potential therapies. What once was dogma, that the central nervous system could not regenerate- has been dismissed.[2]

Although regeneration of the spinal cord has had increasing possibilities, there have not been any successful treatment options commercialized to achieve this complex challenge. Primary efforts have been focused on pharmaceutical interventions. Eighty percent of the damage caused by spinal cord injuries is the direct result of a secondary injury that occurs as the result of the primary SCI. Like a stone dropped in a pond, the secondary injury is caused by waves of chemical reactions released from the epicenter of the primary injury. These releases flow through the spinal cord tissue causing increasing amounts of necrotic or dead spinal cord tissue. This process of chemical release can occur for several months causing a continuum of necrotic tissue. The challenge for a pharmaceutical intervention is that the chemistry of each wave of chemical release is different, so a drug would have to be able to respond to each individual wave. That requires a very powerful drug that would have major side effects and the only drug to attempt this challenge has proven to be toxic to humans. Such was the case with methylprednisolone, which was approved in 1998, and marketed for inflammation but used by physicians in an off-label treatment for in spinal cord injury

patients. Side effects of methylprednisolone when used to treat SCI include psychosis, and kidney failure, glaucoma, cataracts, and severe mood disorders. Therefore methylprednisolone is not longer being used to treat SCI.

The challenges associated with pharmaceutical interventions, led Dr. Yang (Ted) Teng of Harvard Medical School, in the late 1990's to engage Dr. Robert S. Langer of MIT's Langer Lab in discussions involving bio-materials to treat SCI. The concept of implanting a foreign material into the spinal cord had never been considered in any publication, but Dr. Langer was a pioneer in the field of tissue engineering using bio-materials, and together they hypothesized that a sophisticated polymer could potentially implant in a spinal cord and treat a SCI. Between 2000 and 2006, Dr. Langer and Dr. Teng have advanced their theories through their labs and have proven in studies involving 40 animals that they can indeed implant a bio-compatible polymer into the spinal cord to restore normal functioning. Their proof of concept has resulted in a new field of neuroscience referred to as Neuro-Tissue Engineering.

A treatment for spinal cord injuries has never been commercialized. Therefore my thesis will for the first time, provide a business model and strategy to bring the first neuro-tissue engineering technology to market. In Chapter One I will provide a brief overview of the evolution of spinal cord injury treatments. In Chapter Two, I will identify InVivo's business model with market analysis, InVivo's value statement, and the competitive landscape. In Chapter Three, I will conduct a critical strategic analysis of InVivo's customer segmentation, bundle of competencies, present and future mission, and strategic thrusts. Chapter Four will focus on functional strategies for innovation, customer targeting, sales, and operational effectiveness. Chapter Five will provide a forecast of the financial future of InVivo Therapeutics Corporation, where we identify granular metrics for success, forecasted income statement, balance sheet, and cash flow statements. This thesis will conclude with a discussion of InVivo's integrative strategic framework.

Chapter One: Advancements in Spinal Cord Injury Treatment

1.1 Brief evolution of spinal cord injury treatments

The 1940's was a period of rapid change throughout the world. World War II had changed the face of many nations. Millions of people died and millions of people were left with severe disabling injuries. Due to the significant amount of head injuries and spinal cord injuries (SCIs) in WWII, the study of neuroscience experienced its greatest growth, and some would say its birth, during and after WWII. Today, we can look back after decades of great discoveries in neuroscience and observe areas of neuroscience like neurophysiology, where major discoveries have led to significant benefits to mankind.

Current challenges for spinal cord injury repair have been based on the path or direction that the science has taken. Traumatic spinal cord injury repair is an area of neuroscience that has continued to pose significant challenges for researchers, and physicians that focus their work on developing treatment options. Decades of funding have led to discoveries of the process that results in permanent damage to the spinal cord, but treatment options for the spinal cord injury patients have been limited. Currently, the only spinal cord injury option available to physicians is to stabilize the spine with either a spine fixation device or a spinal fusion. After fixation physicians and patients hope that the spinal cord heals itself, but that just does not happen in spinal cord injury patients.

In the late 1990's world renowned MIT Professor Robert S. Langer Sc.D. of MIT, and Neurosurgeon Dr. Yang (Ted) Teng, M.D.,Ph.D. of Harvard Medical School began to develop the first treatment options to restore normal functioning to spinal cord injury patients. Early animal research that restored normal functioning published in 2002 showed great promise, but the injuries were not similar to those injuries typically occurring for humans. In 2003, Rajiv Saigal joined Langer Labs, as a Ph.D. candidate

in Bio-medical engineering. He joined their team focusing on developing solutions for spinal cord injury damage. In late 2005, they were able to restore normal functioning to rodents injured in a similar way that humans sustain spinal cord injuries.

1.2 Personal Experience as a spinal cord injury patient

I was paralyzed for eight days in 1992, and I spent 90 % of my time over the next five years in a body brace and in bed. After two years of struggle and no hope offered from the medical community, in 1994 I began researching the spine and spinal cord disease on the internet. After two years of research, I developed my own recovery plan based on the science of Physical Medicine and Rehabilitation. My wife left her job and came home to take me to the local YMCA, where I worked everyday in a pool and on a treadmill. My wife Robin tied my shoes and drove me to medical appointments all over the east coast for five years. She prayed by my bedside every night and offered me support in tough times. During 1992-1997, I prayed that someone was "out there" working on treatments for spinal cord injuries. In an unexpected series of events, I am now that person "out there" working to bring SCI treatment options to patients.

As with most SCI patients my family, personal, social, and employment aspirations were forever changed. Access to medical information on the internet was the key factor in my recovery and I conducted on-line research everyday. I began to locate other people with similar spinal cord injuries and formed a national support group which grew to over 300 members. I worked with the Christopher Reeves Foundation to provide contacts for patients and family members to talk to about their challenges. After I regained my health, my experience while in bed utilizing computers and the internet, led me into a career in information technologies. Since I am not a physician or a bio-medical engineer I never planned or dreamed that I would join a team of globally renowned scientists from MIT and Harvard to work toward commercializing treatment options for spinal cord injuries. Over 99.9% of spinal cord injury patients do not recover from their injury, so I am part of the less than .01% that experience post injury recovery, and for

that reason I have a focused mission to provide SCI patients with new treatment options.

1.3 InVivo Therapeutics founded to commercialize the discovery

In 2005, I came to MIT as a student to advance my career in information technologies by completing an MBA in the MIT-Sloan Fellows Program for Global Leadership and Innovation. I met Dr. Langer, Mr. Saigal, and Dr. Teng in June 2005. I was asked to join their team as a "listening business person". Initial conversations indicated a treatment option may be ten years away. I began meeting with Mr. Saigal periodically to learn more about their work. Their lab work in the fall of 2005 provided outstanding results, and momentum grew rapidly toward commercializing their science and technology.

I founded InVivo Therapeutics Corporation, (www.invivotherapeutics.com) in November 2005 to commercialize the team's discoveries. We are dedicated to saving lives, and providing individuals paralyzed from traumatic spinal cord injuries (SCI) with their first treatment option to restore normal functioning. We have developed a breakthrough approach to treating spinal cord injuries, based on the patents we are licensing from Harvard and MIT that were co-invented by Robert S. Langer ScD., Yang "Ted" Teng., and Rajiv Saigal.

Chapter Two: InVivo's Business Model

2.0 Business Model

The core of our strategy is to create a new clinical franchise in the spinal medical device marketplace by creating "System Lock-in"[3] which will provide a dominant position in the marketplace and allow us to achieve maximized gross margins for our products and services. We will seek System Lock-in for all of our customer segments including surgeons, hospitals, complementors[4], public and private insurance providers, Department of Defense, and Patients. Since our pricing model will be a value based model, we will seek what the market will bear, but for purposes of business planning we are using pricing based on comparables to current industry solutions, and we have set a US price at $30,000, and a Global price at $22,800 per device.

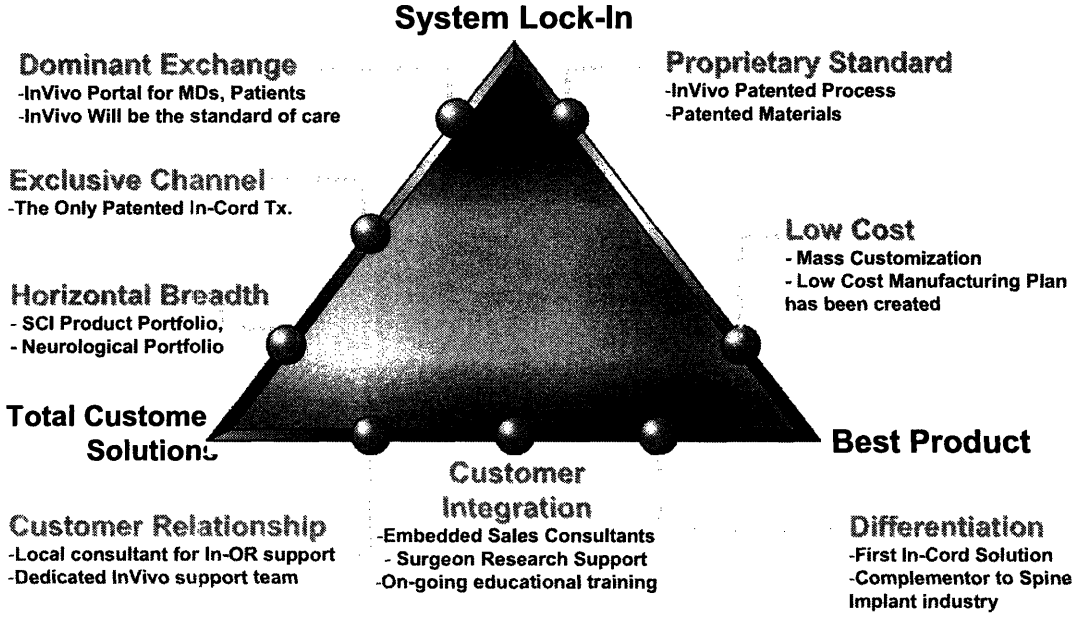


Figure 1: InVivo's Process for System Lock-in

Our model will enable InVivo to expand our strategic options and obtain System Lock-in by strategically migrating around the triangle, clockwise starting with "Proprietary Standards"[5] and ultimately achieving a "Dominant exchange"[6] for spinal cord injury repair.

In summary, to gain system lock-in InVivo will:

- Utilize our proprietary standard for products, materials, and manufacturing to establish ourselves in the market. We will prevent others from copying our technology by using our patent protections, and growing our IP portfolio.
- We have created a very low costs manufacturing model that is detailed in section 4.3 of this thesis; and it will enable us to defeat a low cost competitive threat, as well as maximize profits.
- Provide the "Best Product"[7] on the market for spinal cord injury treatment with sustained investment in R&D.
- Differentiate ourselves in the market by delivering the only neural-tissue engineered treatment option, and going to market as the only Complementor to the top nine spine device companies.
- Utilize a direct sales force to obtain customer integration and customer bonding.
- Redefine the customer relationship by either providing new revenue streams through product portfolio expansion, cutting costs to care for spinal cord injury patients, or providing them with their first option for normal functioning and provide a total customer solution.
- Provide a systemic approach to the patient, offering a portfolio or "horizontal breadth" of treatment options for a wide range of conditions that result from spinal cord injuries.
- Become the dominant exchange for spinal cord injury repair and leverage system lock-in to maintain and grow our market position.

In addition, we will remain aggressive with our research and development efforts to stay ahead of the curve, establishing ourselves as the industries leading spinal cord injury treatment provider. We will be working for FDA approval on our stem cell-based technology

for SCI repair. We expect to have that device on the market in 2013. The stem cell technology will provide us with horizontal breadth[8], and an expanded portfolio of propriety standards to reinforce our system lock-in process. Our first product will achieve system lock-in which will create market branding power and forge the way so that new market entrants with a stem cell technology will have challenges to winning our customer base.

2.1 Market Analysis

In order to be successful in the market we will need to complete a through assessment of the marketplace. Our market analysis will look at the market strategy, the market size, InVivo's value to the market, the competitive landscape and our competitive strategy. Since our product is unique and will be the first to market we will have many options for our go to market strategy, however the foundation for our strategy will be customer bonding

2.1 Market Strategy

As the first product on the market to restore normal functioning to the spinal cord injury patient, our market strategy will target all people involved with treating and supporting the SCI patient. For our analysis we have divided our patient market into two target populations for spinal cord injury treatment. One target is the acute or immediate traumatic spinal cord injury patient who has been injured in the past year, (that population is represented by the incidence rate). The second target market is the chronic spinal cord injury patient who has been disabled for longer than one year (represented by the prevalence statistics).

Our strategy is focused on addressing the consequences of spinal cord injuries and on a natural progression of strategies:

- preventing further tissue loss;
- maintaining the health of living cells;
- replacing cells that have died through apoptosis or necrosis;

- growing axons and ensuring functional connections;
- and strengthening and reestablishing synapses that restore the neural circuits required for functional recovery.

These strategies have led us to a range of therapeutic solutions and priorities for our spinal cord injury technologies, each of which could theoretically be pursued individually or in combination. InVivo Therapeutics will focus on these paths of discovery to expedite a portfolio of products and services to the marketplace.
In Vivo Therapeutics' platform technologies provide a novel approach to the treatment of spinal cord injuries. Of all organizations whose primary focus is spinal cord injury repair, InVivo has an unmatched breadth of development portfolio which will continue to expand over the next few years.

2.1.1 Customer Needs

Our customers require a systemic approach to treating their injuries. They need to gain increased levels of normal functioning from their current state. They require neural repair, increased neural-muscular functioning, improved respiratory functioning, increased muscle mass, and increased bone strength. They require incremental advances in discovery for improving their quality of living. SCI patients need solutions that focus not only on preventing the loss of function, but also on restoring lost functions.

2.1.2 Market Size

The market for spinal cord injury repair is substantial. Based on 2005 incidence, prevalence, and projected growth rates, conservative estimates place the global total addressable market for spinal cord injury repair to have an annual total market size of approximately $20 billion. Depending on the reimbursement rate that we achieve, a value based pricing model could mean a total market opportunity as high as $60 Billion annually.

Since 1973, the National Spinal Cord Injury Statistical Center at the University of Alabama has been the only US government source for spinal cord injury statistics[9]. Their reports indicate that the incidence rate for SCIs in the US for 2005 was 11,000 people, and US

prevalence (chronic condition) to be 250,000 people. We will provide our products to the global market, and the global annual incidence rate for SCI is 130,000 people and the global prevalence for a paralyzing SCI exceeds 2,500,000 people. Due to a growing global and US population, increased societal risks such as higher speed limits for automobiles, increases in the number of people participating in extreme sports, and increases in the number of guns, all lead to a projected annual incidence growth rate of 13%. We believe that predicted growth rate of 13% may not be sustainable because society will create mitigating factors to reduce paralyzing injuries. For example, governments may increase safety regulations such as side curtain airbags in all vehicles. They may regulate the fastest growing causes of SCI like collegiate cheerleading, gymnastics, and figure skating. Therefore, starting in 2010 we have modified the incidence growth rate to 8%.

Table 1: Forecasted SCI Incidence & Prevalence- USA and Rest of World (ROW) 2005-2010

Incidence	**2006**	**2007**	**2008**	**2009**	**2010**
USA	12,430	14,046	15,872	17,935	19,370
ROW	146,900	165,997	187,577	211,962	228,918
Growth Rate	13%				
Prevelance	**2006**	**2007**	**2008**	**2009**	**2010**
USA	262,430	276,476	292,348	310,283	329,653
ROW	2,500,000	2,665,997	2,853,574	3,065,535	3,294,454

Source: National Spinal Cord Injury Statistical Center

Table 2: Forecasted SCI Incidence & Prevalence- USA and Rest of World (ROW) 2011-2015

Incidence	**2011**	**2012**	**2013**	**2014**	**2015**
USA	20,920	22,593	24,401	26,353	28,461
ROW	247,232	267,011	288,371	311,441	336,356
Growth Rate					
Prevelance	**2011**	**2012**	**2013**	**2014**	**2015**
USA	350,573	373,166	397,566	423,919	452,380
ROW	3,541,686	3,808,696	4,097,068	4,408,509	4,744,865

Source: National Spinal Cord Injury Statistical Center

2.2 InVivo market value statement

Our work is not only important from a humanitarian perspective, but we also provide a large financial benefit to all parties absorbing the cost of care. Below are the life-time costs to provide care for a SCI patient. The Net Present Values (NPV) are discounted at a rate of 2%, to adjust for inflation. The NPV to care for a Quadriplegic C1-C4 is $2,800,000 and the NPV to care for a Paraplegic-incomplete is $624,441. Since our pricing model is set at $30,000 per surgery we offer tremendous value to the market. To quote one of our board members, "From a humanitarian and financial perspective the opportunity is huge!"

Table 3: Cost of care for a SCI

Current Cost of Care for a SCI Patient			NPV of Care	NPV of Care
Severity of SCI	First Year	Year 2 thru n	Life-Time Cost injury at 25 y/o	Life-Time Cost injury at 50 y/o
Quad C1-C4	$ 710,275	$ 127,227	$ 2,801,642	$ 1,649,342
Quad C5-C8	$ 458,666	$ 52,114	$ 1,584,132	$ 1,003,192
Paraplegia	$ 259,531	$ 26,410	$ 936,088	$ 638,472
Incomplete Paraplegia	$ 209,324	$ 14,670	$ 624,441	$ 452,545

Source: National Spinal Cord Injury Statistical Center

2.3 Competitive Analysis

Today's competition is a collection of alternative treatments that address symptoms but not the causes. Each of our customer segments have an established response to either treating, reimbursing, supporting, or funding a spinal cord injury. Today their minds are set so InVivo will focus on changing their current way of thinking. We will capture a larger share of their mindset, or a higher level of mindshare. When a traumatic spine injury patient enters an emergency room, the physician will choose their preferred treatment option, so although there isn't any competition for repairing the spinal cord we do have to win mindshare among physicians. The physician may choose to repair only the musco-skeletal system by using spinal fixation devices such as screws, rods, cages, or artificial discs. Their theory is that by creating a "fixed" structure in the spine, an unimpinged spinal cord will heal

itself. In fact, less than 1% of spinal cord injury patients experience a return to normal functioning. We believe that we can restore 80% of the patients normal functioning. Therefore, we believe physicians will adopt our solution as the new "standard of care" for spinal cord injury patients.

There are 8 main players in this market Medtronic, Johnson &Johnson, Synthes, Kyphon, Biomet, Stryker, Zimmer, Abbott Spine, Nuvasive. Together they account for 88.9% of the market share. Below are statistics for the types of operative procedures utilized to repair spinal cord injury. 54.5% had spinal fusion and 48.3% had fixation devices but neither group regained normal functioning and returned to a normal lifestyle.

Table 4: Operative Procedure for SCI Repair

Operative Procedure	N	%
Spinal fusion	3,802	54.5
Internal fixation	3,370	48.3
Spinal decompression	2,098	30.1
Halo	2,042	29.3
Traction	1,803	25.9
Laminectomy	1,122	16.1
Laparotomy	705	10.1
Closure of pressure ulcer	115	1.6
Surgical repair of internal fixation	94	1.3
Surgical repair of failed spinal fusion	63	0.9

Source: National Spinal Cord Injury Statistical Center

2.3.1 Emerging Competition: Stem Cells

We expect that by 2015 competition will emerge utilizing stem cell technologies. One of our Founders, Dr. Yang Ted Teng has been at the forefront of stem cell research and has published along with Evan Snyder, MD, who is regarded and the father of stem cell research. We have had excellent results in our labs utilizing stem cells and our polymer device, but the

complexity of the science and regulatory environment have led us to commercialize the polymer based device without stem cells, as our first product.

The second product in our development portfolio will provide us with a stem cell product to complete against any new entrant. Regulatory experts do not believe that a stem cell based technology can be approved by the FDA and on the market before 2015, so we will have three to four years of a dominant market position in the SCI market with our first product.

2.3.1 Competitive Strategy

Capturing mindshare early in our product development and gaining customer bonding will be critical to our success.

Key components of our competitive strategy are:

- We will utilize our complete bundle of competencies to make sure that we understand our customer deeply.
- We will not focus on beating our competition, instead we will be focused on achieving customer bonding and establishing competitive relationships as complementors to our products.
- Although we will have a first of its kind product, we will resist a product centric mentality and we will include customers, suppliers, and complementors as key constituents in our success.
- We believe that the relevant entity is the extended enterprise.
- We will never treat our customer equally because all customers are not created equal. Through data analysis we will be able to determine which customers are the most profitable and we will provide them with better service in order to increase our opportunity to maximize profit.

Our incidence and prevalence target markets do not benefit from current surgical options. Therefore, if we can establish customer bonding, we believe that physicians will adopt our solution as the new "standard of care" for spinal cord injury patients.

Additional Lock-in will come from:

- **New Standard of Care**- we will be the dominant technology on the market for restoring neurological function after a traumatic spinal cord injury.
- Patent protected MIT and Harvard technology, including the opportunity for manufacturing patents.
- Standard or well practiced surgical procedure –Doesn't require significant training.
- No secondary surgery for device removal – material is absorbed by bloodstream and disposed of by body.
- Low cost of manufacture – providing strong operating margin and net profit margin for the company.
- Once we have established ourselves in the market "customer bonding" will be a key competitive advantage for InVivo.
- Pipeline of improved products to fend of emerging competitors.
- Gold standard credentials in the research and medical communities – doctors likely to adopt our solution.
- Complementary to existing treatments – enlarges market rather than forces us to take market share from incumbents.
- Fast Track FDA approval candidate.
- First to market for needy target market.

2.3.2 Competitive Risk

Today, InVivo's management believes that our technology is the most versatile offering for a variety of applications. With many companies and academic laboratories focused on developing technologies, it is possible that a superior technology exists or can be developed in the short-term. The management team is continually evaluating other techniques and is committed to keeping our technology on the cutting-edge.

2.3.3 Global Market participants

The market for spinal implant devices has a relatively small number of competitors. Nine manufacturers have a market share that exceeds 1%. We view them not only as competitors but also complementors.

Table 5: Global Sales of Spinal Implant Industry

Spine Implant Provider	Market Share in Spinal Devices
Medtronic	40.7%
Johnson & Johnson (Depuy Spine)	16.1%
Synthes Spine	10.4%
Kyphon	6.3%
Biomet	4.7%
Stryker	4.2%
Zimmer	3.0
Abbott Spine	2.1%
Nuvasive	1.4%

Source: Millennium Group 2006 Spine Implant Industry Report

We have had initial discussions with Medtronics and Stryker and they both view us as complimentary to their spinal fixation devices. Based on conversations with industry experts we can conclude that spinal fixation device companies will view us as complimentary. We expect leading spinal fixation companies like Medtronics, Synthes, Johnson & Johnson, Stryker, and Abbott to desire complimentary partnerships with InVivo. The industry for spinal fixation devices is approximately $6 Billion annually, and has a projected annual growth rate of about 18%[10].

2.4 Conclusion

We conclude that we will be able to achieve superior financial results, through the creation of System Lock-in, through customer bonding. Our business model is focused on System Lock-in, and a customer bonding continuum that is mapped to the strategic positions on the triangle and will result in competitor lock-out. Through market analysis we know our target customer and we will provide them with a strong value proposition. Our competitive analysis has concluded that we a great opportunity to establish as

complementors, the spine industries nine market leaders thereby reducing competitive threats and maximizing revenue generating opportunities.,

Chapter Three: Critical Strategic Analysis

We started with a vision statement that identified how InVivo positioned ourselves, and we completed our analysis of InVivo's value proposition to customer segments, bundle of competencies, mission of our business, the strategic agenda, financial evaluation and our management team.

Figure 10 identifies the building blocks that we used to develop our organizational strategy. Each component has a logical fit into each other as the strategy builds to form a firm foundation for InVivo's Growth.

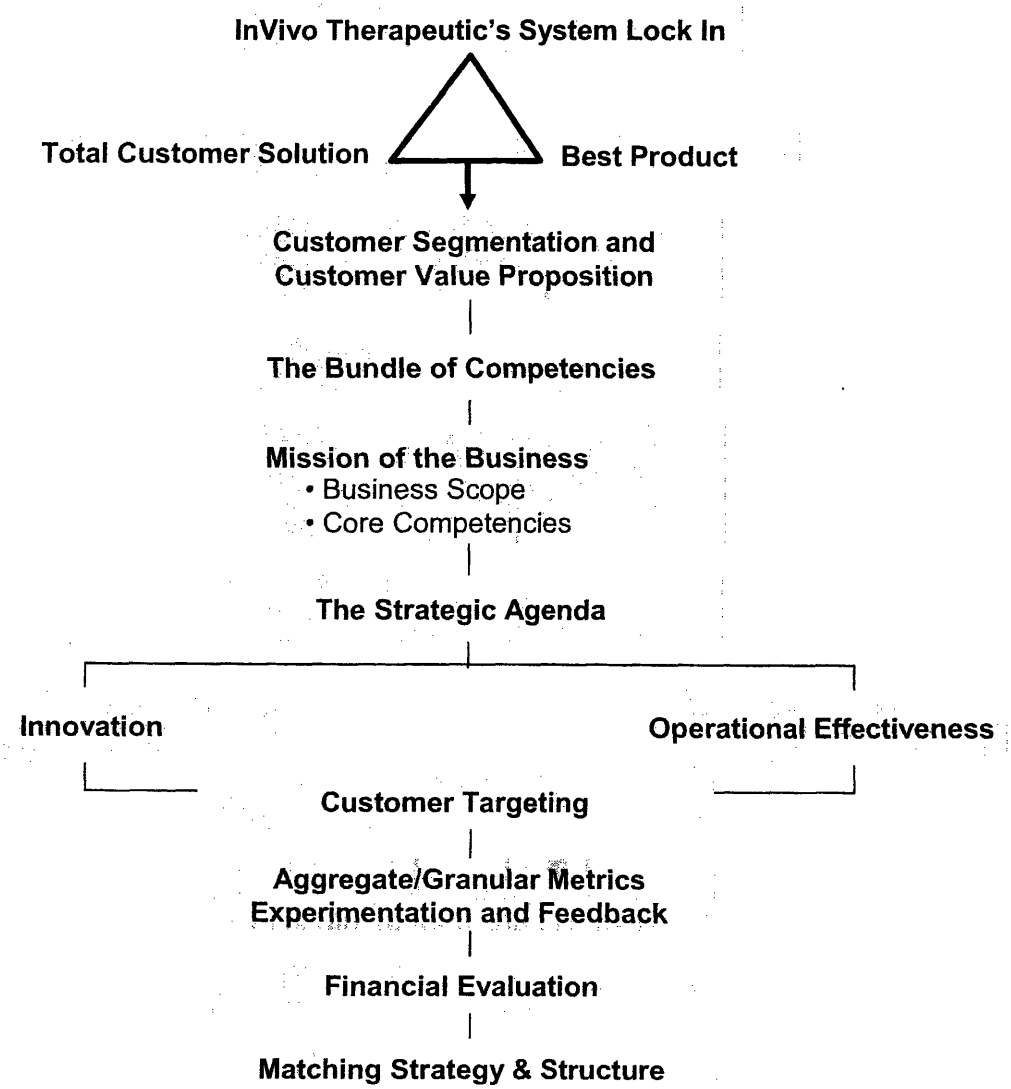


Figure 2: InVivo's Integrative Strategic Framework

Our process to creating this integrated strategic framework has been a detailed and thorough approach. We have explored our options with the necessary industry breadth and depth of knowledge to ensure we will not only effectively get our first product to market, but that we also provide our shareholders with a maximized return on investment.

At the heart of our strategy is our strategic intent. We have defined our strategic intent through a top-down approach from the CEO to the production floor. It is rare to have a CEO with personal experience with the impact that a SCI has from a humanitarian and financial viewpoint. Our strategic intent comes loud and clear from our CEO every day. We will commercialize the first treatment for spinal cord injury repair. Our triangle is an effective tool for describing a meaningful strategic position. We are certain that we can obtain system lock-in and therefore have four of our seven segments positioned between the total customer solution, and system lock-in. We have stated our mission and it is based on our core competencies that incorporate a clear understanding of our business scope. We formed a concise strategic agenda based on all of the information that we have collected.

3.0 Critical Strategic Analysis

InVivo's critical Strategic analysis will include a detailed review of our strategy for customer segmentation, System Lock-in, options for strategic positioning, mission statement, and strategic thrusts. Our customer segmentation will establish a clear set of priorities to identify the importance of each customer. We will create mutual benefits to support system lock-in for each of our customer segments. We have many options for strategic position including proprietary standards, differentiation, redefining the customer experience, horizontal breadth of products, customer integration, exclusive channel, and a dominant exchange for the spinal cord repair market.

3.1 Customer Segmentation

On of our key business dimension will be our direct sales force. We will utilize a direct sales force for consultative selling to establish "customer bonding" in all seven customer segments. Our customer segmentation establishes a clear set of priorities to identify the importance of each customer. We will demonstrate that we have an intimate understanding of our customer's business and how we relate to their objectives. We expect to have a reciprocal learning process with our customer in order to develop mutual trust and respect, based upon concrete mutual benefits to support system lock-in for each of our customer segments.

We will segment our market by:

Thought Leaders	Surgeons	Hospitals	Complementors
Insurance Providers Public and Private	Department of Defense	Patients	

InVivo's Seven Customer Segments

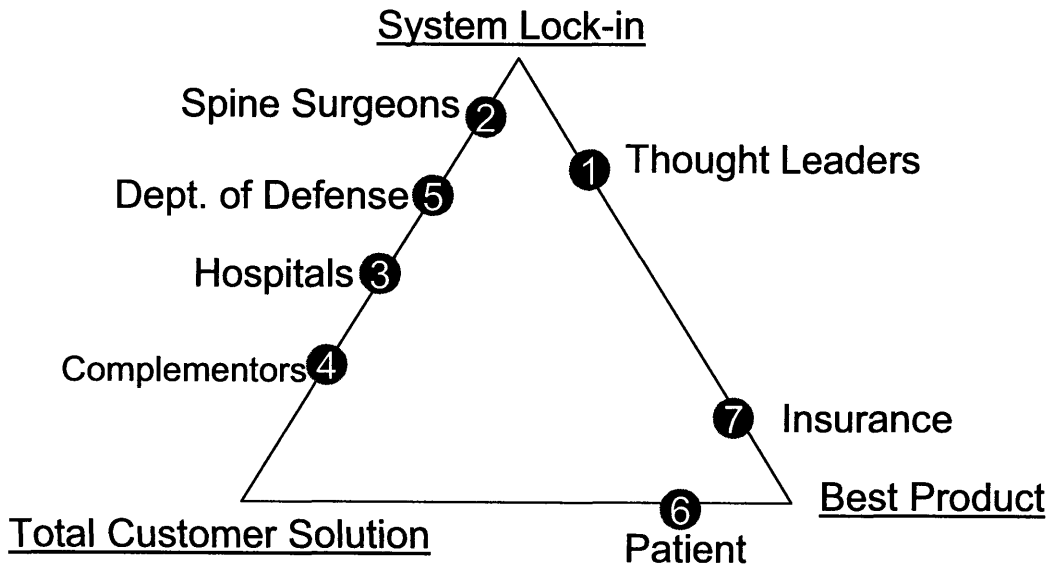


Figure 3: Customer tier plot on the triangle

We have plotted all seven segments in a manner that makes common sense to us. We believe that thought leaders will be focused on novel and proprietary technologies. Almost by definition they are expected to be open minded to new information so we do not see them on the left side of the triangle. We believe that the insurance segment will only be concerned about cost so they sit on the right side of the triangle. Naturally, patients care about the best product, but they will want a differentiated product, and for the SCI patient, that means a product that restores normal functioning. Four of our segments, the complementors, hospitals, department of defense and the spine surgeons will be on the left side of the triangle with very strong system lock-in. We will achieve customer bonding with continually lock them into the InVivo system, and maintain competitive lock-out.

The tables below will provide a detail description of each customer segment. We identify seven business dimensions to align InVivo with the segments. The seven dimensions are products, services, customers in segment, channels, end users, complementors to the segment, and unique opportunities for us to align with the segment. We then identify the value we will offer our customers. The sources of that value are the set of experiences that we provide our customers, the set of "value delivery systems"[11] needed to provide the experiences, and the value appropriation for both the customer and for InVivo Therapeutics

Table 6: Customer Segments

Customer Tier	Description of Segment
(1) Spine Treatment Industry Thought Leaders	• High profile in Spine community for their educational seminars and society meetings • Well published in Peer Review Journals • Usually based in Academic Institutions • Knowledgeable about competitive market • Participates in Spine Industry trade orgs
(2) Spine Surgeons	• Can be high, medium, and low volume. • Completion of a Spine training • High volume surgeon conducts 200+ surgeries/ yr • Based in academic environments • Usually has private practice • Very well compensated

(3) **Hospitals**	• Typically has purchasing power • High volume trauma center • Gate keeper for trauma suppliers • Utilizes buyer groups for steep discounting • Maximizes use of automated IT systems
(4) **Complementors**	• Current spine implant device supliers • Providers of primary care to SCI Patents • Focused on maximizing revenue per surgery • Global distribution network is established • Market growth is 16%
(5) **Insurance Providers**	• Faces very high, life long financial commitment to the SCI patient • Medicare and Medicaid • Workers Compensation Carriers • Healthcare Mgmt Organizations HMO's • Preferred Provider Organizations • Infinity Health Insurance
(6) **Department of Defense (US Army, USMC)**	• Current war zones has increased need for SCI Treatment options. • Focused on reducing death from penetrating SCI • Focused on reducing neurological damage for soldiers • Over 3700 medical hospitals worldwide • MASH units 30 minutes travel from battlefield
(7) **Patient**	• Persistent information seekers to restore normal functioning • Strong desire for pre-injury life style • Dependant on social systems for support • Aggressive to try new options • High stress for family and friends

Table 7: InVivo's Strategic Customer Segmentation Model

Tier 1: Spine Industry Thought Leaders

Business Dimension	Tier 1: Industry Thought Leaders
Products	• Entire Product Portfolio • Custom Devices • Non-Disclosure Agreements for New Technology Developments
Services	• Educational Courses at Spine conferences • Fellowship and Research Support • Clinical Documentation • Outcome Studies • Specialty Study Groups
Customers	• ~300 worldwide
Channels	• Direct Sales Force and Sales Management • Distributors of Spinal Disorder treatment modalities • Product Development Involvement • Professional Services • Local Sales Consultant
End Users	• Neurosurgeons and Orthopedic Surgeons
Complementors	• Both Orthopedic and Neurological Spine Societies, Spine Trauma Solution providers, Biomaterials organizations,
Unique Opportunities	• Patented Materials, next generation approach to spinal cord injuries, Executive team is globally recognized as important Biomedical Innovators

Tier 1: Thought Leaders Value Proposition

Sources	Value Proposition
Set of experiences we will provide the tier	• An association with The worlds leading Bio-medical Researchers from MIT and Harvard Medical School • They will Product Development • be part of an innovative movement in spinal cord injury Treatment. • Influence on Involvement with our new technologies • A reliable partner to support their spine programs
Set of Value Delivery systems needed to provide the experience	• InVivo Neurological Portal • Fellowship Association and Financial Support • Outcomes/Database Service and Financial Support • Product Think Tanks / Development Groups • Educational courses and symposiums • Remuneration for Services Rendered / IP • Research Funds via our grant writing service
Value appropriation	Value gained by the Thought leader • Identify with an innovative biomedical community • Ego reward as part of development, education • Sustained knowledge gain to maintain prestige as thought leader

	Value gained by us • Influential surgeons associate new technology development • Emerging spine surgeons look favorably upon InVivo technologies

Tier 2: Spine Surgeons

Business Dimension	Tier 2: Expert Spine Surgeons
Products	• Entire Product Portfolio • Custom Devices • New Technology Developments
Services	• Dedicated and Integrated Sales Consultant • 24-hour support systems via portal and call center • In-OR Materials support system • Educational, Research, and Fellowship Support • Clinical Documentation • Specialty Study Groups and Outcome Studies • InVivo Neurological Portal
Customers	• ~1750 in the USA, Texas Spine Institute, Rothman Institute, Harvard Medical, Univ. Penn, USF, Stanford Hospital, etc
Channels	• Direct Sales Force and Sales Management • Distributors of Spinal Disorder treatment modalities • Product Development Involvement • Professional Services • Local Sales Consultant
End Users	• Orthopedic Surgeon, Neurosurgeons, rehabilitation physicians
Complementors	• Both Orthopedic and Neurological Spine Societies, Spine Trauma Solution providers, Biomaterials organizations
Unique Opportunities	• Patented Materials, Patented and next generation treatment for spinal cord injuries, Executive team is globally recognized as important Bio-Medical Innovators, Unique Scientific Advisory Board

Tier 2: Spine Surgeon Value Proposition

Sources	Value Proposition
Set of <u>experiences</u> we will provide the tier	• An association with The worlds leading Bio-medical Researchers from MIT and Harvard Medical School • They will be part of an innovative movement in spinal cord injury Treatment. • Influence on Product Development • Involvement with our new technologies • A reliable partner to support their spine programs
	• InVivo Neurological Portal • Fellowship Association and Financial Support

Set of Value Delivery systems needed to provide the experience	• Outcomes/Database Service and Financial Support • Product Think Tanks / Development Groups • Educational courses and symposiums • Remuneration for Services Rendered / IP • Research Funds
Value appropriation	Value gained by the customer • Identify with larger community • Ego reward as part of development , education • Support for larger program Value gained by us • Influential surgeons associate new technology development • Emerging spine surgeons look favorably upon InVivo technologies

Tier 3: Hospitals

Business Dimension	**Tier 3: Insurance Providers**
Products	• Catalog of Products • Integration into their IT Systems • Support for Inventory and Billing Mgmt • Access to our New Technology Developments
Services	• Educational Courses for all staff • InVivo Neurological Portal • Participation as a clinical test center • Research and Fellowship Funding • Clinical Documentation • Outcome Studies • Specialty Study Groups
Customers	• All trauma Centers in the US i.e. Humana, Kaiser, etc. (~300)
Channels	• Direct Sales Force and Sales Management • Distributors of Spinal Disorder treatment modalities
End Users	• Consumers with Spinal Cord Injuries
Complementors	• Orthopedic and Neurological Spine Societies, Rehabilitation Facilities,
Unique Opportunities	• Only solution for SCI and respiratory repair. Scientist are globally recognized as important Bio-Medical Innovators

Tier 3: Hospitals

Sources	**Value Proposition**
Set of experiences we will provide the tier	• Partner to establish them as regional leader in medicine • Positioned as a partner to frustrated consumers • Integration into their IT systems • New Product offering to grow revenue • Reduce cost of for capitated care

Set of Value Delivery systems needed to provide the experience	• Direct Sales Force for case analysis • Access to Outcomes/Database for better patient decision making • Membership in the InVivo Development Groups • Educational courses and symposiums to staff • Research Funds
Value appropriation	Value gained by the customer • New revenue streams • Reduce Costs for capitated patients • Strengthen consumer confidence in their ability to help Value gained by us • Regional Partner with Dominant market position • Distribution Network • Credibility in the community

Tier 4: Complementors

Business Dimension	**Tier 4: Rehabilitation Spine Physicians**
Products	• Catalog Products to significantly drive revenue • Custom Devices • New R&D Philosophy
Services	• Dedicated and Integrated Sales Consultant • 24-hour support systems • Educational, Research, and Fellowship Support • Clinical Documentation • Outcome Studies and Specialty Study Groups • Partner Portal
Customers	• ~25 in the US, 100 Globally
Channels	• Direct Sales Force and Sales Management • Distributors of Spinal Disorder treatment modalities • Professional Services
End Users	• Orthopedic Surgeon and Neurosurgeon
Complementors	• Both Orthopedic and Neurological Spine Societies, Spine Trauma Solution providers
Unique Opportunities	• Patented Materials, next generation approach to spinal cord injuries, Executive team is globally recognized as important Bio-Medical Innovators

Tier 4: Complementors

Sources	**Value Proposition**
Set of experiences we will provide the tier	• An association with The worlds leading Bio-medical Researchers from MIT and Harvard Medical School • They will be part of an innovative movement in spinal cord injury Treatment. • Influence on Product Development • Involvement with our new technologies • A reliable partner to support their portfolio

Set of Value Delivery systems needed to provide the experience	• InVivo Neurological Portal • New Revenue opportunities • Outcomes/Database Service • Product Think Tanks / Development Groups • Educational courses and symposiums • Remuneration for Services Rendered / IP
Value appropriation	Value gained by the customer • New Revenue • Identity as complete product portfolio • Ego reward as part of development , education Value gained by us • Global Distribution Network • Expanded Channel opportunity • Instant surgeon relationships

Tier 5: Insurance Providers

Business Dimension	Tier 3: Insurance Providers
Products	• Catalog Products • Consultant support for candidate qualification • New Technology Developments
Services	• Educational Courses Fellowship and Research Support • InVivo Neurological Portal • ID new candidates in regional markets • Clinical Documentation • Outcome Studies • Specialty Study Groups
Customers	• Medicare, Aetna, Cigna, Blue Cross, etc. (~3,000)
Channels	• Direct Sales Force and Sales Management • Distributors of Spinal Disorder treatment modalities • Product Development Involvement • Professional Services • Local Sales Consultant
End Users	• Insurance consumers with Spinal Cord Injuries
Complementors	• Both Orthopedic and Neurological Spine Societies, Spine Trauma Solution providers, Biomaterials organizations,
Unique Opportunities	• First solution for respiratory repair, First spinal cord injuries treatment. Scientist are globally recognized as important Bio-Medical Innovators

Tier 5: Insurance Value Proposition

Sources	Value Proposition
Set of experiences we will provide the tier	• Proactive Search for their high costs patients • Positioned as a partner to frustrated consumers • Opportunity for clients to return to gainful employment • New technologies that can reduce their costs • Partner to reduce costs associated with SCI patents.
	• Direct Sales Force for case analysis • Access to Outcomes/Database for better decision making

Set of Value Delivery systems needed to provide the experience	• Membership in the T&S Development Groups • Educational courses and symposiums to analysis • Research Funds
Value appropriation	Value gained by the customer • Reduce Costs • Strengthen consumer confidence in their ability to help • Support for larger program Value gained by us • New revenue streams traditionally not available to the SCI marketplace. • Insurance Industry views us as a partner and they will look favorably upon our future SCI products

Tier 6: Department of Defense

Business Dimension	Tier 6: Department of Defense
Products	• Entire Product Portfolio • D.O.D. focused Product: Battlefield plug • Custom Devices for battlefield treatment • New Technology Developments
Services	• Educational Courses to D.O.D. Staff and at Spine conferences • Fellowship and Research Support to V.A. • Clinical Documentation • Joint V.A. research and Outcome Studies • Specialty Study Groups
Customers	• 23,000 DOD physicians worldwide, Pentagon
Channels	• Direct Sales Force and Sales Management focused on the D.O.D. • Distributors of Spinal Disorder treatment modalities to the Gov't • Professional Services • Regional Sales Consultant
End Users	• Neurosurgeons and Orthopedic Surgeons
Complementors	• Both Orthopedic and Neurological Spine Societies, Spine Trauma Solution providers, Biomaterials organizations,
Unique Opportunities	• Patented Materials, Novel Science, Executive team is globally recognized as important Biomedical Innovators

Tier 6: Department of Defense Value Proposition

Sources	Value Proposition
Set of experiences we will provide the tier	• First solution to save the life of a battlefield severed spinal cord • Research Unit focused on D.O.D. Neurological injuries • An association with The worlds leading Bio-medical Researchers from MIT and Harvard Medical School • They will be part of an innovative movement in spinal cord injury Treatment.

	• Influence on Product Development to improve battle injury outcomes • Involvement with our new technologies • A reliable partner to support their SCI programs
Set of Value Delivery systems needed to provide the experience	• InVivo Neurological Portal • Fellowship Association and Financial Support • Outcomes/Database Service and Financial Support • Product Think Tanks / Development Groups • Educational courses and symposiums • Remuneration for Services Rendered / IP • Research Funds
Value appropriation	Value gained by the Thought leader • Identify with an innovative biomedical community • Ego reward as part of development, education • Support for larger program Value gained by us • Key customer segment and leading source for SCI research • Influential surgeons associate new technology development • Emerging spine surgeons look favorably upon InVivo technologies

Tier 7: Patients

Business Dimension	Tier 7: Patients
Products	• Catalog Products • Access to innovation research information and Custom Devices • New Technology Developments
Services	• Educational Courses on Spinal cord Injuries faculty and to send others to attend • Guided Research Support through InVivo Neurological Portal • Outcome Studies • Specialty Study Groups
Customers	• ~11,000/year, 225,000 total US population of SCI patents, 2.5M worldwide
Channels	• Direct Marketing • Call center support • Sales Management • Professional Services • Local Sales Consultant
End Users	• Patients
Complementors	• Insurance providers, Spine Societies, Spine Trauma Solution providers, Bio-Materials organizations
	• Access to next generation approach to spinal cord injuries, Executive team is globally recognized as

Unique Opportunities	important Bio-Medical Innovators

Tier 7: Patients Value Proposition

Sources	Value Proposition
Set of experiences we will provide the tier	• Will receive hope in an often hopeless situation • Alternatives that are innovation with high success rates • An association that feels new and special • Influence on Product Development and future technologies that help people in their situation. • A reliable partner to support their spine programs
Set of Value Delivery systems needed to provide the experience	• Direct Marketing with Call center support providing Professional referral services • Local Sales Consultant contact • Access to reports from Product Think Tanks / Development Groups • Educational courses and symposiums
Value appropriation	Value gained by the customer • Hope for often hopeless situations • Establish relationship with the most innovative firm in SCI treatments. • Sense of empowerment • Support from a new resource Value gained by us • Access to the Consumer empowered marketplace • Word of mouth promotion among SCI patients • Access to clinical trial subjects

In conclusion, we believe that successful segmentation, will result from the value and dimension that our direct sales force can deliver to the customer. We will utilize a direct sales force for consultative selling to establish "customer bonding" in all seven customer segments. Our customer segmentation establishes a clear set of priorities to identify the importance of each customer. We will demonstrate that we have an intimate understanding of our customer's business and how we relate to their objectives. We expect to have a reciprocal learning process with our customers in order to develop mutual trust and respect, based upon concrete mutual benefits to support system lock-in for each of our customer segments.

3.2 Bundles of Competencies

InVivo has many competencies that individually add great value, but when we bundle them into an integrative strategic framework we will create an unshakeable bond with our customers. We focus our competencies on the customer at all times. We will provide the best product, a total customer solution, and lock them into our system. In this section we will identify our competencies and the system that will ensure our customers and InVivo benefit from varying combinations.

3.2.1 The InVivo Triangle: System Lock-in

Due to our strengths based on Best Product, Total Customer solutions, and a Dominant Exchange model, we will not only gain system Lock-in, but also Competitor Lock-Out. The great benefit of utilizing the Delta Model Triangle is that we will expand our strategic options.[12]

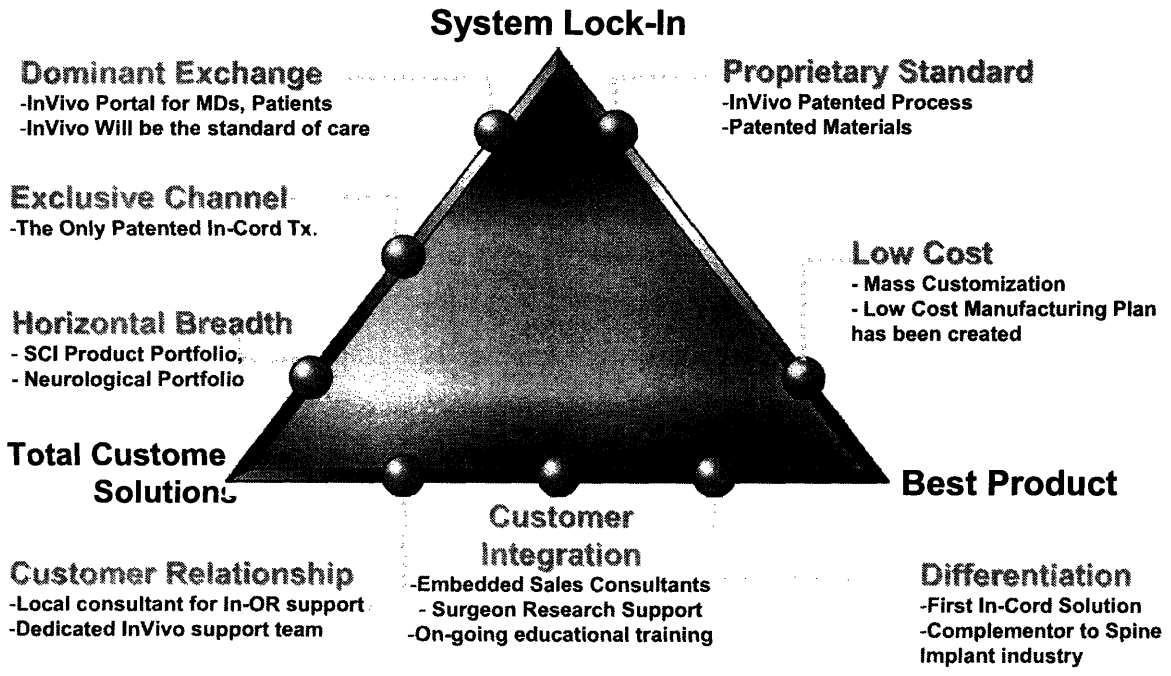


Figure 4: InVivo Therapeutics System Lock-in Model

Our model will enable InVivo obtain System Lock-in created through customer bonding. Our bonding continuum maps to the strategic positions on the triangle. By progressing around the triangle starting with proprietary standards and ultimately achieving a dominant exchange for spinal cord injury repair.

In Summary to gain system lock-in, InVivo will:

- Utilize our proprietary standard for products, materials, and manufacturing to establish ourselves in the market. We will prevent others from copying our technology by using our patent protections.
- We have created a very low costs manufacturing model that is detailed in section 4.2 of this thesis, and it will enable us to defeat a low cost competitive threats, as well as maximize profits.
- Provide the Best Product on the market for spinal cord injury treatment
- Differentiate ourselves in the market by delivering the only in-cord treatment option, and going to market as the only complementor to the top 8 spine device companies.
- Utilize a direct sales force to obtain customer integration and customer bonding.
- Redefine the customer relationship by either providing them with new revenue streams through product portfolio expansion, cutting their costs to care for spinal cord injury patients, or by providing them with their first option for normal functioning
- Provide a systemic approach to the patient and offer a portfolio of treatment options to treat a wide range of conditions that result from a spinal cord injury.
- Become the dominant exchange for spinal cord injury repair and leverage system lock-in to maintain and grow our market position

Our path toward system lock-in starts with proprietary standards. In order to maintain propriety standards we will create a large legal budget that will focus on continued patent filings around our technology. In addition, we are engaging with production engineering consultants from Stanford University to design and establish manufacturing equipment and processes that we will patent. We know that our product will require unique production equipment and our patents will prevent others from obtaining the necessary equipment to produce similar devices.

The foundation for InVivo's Bonding will develop through:

1. Best Product: Customer perception
    a. Focused on differentiation
2. Total Customer Solution: Putting the customer at the heart of InVivo
    a. Redefining Customer Experience
    b. Horizontal Breadth
    c. Customer Integration
3. System Lock-in:
    a. Restricted Access- barriers for competitors to compete
    b. Dominant Exchange
    c. Proprietary Standards

In addition we will remain aggressive with our research and development efforts to stay ahead of the curve and establish ourselves as the industries leading spinal cord injury treatment provider. We will be working for FDA approval on our stem cell based technology for SCI repair and we expect to have that device on the market in 2012. The stem cell technology will provide us with horizontal breadth, and an expanded portfolio of propriety standards to reinforce our system lock-in process. Our first product will achieve system lock-in and that will provide us market branding and forge the way so that our the new market entrants that may try to enter the market with a stem cell based technology.

3.2.2 Options for Strategic Positioning

InVivo will be taking advantage of Eight options for strategic positioning.

1. Low Cost - providing a price advantage to the customer
2. Differentiation- our products are truly distinctive and they will offer unique features that the customers value beyond cost

3. Redefining the customer experience– we will alter the relationship with customers from the point of acquisition to the complete lifecycle of ownership.
4. Horizontal breadth- we will provide a complete set of products and services around the SCI patients needs
5. Customer integration- we will work with our customers to partner in a way where we will perform activities typically conducted by the customer such as billing to insurance, inventory control, and patient follow-up
6. Exclusive channel- restricted access
7. Dominant exchange- InVivo's value will grow everyday as more people suffer a SCI and we remain the only place for SCI repair we will create an unmatched value in the market and thus dominate the market.
8. Proprietary Standards- offers the ultimate profit model, and highest profit margins

The table below provides InVivo's defined list of strategic options

Table 8: Product Centric Strategic Options

Best Product	Centered on Product Economies	
Low Cost	- Unique innovation will not face price competition, however there will be risks of substitution - Positioned to be price competitive to SCI solutions in the market.	- InVivo will command a price premium and we will focus on Differentiation
Differentiation	- First in-Spinal Cord treatment Treats the root cause of paralysis. Protected by patents. - First to market for this innovative solution to repair a SCI. - Permits "in the OR customized" product creation specific to each patient. - Created a new SCI product category.	- As Market leader with protected patents we will have a key differentiation at product launch

Table 9: Customer Focused Strategic Options

Total Customer Solution	Oriented to customer economies	
Redefining the customer experience	- One stop shop for SCI and neurological disorders - Training for organization to support our treatment modalities - Integrate the InVivo Portal as part of the own Go-To-Market Strategy - Empower the physician with the first custom in-spinal cord treatment for SCI. - Expanding the physicians own service offering to patients. - Extends Physicians Product and Service portfolio for a total solution.	- Our solution positioning is based upon an intimate knowledge of the customer base leading toward an effective customer segmentation and a differentiated treatment for our customer tiers
Horizontal Breadth	Complete portfolio of solutions based on our core technologies. Complete set of product and service offerings that treat the full range of spinal cord injuries	We are seeking a dominant position in neurological treatment modalities in order to maximize our share of healthcare dollars spent on neurological disease.

Table 10: Complementor Focused Strategic Options

System Lock-In	Focus on Complementor Economics	
Customer Integration	- Fully complimentary to current treatment modalities. - Empower the surgeon to improve patient outcomes through substitution or by leveraging their current methodology to grow revenue. - Consultants and Portal will provide a complex web of connections with the surgeon that enhances their ability to meet patient needs while growing revenue by using our product.	Our firm is a bundle of competencies that will be brought to the market in a manner that will increase per patient revenue and provide treatment options that are not possible today. We are creating a new product categories
		Our firm is a bundle of competencies that will be brought to the market in a

Restricted Access	- Patents on processes and materials provide significant barriers that make it difficult for competitors to compete for the spinal cord injury market.	manner that will increase per patient revenue and provide treatment options that are not possible today. We are creating a new product categories
Dominant Exchange	InVivo's Brand and SCI Portal will provide an interface for all participants in our segments. It will be difficult to displace once we achieve critical mass	This is the most accessible of all of the systems lock-in options. The first mover advantage is critical.
Proprietary Standard	Our tier participants will receive the first of its kind solution to SCI's. Our adoption rate will be high due to the complimentary nature of our core technologies	If it can be achieved the rewards are enormous.

It is clear that our strategic options provide us with competitor lock out and we will be able to utilize all eight options to maintain not only our market position but strong financial performance.

3.2.3 InVivo Mission Statement

InVivo's mission is clear, we intend to be the dominant exchange in the SCI repair market. However, if we are to attain and then maintain a dominant position we need to keep our internal organization focused our product Scope, services scope, customer scope, end-user scope, channel scope, complementor scope, geographic scope, unique competencies.

Our mission is evolving every day and you can see in the table 11 below that we have a thorough and detailed mission that is the direct result of our ability to expand our strategic options, through the effective application of the Delta Model.

Table 11 identifies InVivo's present and future mission in regards to our eight areas of focus. We believe that our mission statement makes concrete the strategic options that we identified using the triangle. We have a defined business scope so we know where

to compete in the market. We know our core competencies, plus the resources and capabilities we need to succeed.

InVivo's Mission Statement

Providing innovative neurological treatments for the Spinal Cord Injury patient through a network of global healthcare professionals

- Through patented materials and processes to treat in-cord spinal injuries
- Utilizing world class research from MIT and Harvard
- Providing multiple modalities of treatment to treat the physical deficits and to improve quality of life issues
- Delivering pharmaceutical solutions to enable the healing process
- Exploring new combinations of treatment options to maximize outcomes
- Moving research from the lab to the physicians black bag
- Creating an unmatched web based InVivo information portal for the clinician, patient, and interested parties
- Focused determination to provide a continuum of care and treatments from point of injury through the period of recovery and healing

Table 11: InVivo's Evolving Mission Statement

	Now	Future
Product Scope	-Contusion Treatment -Respiratory Treatment -Bone, Muscle and Tissue Engineering -Functional Recovery Through PM&R	-Complete portfolio of Neurological disease solutions. -Respiratory tx. for ALS, MS, SCI
Services Scope	US based consultants - InVivo Portal launch	-InVivo Portal provides integrated solutions -24/7 global response team -Integration into Hospital Admin systems -Web based training -Licensing for Pharmaceutical tx.

Customer Scope	US based thought leaders, DOD, High Vol. surgeons, rehab physicians, emerging surgeons, Insurance providers and patients	-Global thought leaders, DOD, High Vol. surgeons, rehab physicians, emerging surgeons, Insurance providers and patients - Advanced bonding with all segments using technology to integrate into their business processes - anticipate buying needs
End-User Scope	Not at this time	-Consumer driven markets created demand for Patient education via Portal
Channel Scope	-Direct Sales to all tiers in large regions -Direct sales for all tiers to indirect channels in medium size markets	-Direct sales to all tiers in medium sized regions -Direct sales to indirect channels in smaller markets-Global direct sales force and distributors with advanced sales force training-Licensing of pharmaceutical tx. to biotech's
Complementor Scope	- Thought leaders - Insurance Providers - Spine Foundations and Research grants organizations -spinal fixation devices	-Spinal fixation devices -Artificial Disc Providers -Neurological disease solutions
Geographical Scope	North America	North America, Europe, Asia, China, Hong Kong, Japan, and Latin America
Unique competencies	- First in-cord Spinal treatment - World class researchers from Harvard and MIT -Patented Materials -Bone and Muscle treatments	- Pharmaceutical Solution for respiratory problems -Global provider of neurological disease solutions - Expanding world class researchers

InVivo's mission statement highlights the changes that we expect to realize as we grow InVivo from a startup to a dominant player in the SCI market. We fully understand that it is our ability to adapt to change will be the cornerstone of our success, and that is why we have a strategy set forth in table 11 to contrast the difference between our existing

scope and out future scope of business. Our mission statement will provide the flexibility required to evolve as we move forward.

3.2.4 Strategic Thrusts For A Strategic Agenda

Our strategic agenda is comprised of four components- strategic thrusts, managerial accountability, business processes, and performance. We studied the market to fully understand the demand side of the business, and we have studied the category market segment to fully understand the supply side, and as a result we are now able to identify the action-oriented issues that collectively capture the totality of the tasks needed to implement our mission and the desired strategic positioning of our business.

The strategic thrusts must be aligned with our organizational structure, business process, and performance. In table 12, we have identified our strategic thrusts by starting with the customer and they are supported by our segmentation, our triangle, and our mission statement. The thrusts are pragmatic tasks to make InVivo a success. We list them in order of priority and we map them to our organization structure assigning individual responsibility and authority to each task. In a general sense the tasks will provide us with differentiation, a market strategy, and a value proposition.

In table 12, we identify the 13 thrusts that we have identified as the most important. They fall into three categories. Building internal capabilities, solidifying core markets, and building the US market. We have made executive responsible for each task and assigned a one or a two based on ownership. The primary owner of the task is identified with a one, and the secondary owner is identified by a two. The performance measures have been kept simple and measurable.

Table 12: Strategic Thrusts

	Strategic Thrusts	Organizational Units							Performance Measures
		CEO, Frank Reynolds	CFO, Konstantin Rozanov	VP Mkt, Paul Mraz	VP Sales, Mike Panos	CSO, Dr. Yang Teng	VP Eng, Ted Acworth	Business Process	
	Build Internal Capabilities								
1	Raise First Round of Funding	1	1					B	Achieve funding in live with milestone events
2	ID & Engage Thought Leaders & Neuro's	2		2	2	1		CT	# of leaders enaged and enrolled in courses
3	ID and Patent all IP for the business	1		2	2	1	2	B	Patent applications
4	Develop the InVivo Core device	1		2		1		I	FDA steps completed
5	Develop Compound C	1		2		1		I	FDA steps completed
6	Secure Research Lab Agreements	2	2			1		OE	List of lab options
7	Advance the research through animal stages	2				1		I	Movement thru monkey model
8	Meet with Manufatcturing partners	1				1	2	OE	3 options for Manufacturing
9	Create education program for thought leaders			1	1			I	Reaching program milestones
	Solidify Core Markets								
10	ID Complimentors and Partners	1	2	2	2	2		B	# of targets and partnerships
11	Meet with Pentagon officials	1				1		CT	meetings with senior officials at Pentagon
	Build US Market								
12	Create the InVivo Portal			1	1		2	CT	# of website hits per day
13	Patient Advocay Groups			2	1			CT	# of groups promoting us to the client base

Business Process

B: Business Model
OE: Operational Effectiveness
CT: Customer Targeting
I : Innovation

3.3 Conclusion

Our strategic thrusts support a strong strategic agenda. We have developed a comprehensive plan to meet our customer's needs, and we have stretched our organization to achieve our objectives. Based on the talent we have and the commitment of our employees I think that our plan will be easy to implement. The climate for work is excellent and I do not believe that the strategic agenda will leave us vulnerable to competition

Chapter Four: Functional Strategies

The business unit is the focus when selecting a strategy and the business process is the focus when executing the strategy[13]. We have developed our overall strategy for InVivo, and I will conduct further analysis of our processes for innovation, customer targeting, and operational effectiveness to ensure that we can execute on our strategy.

4.0 Innovation

Innovation drove InVivo's into existence, and it will provide us with a continuous stream of new products and services to maintain our viability as a business. Our innovative processes mobilize our scientists, manufacturing, and marketing.

In the late 1990's Dr. Teng met with Dr. Langer to discuss the possibilities of placing a foreign material in the spinal cord to promote healing of spinal cord injuries. Their work began in 1998, and in 2002 they had proven that polymer based materials invented by Dr. Langer could indeed restore normal functioning to rats with spinal cord injuries. They created a new field in science called Neuro-Tissue Engineering, and we will bring the first neuro-tissue engineered product to market in 2010. This discovery was not the first important discovery for either scientists. Over a 30 year period, Dr. Bob Langer patented over 575 inventions and is currently #2 in the history of patents behind Thomas Edison, and he is a member of the Inventors Hall of Fame. Dr. Ted Teng has over 20 patents, and has had over 200 research articles published in peer-to-peer reviewed journals. Innovation is at the core of all the work we do at InVivo Therapeutics.

We believe that incremental discoveries are the spinal cord injury (SCI) patient's best opportunity for improving their quality of living. Spinal cord injury research should focus not only on preventing the loss of function but also on restoring lost functions. Our research toward addressing the consequences of spinal cord injuries focuses on a

natural progression of strategies: preventing further tissue loss, maintaining the health of living cells, replacing cells that have died through apoptosis or necrosis, growing axons and ensuring functional connections, and strengthening and reestablishing synapses that restore the neural circuits required for functional recovery.

These strategies have lead us to a range of therapeutic solutions and priorities for our spinal cord injury research, each of which could theoretically be pursued individually or in combinations. InVivo Therapeutics will focus on these paths of discovery to expedite a portfolio of products and services to the marketplace, with our focus on meeting the needs of spinal cord injury patients.

In Vivo Therapeutics' platform technologies provide a novel approach to the treatment of spinal cord injuries. Off all organizations whose primary focus is spinal cord injury repair, InVivo has an unmatched breadth of Development portfolio and it will continue to expand in the next few years.

4.0.1 Products

We believe that our Development Portfolio provides us with a 4 pronged product portfolio that can be used individually or in multiple combinations.

Product A: Polymer based Medical Device for the repair of spinal cord tissue code named "InVivo Core"
Product B: Tissue Engineering that utilizes Neural Stem cells for spinal cord injury repair code named "InVivo Core Cell"
Product C: Pharmaceutical Treatment for Respiratory Dysfunction associated with SCI code name "Compound" "C"
Product D: Physical Medicine and Rehabilitation program code named, "Frontera Program"

4.1.1 Product Details

The ideal device for treating spinal cord injury should perform six functions:

- bridge the lesion
- shunt fluid
- mitigate secondary injury
- conduct electrical impulses
- naturally erode in vivo
- and be capable of delivering cell transplants.

We have designed a novel device to perform all of these functions in a way that has never been done before and the results have been groundbreaking. Our lab has developed scaffolds from polypyrrole, a synthetic biomaterial that is capable of conducting electricity and naturally eroding in the spinal cord.

Product A: Polymer based Medical Device for the repair of spinal cord tissue code named "InVivo Core"

Electrical signals in the form of action potentials are the means of signaling for billions of cells in the central nervous system. Numerous studies have shown that this electrical activity is not only a means of communication, but also necessary for the normal development of the nervous system and refinement of functional neural circuits. In the case of spinal cord injury, cell-to-cell communication may be interrupted and the mechanisms of normal neurological development imply that electrical activity should be part of the restoration of functional connections. Such activity is important for the survival of existing cells and the incorporation of any transplanted cells (such as neural stem cells) into working circuits. Our lab has developed scaffolds from polypyrrole, a synthetic biomaterial that is capable of conducting electricity and naturally eroding inside the body.

Spinal cord injury involves not only initial tissue injury, but also devastating secondary injuries. These events include glial scarring, myelin inhibition, demyelination, cell death, lack of neurotrophic support, ischemia, free-radical formation, and excitotoxicity. There is significant evidence that programmed cell death in addition to passive necrosis takes place. For example, oligodendrocyte death continues for weeks after injury. However, the apoptotic mechanisms are poorly understood. An environment antagonistic to axonal regeneration is formed. Besides damaged regeneration pathways, hyperexcitability and spasticity, there are further complications. Over time, muscle mass is lost as a result of non-use. The end result of these insults invariably is lost function, the extent of which is determined by the severity of the lesion. Even in the case of incomplete motor function loss, common problems include posture, reduced walking speed, abnormal balance and gait, and lack of sufficient weight-bearing.

Figure 4 identifies the process of secondary injury. An initial or primary lesion is created through trauma to the spine. The primary lesion is typically fluid filled. Secondary injury or neurosis occurs as the primary lesion causes the tissue surrounding it to die. The secondary damage occurs for several months after injury.

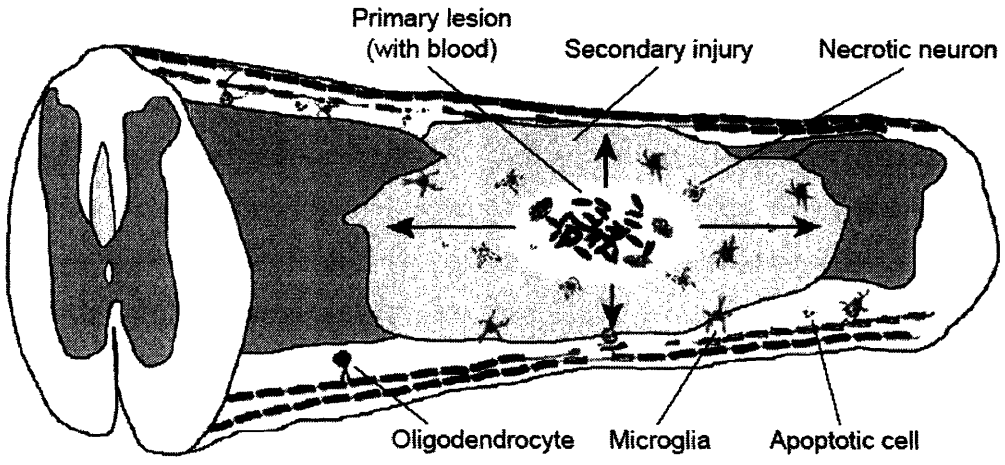


Figure 5: Progression of secondary injury

Understanding these pathophysiological mechanisms, we sought to create a novel treatment solution that would mitigate secondary injury and promote recovery. Our rational design corrects many such mechanisms in a single device. Encapsulation of the central necrotic area minimizes secondary injury by inhibiting cell-cell signaling with inflammatory cytokines. Shunting the fluid-filled cyst reduces pressure buildup within the cord and decreases injury to neurons. Bridging the gap formed by the cyst allows a pathway for regrowing neurons to reach the caudal side and form functional synapses. An electrically conductive material allows conduction of endogenous electrical activity from surviving neurons, promoting cell survival. Any such material should be bioresorbable in situ, such that it naturally erodes once its function has been performed. Finally, a three-dimensional scaffold creates a substrate by which cells can be grown in vitro and then transplanted in vivo. A hollow cylindrical scaffold made of polypyrrole (PPy) meets all of these design requirements. A schematic of our design in situ is shown below.

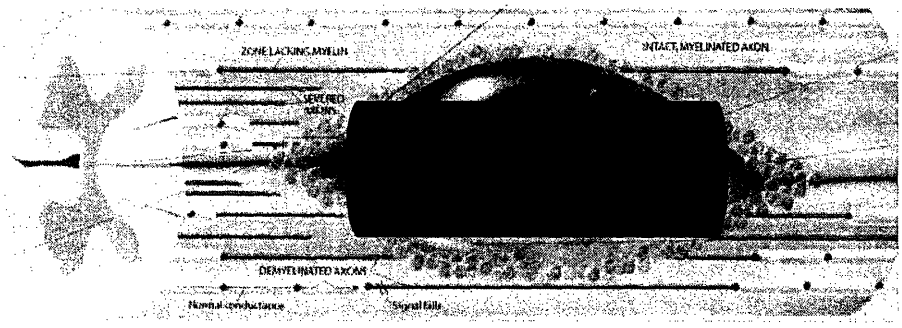


Figure 6: Schematic representation of the polypyrrole scaffold inserted around the center of the lesion area in order to protect surrounding tissues.

For the many reasons discussed above, electrically conductive implants seem promising in the treatment of neural injury. Our current work with polypyrrole extended previous work by our group showing that a non-conductive, biodegradable PLGA scaffold seeded with murine neural stem cells improved recovery of hemisected spinal cord injury in rats. In an effort to produce more clinically translatable results, we implemented the more widely used and clinically relevant contusion model of SCI. In the first *in vivo* study, a 25mm contusion injury was delivered via the NYU Impactor on Sprague-Dawley rats. Immediately following injury in the two treatment groups, the cord

meninges were incised with a short (approximately 1-3mm) cut, allowing for neurosurgical decompression and creating a space for insertion of the tube. In scaffold treatment groups, the implants were inserted into the cord, targeting the central canal and surrounding parenchyma. After implantation, the dura was covered and sealed using the Duragen collagen matrix and overlying tissues sutured closed. Basso-Beattie-Bresnahan (BBB) scoring, the standard quantitative metric in the spinal cord injury research field, was used to evaluate open-field locomotion at one day postsurgery and at weekly time points over the course of 10 weeks post-injury.

Results from the polypyrrole scaffold showed functional locomotor improvement as early as 2 weeks post injury. The amount of functional recovery relative to non-treated controls continues to increase for up to 6 weeks, as shown above. Treated animals are capable of weight-bearing and functional stepping, where non-treated animals show greatly diminished hindlimb function. Magnetic resonance images proved our hypothesis that the fluid filled cyst would be reduced with a cylindrical implant. As shown below, the spinal cord is more intact and the cyst is barely visible when treated with polypyrrole.

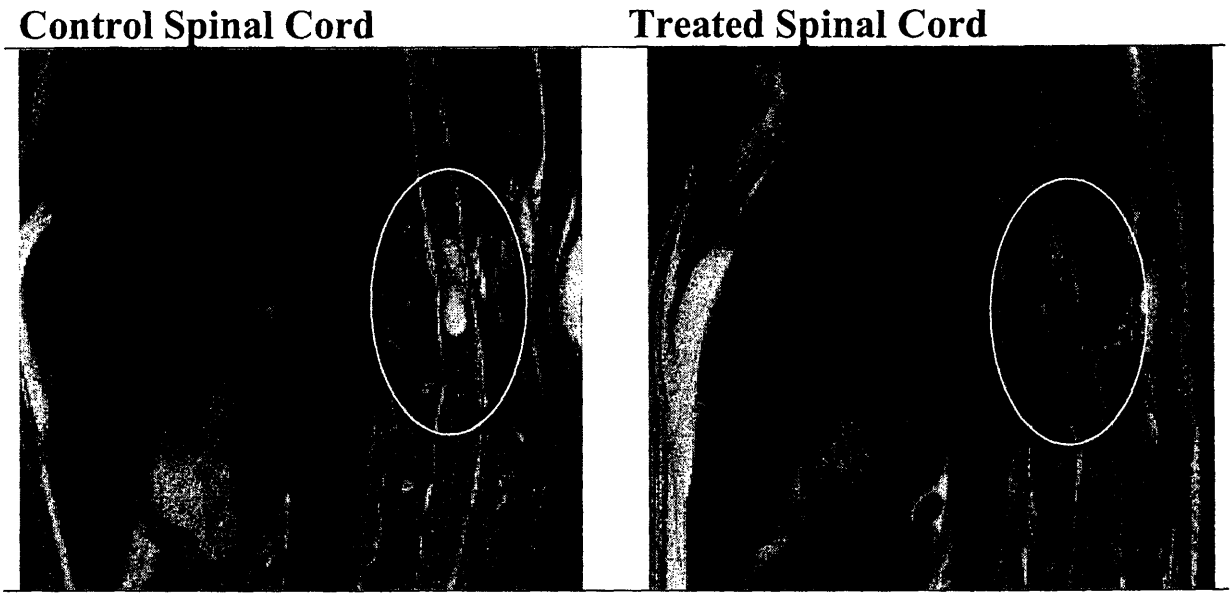


Figure 7: MRI showed reduced fluid filled cyst (appears bright white in the T2 weighted MR image) formation in rodents treated with a PPy scaffold (shown on right) relative to untreated control (shown at left).

Product B: Tissue engineering that utilizes Neural Stem cells for spinal cord injury repair

Our second product will include all of the science in product one and but add stem cells to the polymer. We are focused on Molecular mechanisms that underlie or enhance experimental therapeutic strategies of neural stem cells for the frequent and challenging issues of experimental spinal cord injury (SCI) and neurodegenerative diseases that are clinically relevant. In addition, we have a primary focus on using polymer scaffolds to potentiate neural stem cell (NSC) mediated repair of the injured spinal cord through mitigating neurodegeneration and creating regeneration promoting environment.

Product C: Pharmaceutical Treatment for Respiratory Dysfunction associated with SCI code name "Compound" "C"

Recovery from a SCI will require a systemic approach to treating the patient. Many SCI patients suffer respiratory damage and respiratory distress. Dr. Teng has patented a new drug that we have code named "Compound C". In lab studies Compound C has proven to restore respiratory functioning to normal, while building muscle mass for the patients. Dr. Teng has made significant contributions in understanding secondary injury mechanisms and respiratory dysfunction after experimental SCI. His team established the first animal SCI model showing chronic respiratory abnormalities. They have also initiated new study projects on examining and treating muscular and bone disorders resulting from SCI. As the result of his work, Dr. Teng has patented a new drug not only for SCI but also for the treatment of respiratory disease associated with ALS (Amyotrophic Lateral Sclerosis), Parkinson's Disease, and Multiple Sclerosis.

Product D: Physical Medicine and Rehabilitation program code named, "Frontera Program"

Due to the severity of injury all SCI patients require a physical medicine and rehabilitation program to support healing and strengthen damaged tissue. It combines Physiatry and rehabilitation to maximize the patient's recovery benefits. InVivo is in the process of engaging some of the best Physical Medicine and Rehabilitation physicians in the US to develop a program that will be recommended along with our device

Physiatry

A Physiatrist is a physician who creatively employs physical agents as well as other medical therapeutics to help in the healing and rehabilitation of a patient. Treatment involves the whole person and addresses the physical, emotional and social needs that must be satisfied to successfully restore the patient's quality of life to its maximum potential.[14]

Physiatrists are physicians who treat a wide range of problems from sore shoulders to spinal cord injuries. The focus of the specialty is on restoring function to people. Physiatrists treat acute and chronic pain and musculoskeletal disorders. Physiatrists also treat people with spinal cord injuries, brain injuries, strokes, amputations, cancer, and multiple sclerosis. All require a long-term rehabilitation process. A physiatrist may treat patients directly, lead an interdisciplinary team, or act as a consultant. Physiatrists offer a broad spectrum of medical services. They do not perform surgery. Physiatrists may prescribe drugs or assistive devices such as a brace or artificial limb. They also use diverse therapies such as heat and cold, electrotherapies, massage, biofeedback, traction and therapeutic exercise. Physiatrists treat diseases, disorders, impairments, disabilities, handicaps, and social limitations.

Physiatrists are board-certified via a two-step process through the American Board of PM&R after successful completion of an accredited residency program. Part I of the boards consists of a written exam which is taken upon graduation from residency

training. Part II is an oral examination which is taken after one year of private practice.

Rehabilitation

Rehabilitation is defined as the development of a person to the fullest physical, psychological, social, vocational, avocational and educational potential consistent with his or her physiological or anatomic impairment and environmental limitations. A team works to obtain optimal function even with residual disability, even if the impairment is caused by a pathologic process that cannot be reversed.

Rehabilitation is a concept that should permeate the entire health care system. It should be comprehensive and include prevention, early recognition, and outpatient, inpatient, and extended care programs. Anticipated patient outcomes of such a comprehensive and integrated rehabilitation program should include increased independence and an improved quality of life.

4.0.2 InVivo Therapeutics™ Intellectual Property

Our intellectual property is based on 3 patents co-licensed from MIT and Harvard. All of the licenses are based on inventions by 3 of our 4 founders. Two of the inventions have had provisional patents filed. We refer to one provisional patent by code name "closed door" and it was co-invented by Bob Langer, Dr. Teng, and Rajiv Saigal. The second provisional patent referred to as code name "open door" and it was co-invented by Dr. Teng and Bob Langer. The third patent is filed and claims have been agreed to by the USPTO, and we referred to it as code name "Compound C" and Dr. Teng is the sole inventor of Compound C.

We have a trademark application into the USPTO for InVivo Therapeutics™, and we expect to receive final approval before June 30, 2006.

We are also considering the use of Trade Secrets to extent the life of patents we will ultimately file for our technologies. Bob Langer and Dr. Teng have histories of being brilliant inventors and it is possible that we can secretly continue to develop

technologies in our labs a little longer than your typical life science firm, because very few people think like Bob and Ted. We want to be clear that this is not our strategy but a potential tool for patent life extension that may be utilized in isolated circumstances.
We do intend to be aggressive in obtaining patents for the potential threats to our Intellectual Property, our manufacturing equipment and our manufacturing processes.

Intellectual Property Risk - InVivo relies on its proprietary intellectual property to offer customers the leading technology and capture some of the value created from that technology. Imitators present a potential risk to the company's ability to capture value from its current and future inventions. The management team continues to work with the MIT Technology Licensing Office, Harvard and our own legal council to protect the integrity of our patented and patent-pending technologies. Additionally, the company will continue an aggressive patent strategy and is prepared to invest in enforcing our patents against imitators.

4.0.3 Products Regulatory Plan for Approval

InVivo is in discussion with a senior executive from Johnson & Johnson to assume the role of VP Regulatory Affairs. Their responsibility will be to strategize and implement a plan that will establish a series of clinical tasks and data collection that will support obtaining and then maintaining regulatory approval for our products. In addition it will be critical that our regulatory plan support a plan to collect the proper information for reimbursement in our target markets and to support our competitive claims.
Based on conversations with the FDA, we expect to receive Fast Track status for our medical device. We expect to have a polymer based medical device for SCI repair approved and on the market in 2010. Separately we will work to develop and gain FDA approval for our stem cell based technology for SCI repair and we expect to have that device on the market in 2012. We will license our patent for our SCI drug to a pharmaceutical partner to create a revenue stream so we will not be required to be engaged with the FDA for Compound C.

We do believe that our device will fall under the FDA category of significant risk device, so we expect that we will seek FDA approval for an IDE(Investigational Device Exemption) application, and we will have Pre-IDE meetings with the FDA.
Components of our IDE application:[15]

1. InVivo's investigational plan
2. Prior investigations
3. The device good manufacturing practices
4. IRB actions
5. Investigator agreements
6. The subjects informed consent
7. Device labeling requests
8. The cost of the device
9. Other matters that we deem important to gain IDE approval.

We will notify the FDA if we have any desire to modify the investigational plan to gain approval for modifications. Naturally we will comply with all Good Clinical Practices.
InVivo Therapeutics™ will be the sponsor of all clinical trials. We expect that our trial will be approved by the IRB of the Veteran's Administration Hospital of Boston and conducted in conjunction with their Spinal Cord Injury Research Center.

Our investigators will ensure:

1. The investigation is conducted in accordance with a signed agreement, the investigational plan and FDA regulations.
2. The investigator will protect the rights, safety, and welfare of all subjects under their care.
3. They will control all devices under their care, and ensure that an informed consent is obtained from subjects.
4. They will also comply with record keeping and reporting requirements.

If the FDA deems necessary and before they have approved our device, InVivo is willing to consider permitting the device to be used for a unique emergency, compassionate use, or treatment use.

4.0.4 Product Clinical Development Plan

Table 13: Clinical Development Plan

Time Frame	Planned Action
Jan 06-June 06	Pre-Clinical rodent studies and device improvements
June 06 - Feb 07	Complete Follow-up rodent studies, further characterization of device and further iterations of design
Mar 07 - Dec 07	Prove efficacy in Monkey model of spinal cord injury
Jan 08 - Sept 08	FDA Investigational Device Approval and Pilot Study
Oct 08 - Dec 09	FDA Pivotal trial
June 2010	FDA Approval and Fill Product launch
2011	Postmarketing Studies

For the rest of 2006, we intend to continue to develop iterations of our polymer device to determine if we can improve the outcomes that we are recording in the lab. Once we have finalized the device's novel design we will advance the final design to the monkey model. After efficacy is proven in the monkey model, we will present our data to the FDA in early 2008 in effort to gain approval for a pilot study. Our pilot study will evaluate the safety of our device under controlled conditions and to provide data supporting broader performance testing in a larger population. The trial will be in a single center and our goal will be to prove that in combination with data from bench testing, animal studies, and results from the pilot study the device is ready for a pivotal trial. The pivotal trial will established through reasonable evidence that our device is safe and effective. In addition, when compared to alternative treatment options, the effectiveness of our device is expected to be "not worse than other available treatment options.

Key data collected will be related to device performance, but we will also collect data related to patient response and perceptions. If we determine that device modifications are required to gain a larger population or to achieve acceptable results to advance to a

pivotal trial then we will make those modifications and re-evaluate the device during another pilot study.

Since all aspects of this data will support label approval at the FDA we will ensure that we capture all of the information possible to ensure the possibility of expanded label claims. We will continue post marketing studies to obtain data that can help us improve our device and to provide the patients with a better product. It is possible that the FDA will require post marketing studies so keeping them in our plan meets our needs and as well as the needs of regulatory bodies.

We will conduct a well controlled clinical trial. We will be especially careful to eliminate unexpected sources of bias and confounders by making adjustments to our clinical trial strategy.

Key Elements of our Clinical Investigational Plan[16]

1. Device Description
2. Study Objectives
3. Study Design
4. Study Population
5. Treatment regimen
6. Establish control or baseline measures
7. Determine endpoints for evaluation to support effectiveness and safety
8. Definition of trial success
9. Study procedures and duration
    a. Screening and assignment to treatment
    b. Assessments and follow-up
    c. Post procedure physical medicine and rehabilitation training plan
10. Sample size determination
11. Data analysis plan
12. Risk analysis
13. case report forms

14. informed consent forms
15. Investigational site(s) and IRB information
16. Data Safety Monitoring Board
17. Monitoring plan

We will conduct a well controlled clinical trial. We will be especially careful to eliminate unexpected sources of bias and confounders by making adjustments to our clinical trial strategy.

Our three prime focuses of our clinical trials are to ensure quality results are:

1. A study designed to support the required analysis
2. A suitable control group or baseline study
3. objectivity in outcome measures that are validated and clinically relevant

4.1 Customer Targeting

InVivo must establish the business to customer interface. We must attract, satisfy, retain customers, and ensure that we maintain customer relationships. There will be significant financial and humanitarian incentives for product adoption in all of our customer segments. Our product will be positioned as a novel and best in class solution for the treatment of spinal cord injuries. We will leverage our global award winning salesmanship, strong research base, as well as Dr. Teng's and Dr. Langer's reputation to capture mindshare and achieve penetration.

The key indicator of the success of our marketing strategy is whether we create an unbreakable customer bond. We will provide the market with the best product, and a total customer solution. Our customer bonding will solidify our system lock-in with all of our customer segments. We will be able to achieve best product because of our differentiation. No one in the market will have a solution comparable to InVivo. Next we will redefine the customer relationship for our entire market by providing all seven of our segments with the opportunity to achieve their goals. All of our segments need to either

increase revenue or cut their costs and we can align our objectives with their objectives for a win-win partnership. Once we have established best product and redefined the customer relationship we will move toward a dominant market position by creating a new "standard of care" and thus a dominant exchange. We will create customer system lock-in and as the result we will create a new clinical franchise in the spinal surgery market.

Customer bonding is not an event but rather an ongoing four stage process that increases in value to InVivo as we advance through the bonding process.

- First, our products dominant design which provides us with first mover advantage. The dominant design is usually based on performance, capabilities, service and price.
- Second, customer lock-in where we focus to meet the exact needs of all of our customer segments. Those needs include education, portfolio of products, pricing structure, and brands that add to their own value chain.
- Third, the competitor lock-out stage, where market participants from our suppliers, partners, and customers are all drawn to our product.
- Finally, once we have competitor lock-out we will add complementors to our business model such as our plan for a physical medicine and rehabilitation program to complement our device.

Our marketing strategy will begin implementation in 2007 in order to begin to win mindshare of all 7 of customer segments. We have clearly defined our segments and we will pursue them with a value oriented business model

4.1.1 Pricing

InVivo pricing model will be a value based model. We have engaged the center for Medicaid & Medicare Services (CMS) to establish a strategy to win a best pricing model

for InVivo. CMS establishes the reimbursement rates for Medicare and Medicaid procedures through a system of Diagnosis Related Group or DRG's. Based on our conversation it does appear that InVivo will seek a new DRG for our products because we do not fall into any of the existing DRG's.

To gauge our pricing model we examined the current DRG system and we do believe that we will receive reimbursement that is substantially higher than the highest current spine related DRG, which is DRG 496. Our rational is based on the R&D investment, complexity of the procedure and required skill set to perform and support the procedures, Hospital composite factors, DRG Weights and rate differentials

Current spine related DRG's cover DRG's 496-500.

Table 14: DRG's, procedure and costs

DRG	Procedure	Medicare Rate	Hospital Direct Cost
496	Anterior-Posterior Spinal Fusion	$8,000	$23,590
497	Spine Fusion w/cc	$4,000	$18,211
498	Spine Fusion No CC	$4,000	$13,114
499	Back-Neck No fusion w-CC	$1,500	$1,097
500	Back-Neck No Fusion No CC	$1,500	$1,375

Source: California Division of Workers Compensation

You can see that Medicare and hospital rates vary widely and we will pursue the best price possible. Based on the current costs to care for a SCI Patient, we have determined that we will be able to achieve a mimimun price of $30,000 in the USA and $22,800 in the international market.

4.2 Sales Strategy

The focus of our sales strategy is on customer bonding. While the data on our products will speak for itself, the message will need to be carried diligently & personally by proven & sophisticated Sales Consultants (SC's) Their mission will be to capture the top-50 teaching facilities/trauma centers during year-one and expand to the top-300 in

year-two. Initial phase of sales activity will be about quality vs. quantity. The performance & results during this phase are crucial in establishing a formidable foundation & reputation to build upon. All pertinent personnel (Drs. Teng/Langer & clinicians from study-sites) will be heavily involved in ensuring positive outcomes during this introductory phase (training, education, site visits, etc.).

Steps in our Sales cycle to create customer bonding with spine surgeons[17];

- Research – identify all existing attending physicians involved in the treatment of spinal cord injuries in SC's geography
- Become Expert – the ability of a SC to gain quick access & earn credibility will be proportionate to their ability to talk at a level close to a physician. SC's will require extensive training.
- SC's will initiate direct contact with physicians via:
    - Information packet delivered to physicians via "Fed-Ex"
    - Follow-up telephone call 24-days after receipt of packet
    - Schedule face-to-face appointment with physician within 3-5 days after receipt of packet
    - Appointment will consist of interviewing/assessing physicians existing methodology in treating spinal cord injuries. Appointment will conclude by securing commitment from physician for "next step" (site visit)
    - SC's may also conduct weekly dinner and/or breakfast seminars for surgeon groupings of 5 at a time.
    - SC's will be able to schedule 1 "hot" physician per month for a visitation to one of the established clinical study-sites. (Clinical Study Sites will have previously agreed to this arrangement from a condition in our agreements with them). This visit will be purely to advance the education & increase the likelihood of adoption. This would be strictly observation – not training.
    - There will be 10 "Training Courses" in year-one. 2 each in Northeast, Southeast, Midwest, Southwest, Northwest. This will be a 36-hour training for physicians only. It will include didactic presentation, interactive

discussion with a panel & involve hands-on clinical training. These courses will be led by physicians from the Clinical Study Sites. Training courses would provide a CEU for physician – and a formal certification from InVivo to use the product. It would be mandatory for physicians to be certified prior to utilizing the product on actual patients.

- SC's will also access physicians at hospital "Grand Rounds" (attending physicians present on leading-edge medical issues/techniques and or "Journal Club" (resident/fellow physicians sharing of best-practices). These events are opportune times to generate interest & fortify relationships.
    - Devise customized Marketing-Plan for physician/hospital to market the product/procedure
    - Generate interest from local media channels
    - Help construct press-releases
    - Schedule Surgeries – upon physicians being trained, it will be imperative for them to utilize what they have learned soon after the course has been completed. The timing of surgeries is not predictable. SC's should by 110% prepared to be at the beck-and-call of a 1st-time user (weeknights, weekends).
    - SC's will be on call 24/7 – to both accommodate 1st-time users and to be a resource for existing users.
    - Physician and/or hospital staff is equipped & instructed to contact SC as soon as a surgery using InVivo product has been scheduled.
    - SC's will quickly travel to hospital to consult physician (discuss patient condition, review radiographic assessment, agree on treatment)
    - SC's will be present in the surgical-suite/O.R. while surgeon is performing surgery. SC will consult physician intra-operatively and instruct physician's supporting cast.
    - SC's will manage personal inventory & be prepared for both demonstrations & actual usage in surgery. Upon facility becoming regular user, inventory will be stocked at facility. Inventory will be provided via consignment & managed by SC thereafter.

- SC's strategically pursue any & all potential users. Interest & bonafide leads will be quickly sifted & focuses upon. Existing users will supported exhaustively.

Medical devices are purchased for 3-reasons (in this order):

1. Product Performance;
2. Relationships;
3. Price.

Outstanding Sales Professionals building a loyal customer base is nearly as important as the product itself.

4.2.1 Target Market Penetration

The sales strategy will be centered on major metropolitan areas within the United States. The initial sales force will be responsible for engaging the industry thought leaders in order to capture mindshare and we expect that process to begin in late 2007, concentrating on 300 industry thought leaders that we have identified through 2008. The breadth and depth of their efforts will depend on our progress in our labs.

In 2009 as we near CE Mark and FDA approval our sales strategy will expand in to include surgeons and hospitals that are in major metropolitan areas within the United States, as well as the prominent medical centers in Europe. Special attention will focus on the top 50 academic hospital systems in the US that perform spine surgery using implantable devices. In addition to the hospitals we will engage rehabilitation physicians.

Top 12 Target hospitals each conducts over 500 spine fixation surgeries per year.

Table 15: Top Twelve Hospitals for Spine Fixation procedure

Hospital	Location
UPMC Presbyterian	Pittsburgh, Pennsylvania
Memorial Mission Hospital	Ashville, North Carolina
Abbott-Northwestern Hospital	Minneapolis, Minnesota
SW Texas Methodist Hospital	San Antonio, Texas
Riverside Methodists Hospital	Columbus, Ohio
St. Mary's Hospital	Rochester, Minnesota
Methodists Hospital	Houston, Texas
William Beaumont Hospital	Royal Oak, Michigan
Boston University Medical Center	Boston, Ma
Moses H. Cone Memorial	Greensboro, NC
Covenant Medical Center	Lubbock, Texas
Mass General Hospital	Boston, Ma

Source: Millennium Group 2006

By concentrating on the top 50 institutions we will be able perfect our product pitch before beginning a sustained rollout to the rest of the country. This product is likely to have strong word-of-mouth propagation, so the "InVivo Message" should expand to their surrounding communities. Since we will be in the field, we will be able to mitigate the potential for negative feedback. In the second year, we will begin to expand our efforts to the other customer segments including insurance, department of defense. Effort with thought leaders should have led to increased awareness in all customer segments.

4.2.2 Sales Force

We have identified a Sales Executive from Stryker Spine to join InVivo Therapeutics™ as President of North American Sales. Recently he has turned down the National Sales Director position at Stryker because of his families desire to live in New England. Michael has achieved his peak executive level at Stryker and he is looking for a national position in the spine industry that permits him to live in New England

Sales Consultants (SC) will be driving force in customer bonding and branding the InVivo message. InVivo products will be positioned as revolutionary and quickly become standard-of-care for spinal cord injuries. In anticipation of FDA approval, InVivo will employ 25 direct Sales Consultants 6-months prior to formal launch of product. The ideal SC will have a minimum of 8-years of proven sales experience, with at least 3-years in the medical sales related to spine. Initial 25 SC's will be provided a salary for 6-months, a "draw" (financial guarantee) for an additional 6-months, and finally will be compensated strictly on performance of the product in their geography after 1-year. Within 2-4 months of formal launch of product, rapid adoption of InVivo product will be in process within the geographies of the existing 25 SC's. Upon this traction and market validation, an additional 3-4 SC's per month will be added, in a predetermined sequence of geographies. There would be approximately 50 full-time SC's within 10-months of formal launch of product.

Initial 25 SC's will be strategically located proximal to:

1. Metropolitan areas with highest incidence of spinal cord injuries
2. Thought-leaders and/or clinical study sites
3. Major teaching facilities and/or leading trauma centers
4. Teaching facilities are the most valuable accounts in building a sustainable business in medical devices.
5. Additional SC's will be placed sequentially to focus upon next most desirable geographies.

There will be one Director of Sales. He/she will be implemented no later than January 2007. Two Sales Managers (East/West) will be implemented to recruit/hire/manage initial phase of 25 SC's (minimum of 7-months prior to formal product launch). Within one-year of formal product launch, there will be 5 Sales Managers, 50 SC's and 1 Director of Sales.

The skill sets required for our new hires into sales our sales force will mirror the skill sets in the marketplace. Their skill sets will be based on salesmanship, not clinical

backgrounds. We expect them to have a consistent curiosity about science. For our high volume sales reps, they will be assigned an assistant for the hospital setting and the assistant background will be more technical. They may be a former surgical technician

We will provide our sales force with the following intensive training to the entire sales force.

Table: 16 Salesperson Training Program for New Hires

Anatomical Training	Neuro-Clinical training
Ortho-Clinical training	Surgical procedural training
Spinal Cord and Spine disease models	Medical Semantics
Product specifications	InVivo's R&D Philosophy
Salesmanship and selling parameters	

4.2.3 Market Geography and Reference-ability

In the spine device market regional loyalty is very important so have strong references will be a key to our success. We will initially target our segments on a regional basis so we can create a "buzz" around a region about InVivo's Value to the SCI Market.

Since we ill obtain our CE Mark in 2009 before the US we will be able to implement our European and Japanese market penetration plans and we will obtain market share as identified below. Due to reimbursement challenges we will experience a slower rollout in the first three years until we obtain reimbursement approval status from both public and private insurance carriers.

We will focus on the US market in our initial launch of our product at the end of 2010, and we will expand globally in 2012. We will base our US operations in Massachusetts, Asian operations in Singapore, European operations in Ireland, and South American operation in Puerto Rico.

Table: 17 Forecasted Markets Share

	2010	2011	2012	2013	2014	2015
US Incidence	1%	5%	15%	20%	20%	20%
Global Incidence	.025%	1.25%	2%	5%	5%	5%

Similarly to the US, for Europe, Asia, Latin America, Canada, Middle East, Africa, etc. InVivo will have direct employees sometimes involving subsidiaries in each country or depending on the business climate we may contract with independent distributors or take on a strategic partner for larger regions. Although we would lose some level of control for customer bonding, the financial risks are different when using distributors because they get paid commission on gross sales price. Internationally, these will be stocking distributors who buy your product at an agreed to transfer price, take title to the product and sell it in their territory at prices that they are agreed upon by InVivo and the vendor. These distributors will do a lot more for us in some regions of the world than InVivo may be able to do for ourselves if we tried to establish a subsidiary. Training, brochures, sales, support, billing, etc. are all things that we can not be managed very easily unless we have translators for 100 languages and can roll out a global footprint in a compressed time period.

4.3 Operational Effectiveness

We must be able to deliver quality products to our customers, as promised, and when promised. We will be responsible for human life and we will take that responsibility seriously. We must ensure that we can control all elements of the supply chain from order processing, raw materials ordering, manufacturing, warehousing, and distribution. Since we will be proving a highly regulated product to the market I will provide a details strategy for manufacturing to ensure that we meet both European, and FDA manufacturing requirements.

4.3.1 Manufacturing Strategy

Our devices will comply with the FDA's good manufacturing practices. The methods, facilities, and controls utilized by InVivo Therapeutics™ manufacturing processes, packaging, and holding will comply with the Food, Drug, and Cosmetic Act. Specifically we will comply with 21 CFR 820, which covers quality system regulation.

Our product consists of a hardware component and a set of surgical procedures for installing the hardware component into the patient. We intend to do our Research & Development in-house, and with our founding teams at MIT and Harvard, including continuing to develop our proprietary designs and our own hardware subcomponents such as installation alignment guides.

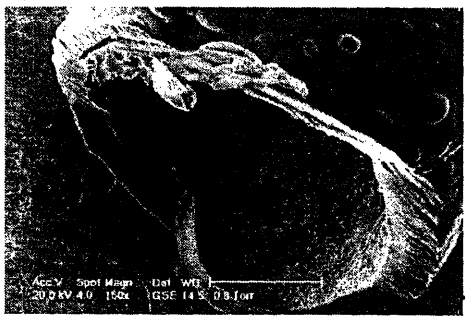
Manufacturing will be outsourced to limit InVivo's investment in capital equipment overhead, allow InVivo to retain focus on its core competence, and make the company itself more transactable at higher gross margins. Our manufacturing partner will bring a skillset that InVivo lacks (manufacturing, quality, logistics, FDA, etc). Initial overall cost will be higher but risk is lower and long-term profit will be greater. Finding a manufacturing partner with knowledge in electrochemical polymerization or similar processes will greatly shorten time-to-market. And since this is not a rare capability, InVivo will retain good power relative to this supplier.

Eventually, with the development of a manufacturer quality assurance program, the entire product will be drop shipped from our outsourced manufacturer. Product will be inspected, sterilized, and packaged at Manufacturing facility. Product will be shipped directly from to distributor(s) who will handle all logistics, warehousing, and interaction with end-customer (hospitals/doctors).

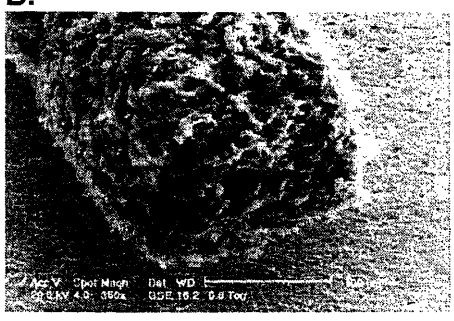
4.3.2 Manufacturing Process

The pattern of the conductive template for electrodeposition of PPy controls the shape of the PPy scaffold that is created. By controlling the template, we can manufacture polymer scaffolds ranging from thin lines to rectangular planar implants. Tube-like PPy scaffolds (shown above) were produced by plating the PPy onto a conductive wire mold. This technique can be scaled to produce scaffolds of any length, inner diameter, and outer diameter. Furthermore, surface roughness can be controlled with electroplating temperature (shown in the figure below). We developed a new technique for scaffold extraction from the template by application of a negative potential in a saline solution. The negative potential causes electrochemical reduction and slightly increases the size of the scaffold. It can then be mechanically dissociated from the platinum wire mold with minimal applied force, resulting in no damage to the material. This new technique improved greatly on the prior method of etching the inner wire with harsh organics, making any resulting devices unsuitable for implantation. For in vivo tests in rodents, PPy tube scaffolds were created by electrodeposition of erodible PPy at 100μA for 40min onto 250μm diameter platinum wire. This was followed by reverse plating at 3V for 20 seconds, allowing removal of the scaffold. The resulting tubes of 10-15mm length were sectioned into 3mm long pieces for implantation.

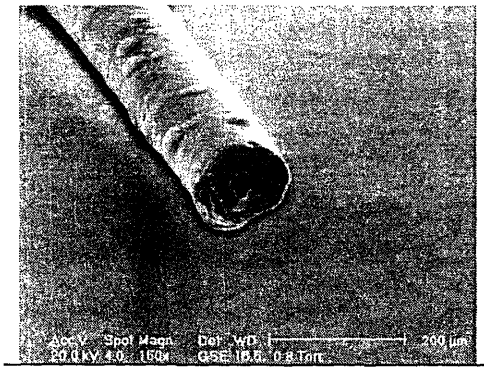
A.



B.



C.



D.

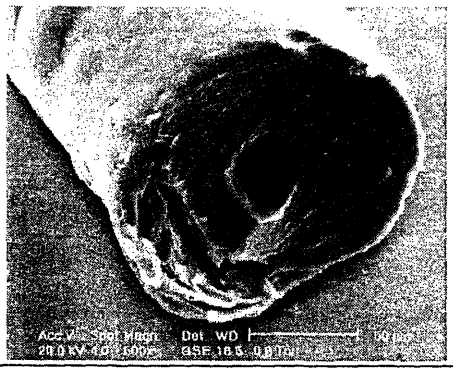


Figure 8: SEM images of microfabricated PPy tubes. A. Murine neural stem cells seeded inside of a 600µm inner diameter tube (150X). B. High-magnification (350X) view of 25µm inner diameter tube. Rough surface texture is a result of low electrodeposition temperature (4°C). C. Lower magnification (150X) view of a 25µm inner diameter tube created with a smooth surface texture by electrodeposition at 24°C. D. Higher magnification (500X) view of same tube as in C

InVivo will meet "Good Manufacturing Practices" specified for FDA approval. Manufacturing will be outsourced, and will limit InVivo's investment in capital equipment and overhead. Our manufacturing partner will bring a skillset that InVivo lacks (manufacturing, quality, logistics, FDA, etc). Initial overall cost will be higher but risk is lower and long-term profit will be greater. Our manufacturing partner will have knowledge in electrochemical polymerization and greatly shorten time-to-market. We have developed a concept design that scales the "One-by-one" electrochemical polymerization process into a "Bulk Reactor" process that can produce 1000 Cores per batch in the same time as the One-by-one process. Bulk Reactor could produce up to 1,000,000 Cores per year at a low costs.

4.3.3 Manufacturing Plan

InVivo's manufacturing plan is outlined in the diagram below.

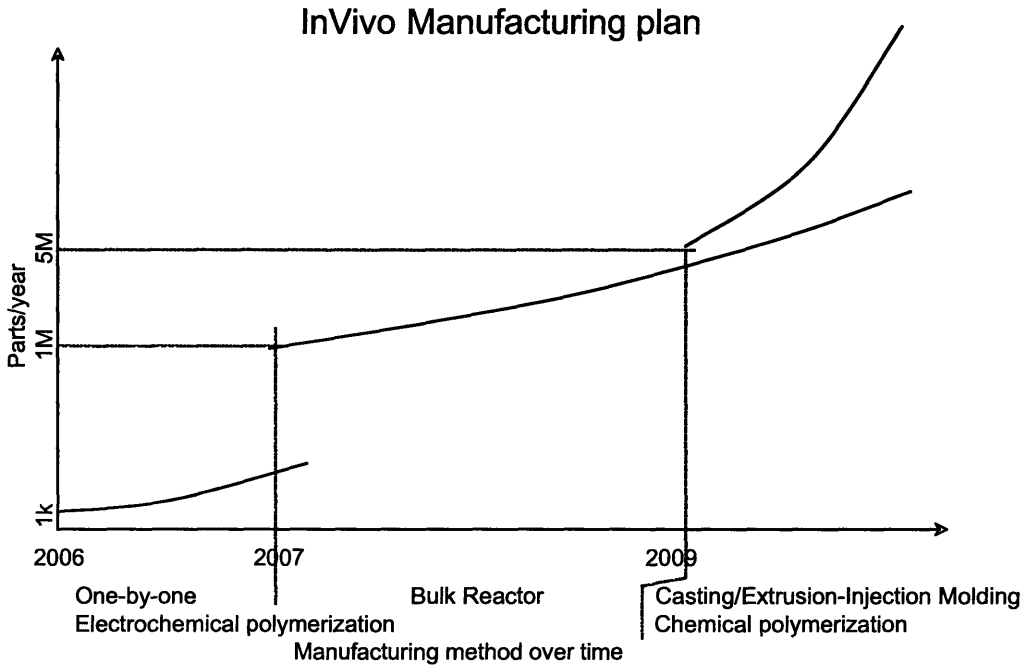


Figure 9: Forecasted Manufacturing Volumes

4.3.4 Core Hardware One-by-one

Our current prototype Core is functional in all regards. Component parts have been manufactured in the laboratory, and major manufacturing risks have been reduced. The team is ready to scale up to mass manufacture based on the demonstrated manufacturing process described below.

Manufacturing process for Polypyrrole Scaffolds:

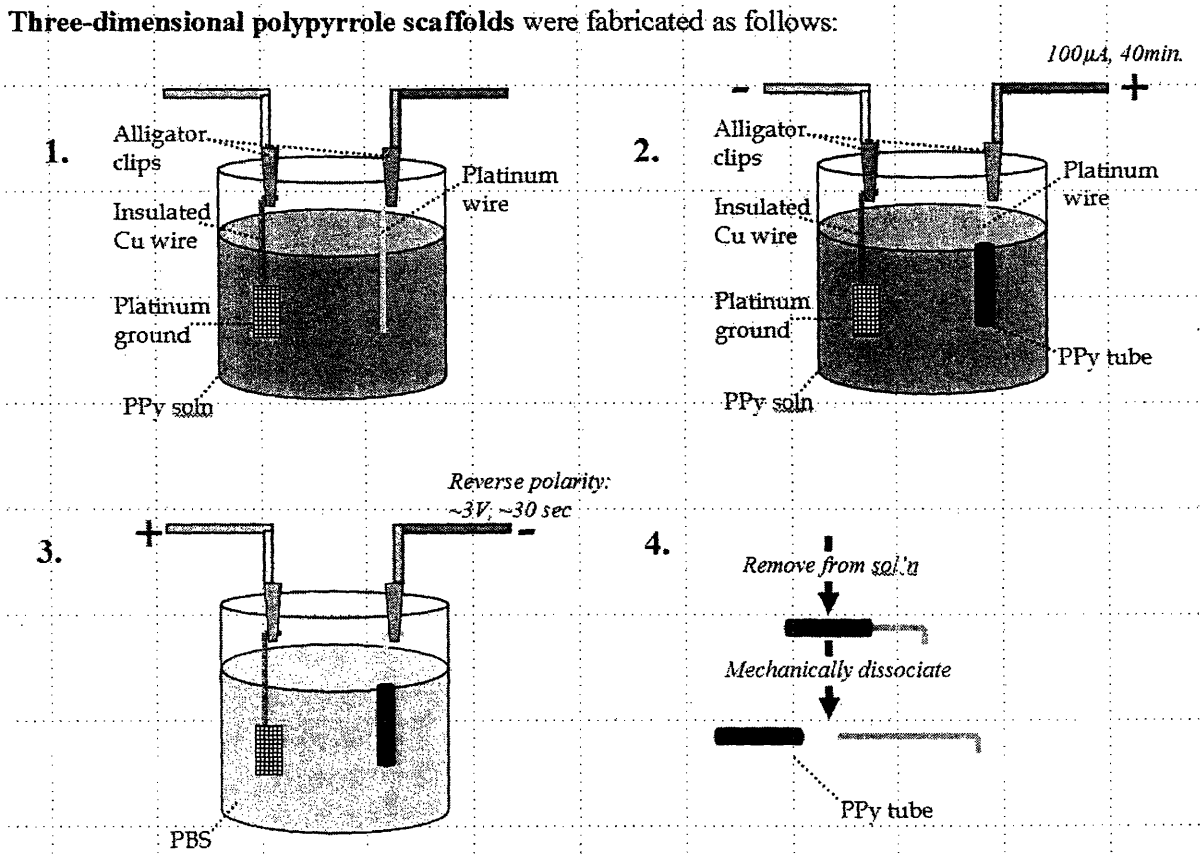


Figure 10: Manufacturing Process

This method is currently producing 10's of Cores per day, and can easily be scaled up to 1000's per year. This method is proven but has long cycle time, high labor costs, and relatively inconsistent quality.

4.3.5 Core Hardware Bulk Reactor

We have sourced a number of manufacturing partners and have begun discussing cost estimates for outsourced manufacturing of our Core product.

We have developed a concept design that scales the "One-by-one" electrochemical polymerization process into a "Bulk Reactor" process that can produce 1000 Cores per batch in the same time as the One-by-one process.

The Bulk Reactor utilizes the same proven electrochemical polymerization process used by the One-by-one process, but arranges 1000 platinum wires instead of just one in the PPy solution. 1000 Platinum ground electrodes are evenly distributed between the Platinum wires, giving a more uniform current field and thus deposition uniformity. The wire field is located between two non-conducting parallel plates, causing an improved quality of the Core ends and saving on costs of any rework to clean up the Core ends. The Bulk reactor has added benefit of easy/automated core dissociation/ejection. Increasing bulk reactor matrix size effectively shortens cycle time. The Bulk Reactor would cost approximately $100,000 to manufacture and enter into production, and could produce up to 1,000,000 Cores per year. Additional Bulk Reactors can be brought on-line to scale up production to 5,000,000 Cores per year and beyond.

The Bulk Reactor is an extension of our proven method, and enjoys medium cycle time, low labor costs, and improved, consistent quality.

4.3.6 Core Hardware Casting/Extrusion-Injection Molding

Beyond 5,000,000 Cores per year the Bulk Reactor process becomes less cost efficient than a chemical polymerization based casting process or extrusion or injection molding. For an investment of approximately $250,000 – 500,000 a casting or molding production process might be developed that can produce 5,000,000 Cores per year and beyond, at an extremely low cost per Core.

These methods offer high upside potential: High likelihood of feasibility, short cycle times, low labor costs, and high quality.

Casting/Extrusion-Injection Molding are significant developments and will likely spawn business ventures bigger than original InVivo product

4.3.7 Facilities

InVivo currently leases office space in the Cambridge Innovation Center, Cambridge, Massachusetts. With funding InVivo intends to lease office, laboratory and shipping space in or near Boston, Massachusetts.

As we grow globally we expect to service and support Asia from our Asian headquarters that we establish in Singapore, and we will service and support Europe from a European headquarters in Ireland.

4.4 Conclusion

Our strategy based on system lock-in will not be successful unless we are able to lock our internal support process into our strategy. Our capability to effectively execute the strategy must be directly aligned with our functional strategies. From our inception InVivo has been focused on Innovation. One of our unique capabilities is that all of our founders are business focused inventors, so during the innovation process, the functional strategies, and the business model are on a continuum of alignment resulting in a seamless integration of our innovation, customer targeting, and operation effectiveness into our business model and strategy. We have a natural and tight fit between our strategy and functional support departments.

Chapter Five: Finance Evaluation and Ownership

5.0 Financial Projections

Capital Risk - As a startup company, InVivo lacks the substantial financial resources of our more established competitors, some of who have over $100 Million of liquid assets to support their business investments. InVivo will be raising institutional funding to help support its operations, however this funding will not put us on equal footing with our more established spine device marketers in the market

5.1 Summary Financials and Staged Investments

We will begin to capture mindshare in 2007. We expect CE Mark in 2009 and FDA approval in 2010. We are forecasting $16M for revenue in 2010. We are forecasting revenue of $89.6M in 2011. We will expand sales effort for 2012 and we forecast $203.4M in 2012. We expect global revenues for 2013 to be $447.6M and global revenues in 2014 to be $502.8M. We will be focused on low cost production, and we have a solid manufacturing plan. We will have a strong profit position and earn our first profit in 2011.

5.1.1 Assumptions behind Revenue Projections:

- The sales projections are based on an analysis of the current spinal cord injury statistics. In the U.S., there are approximately 11,000 new injuries. The US government has estimated that in the near term the number of new incidences will by about 13% per year due to changing demographics. In the rest of the world, the estimated number of new annual injuries is approximately 130,000.
- There are currently no competitors offering any product with similar treatment potential. FDA approval is expected by mid-2010, and European regulatory approval is expected in advance of FDA approval and as early as 2009. The estimated market share is thus expected to grow from 1% in 2010 to 20% by 2013 in the U.S.; the estimated market share for the rest of the world is below 1%

during rollout and increases to 5% by 2013. Actual market share may be significantly higher, especially if the product is deemed a standard of care for such injuries.

- The price of the product is set to $30,000 in the U.S. and $22,000 abroad. The latter is based on industry experience relating to the protection of domestic sales. The $30,000 price is both cost and value driven:
    - In the first several years, approximate per unit costs include manufacturing and license fees of $10,000, sales personnel of $8,000, overhead of $1,000-$4,000, and R&D of $1,000-$2,000. The total product cost is estimated to be in the range between $20,000 to $25,000 and declining over time.
    - Current treatment costs of spinal cord injuries range from just over $200,000 to $700,000 in the first year for a lifetime cost from half a million to several million U.S. dollars. The price of $30,000 is very competitive in this setting and is not exceptional for medical devices.
- In addition to the projected device sales, additional upside is expected from a patented complementary drug, which also has a wide range of additional unrelated applications, and a therapy program.
- Our work is not only important from a humanitarian perspective, but we also provide a large financial benefit to all parties absorbing the cost of care. Below are the life-time costs to provide care for a SCI patient. The Net Present Values (NPV) are discounted at a rate of 2%, to adjust for inflation. The NPV to care for a Quadriplegic C1-C4 is $2,800,000 and the NPV to care for a Paraplegic-incomplete is $624,441. Since our pricing model is set at $30,000 per surgery we offer tremendous value to the market. To quote one of our board members, "From a humanitarian and financial perspective the opportunity is huge!"

5.1.2 Assumptions behind Cost Projections

- Costs are based on actual expenses and industry benchmarks.
- The main direct costs stem from manufacturing, license fees, and costs of the highly trained sales agents who will not only help with penetration, but also help

with the surgical procedures in the trauma hospitals (as is typical in the spinal cord market). There are 300 Trauma Hospitals in the US; however the top 20 hospitals cover the vast majority of trauma cases in the country. This helps reduce sales expenses

- Indirect costs include research and development as well as general and administrative costs.

5.2 Milestones: Value Creating Events

Table 18: Milestones and value creating events

Milestone	Date	Cumulative Investment
Pre-Clinical & IDE	Dec 2007	$6M
Feasibility Trial	Sept 2008	$14M
CE Mark Approval	Sept 2009	$28M
Pivotal Trial	Jan 2010	$52M
US FDA Approval	June 2010	$61M

A: January 2006 to February 2007 – Complete Preclinical Studies
B: March 2007 to December 2007 – Complete Monkey Efficacy Study
C: January 2008 to September 2008 – FDA IDE, complete Pilot Study on Humans
D: October 2008 to December 2009 – Conduct FDA Pivotal Trial
E: January 2010 to June 2010 – Get FDA Approval and Product Launch
F: July 2010 to December 2012 – Achieve penetration: Main Trauma Hospitals

- We anticipate $55 M of funding over three rounds.
- As can be seen from the Cash Flow Statement above, we have tied each funding round to achieving certain milestones, each of which will significantly reduce the uncertainty in our product and hence increase valuations.
- In the immediate future, we are looking to raise about $1,000,000 to formalize our company structure and complete preclinical studies (Milestone A). We then anticipate the following funding needs:
    - Series A $ 5 M to reach Milestone B (Complete Monkey Efficacy studies)
    - Series B $ 10 M to reach Milestone C (Complete IDE, Human Pilot Study)
    - Series C $ 40 M to reach Milestones D & E (Pivotal Trial, Product Approval & Launch)

5.3 Exit Strategy

We believe that we will be an extremely attractive target for a number of companies in this space, since our product is extremely complementary to existing products in the market. There are 8 main players in this market: Medtronic, Johnson &Johnson, Synthes, Kyphon, Biomet, Stryker, Zimmer, Abbott Spine, Nuvasive, that account for 88.9% of the market share. As can be seen from the recent acquisition of Link-Spine by Johnson & Johnson, the valuations in the spine medical device market are to the range of 5X-6X Revenues. Given our projected revenues over the next several years, protected by our patents, we expect that a number of companies will be very interested in our product. To further this end, we have Bob Langer, and Stan Lapidus on our advisory board, and we have already had indications of interest in our product from Synthes, and Medtronic. We also believe that there will be high demand from the public markets if we were to IPO. Given that we expect to have positive earnings by 2011, this should position us well for either a successful acquisition or an IPO within the next 5-7 years.

Income Statement

(In Thousands)	2006	2006E	2007E	2008E	2009E	2010E	2011E	2012E	2013E	2014E	2015E
Sales Revenues											
Devices (U.S.)						$5,142	$28,880	$97,315	$145,739	$163,693	$183,861
Devices (International)						$11,313	$63,536	$112,453	$315,767	$354,669	$398,364
Device License Fees						$494	$2,772	$6,293	$13,845	$15,551	$17,467
Net Sales Revenues						$15,962	$89,644	$203,474	$447,660	$502,812	$564,758
Cost of Goods Sold						$6,978	$31,590	$65,065	$147,286	$152,661	$157,998
Gross Margin	$0	$0	$0	$0	$0	$8,984	$58,054	$138,409	$300,374	$350,151	$406,760
Gross Margin (%)						56%	65%	68%	67%	70%	72%
General and Administrative Expenses	$12	$36	$1,870	$3,438	$4,335	$5,266	$6,317	$7,364	$8,580	$9,823	$11,308
Marketing and Sales	$0	$0	$450	$800	$1,200	$5,588	$19,683	$36,161	$78,118	$87,594	$98,237
Research and Development	$0	$0	$1,800	$2,745	$4,118	$6,176	$9,264	$9,264	$9,264	$9,264	$9,264
Net Interest Expense	$0	$0	$0	$0	$500	$3,000	$3,000	$3,000	$3,000	$3,000	$3,000
Earnings Before Taxes	($12)	($36)	($4,120)	($6,983)	($10,153)	($11,046)	$19,789	$82,619	$201,411	$240,470	$284,950
Tax Expense							$6,926	$28,917	$70,494	$84,164	$99,733
Net Income	($12)	($36)	($4,120)	($6,983)	($10,153)	($11,046)	**$12,863**	**$53,702**	**$130,917**	**$156,305**	**$185,218**
Profit Margin (%)						-69%	14%	26%	29%	31%	33%
Milestones			A	B	C	D	E		F		

5.5 Cash Flow Statement

Statement of Cash Flows (In Thousands)	2006	2006E	2007E	2008E	2009E	2010E	2011E	2012E	2013E	2014E	2015E
Cash Flow from Operations											
Sources: Device Sales	$0	$0	$0	$0	$0	$16,456	$92,417	$209,767	$461,505	$518,363	$582,225
Uses											
Research and Development	$0	$0	$1,800	$2,745	$4,118	$6,176	$9,264	$9,264	$9,264	$9,264	$9,264
Production and License Fees	$0	$0	$0	$0	$1,855	$18,689	$44,194	$78,646	$172,531	$154,224	$172,784
Marketing and Sales	$0	$0	$450	$800	$1,200	$5,588	$19,683	$36,161	$78,118	$87,594	$98,237
Other	$12	$36	$1,870	$3,438	$4,835	$8,266	$9,317	$10,364	$36,101	$83,317	$98,472
Total Uses	$12	$36	$4,120	$6,983	$12,008	$38,719	$82,458	$134,436	$296,014	$334,399	$378,758
Total Cash Flow from Operations	($12)	($36)	($4,120)	($6,983)	($12,008)	($22,263)	$9,959	$75,331	$165,492	$183,964	$203,467
Cash Flow from Investing											
Uses: Acquisition of Fixed Assets	$1	$0	$600	$915	$1,373	$2,059	$3,088	$3,088	$3,088	$3,088	$3,088
Total Cash Flow from Investing	**($1)**	**$0**	($600)	($915)	($1,373)	($2,059)	($3,088)	($3,088)	($3,088)	($3,088)	($3,088)
Cash Flow from Financing											
Seed Financing	$15	$100	$0	$0	$0	$0	$0	$0	$0	$0	$0
Series A (Post Milestone A)	$0	$0	$5,000	$0	$0	$0	$0	$0	$0	$0	$0
Series B (Post Milestone B)	$0	$0	$0	$10,000	$0	$0	$0	$0	$0	$0	$0
Series C (Post Milestone C)	$0	$0	$0	$0	$15,000	$25,000	$0	$0	$0	$0	$0
Total Cash Flow from Financing	**$15**	**$100**	**$5,000**	**$10,000**	**$15,000**	**$25,000**	**$0**	**$0**	**$0**	**$0**	**$0**
Total Cash Flows	**$2**	**$64**	**$280**	**$2,102**	**$1,619**	**$678**	**$6,871**	**$72,243**	**$162,403**	**$180,876**	**$200,379**
Cash Balance	**$2**	**$65**	**$345**	**$2,447**	**$4,067**	**$4,745**	**$11,616**	**$83,859**	**$246,262**	**$427,138**	**$627,516**
Funds Used	$13	$36	$4,720	$7,898	$13,381	$40,778	$85,546	$137,524	$299,102	$337,487	$381,846
Funding Needs	$0	$36	$4,720	$7,898	$13,381	$24,322	$0	$0	$0	$0	$0
Milestones		A	B	C	D	E		F			

5.6 Breakeven Analysis

In reviewing the cash flow statement we will be cash flow positive in 2011

5.7 Granular Metrics

Identifying key granular metrics that we will utilize to determine how we are meeting objectives is very important to InVivo. Granular metrics are necessary to succeed because:

- The can identify the natural economic concentrations and inherent variability in Business.
- The represent the performance drivers, which will often occur at the detailed intersection of three dimensions highlighted in the Delta Model: product, customer, complementor.
- The enable a customized response of a customer and complementor specific level, which is so critical to secure bonding[18]

We have identified six granular metrics as critical indicators that should be subject to variability analysis. These ratios will be reviewed monthly to ensure we are aligning strategy with execution.

1. Sales/R&D Expense Ratio
2. Marketing Expense/Non-Operating Income Ratio
3. Administration Expense/Sales Ratio
4. EBITA/Sales Ratio
5. Non-Operating Income/R&D Expense Ratio
6. Strategic Expense/Operational Expense Ratio

The final ratio may appear unusual so I will provide a definition. We will be splitting the Income Statement in terms of operational and strategic expenses to ensure that our operational and strategic expenses are in alignment to achieve financial objectives.

5.8 Ownership

Today, the company is equally owned by all four founders, but in 2007 we will be establishing a ISO pool, a management & employees pool, and we will experience dilution to raise capital. Over the next few years we will experience levels of dilution as necessary to fund our efforts and achieve our objectives. We do have two clear options for an exit strategy in either an IPO or Sale, so the ownership structure is not as clear as we move toward FDA approval in 2010.

Table 19 2006 Shareholders

Shareholders	**Percentage**
Frank Reynolds	25%
Bob Langer	25%
Yang "Ted" Teng	25%
Rajiv Saigal	25%

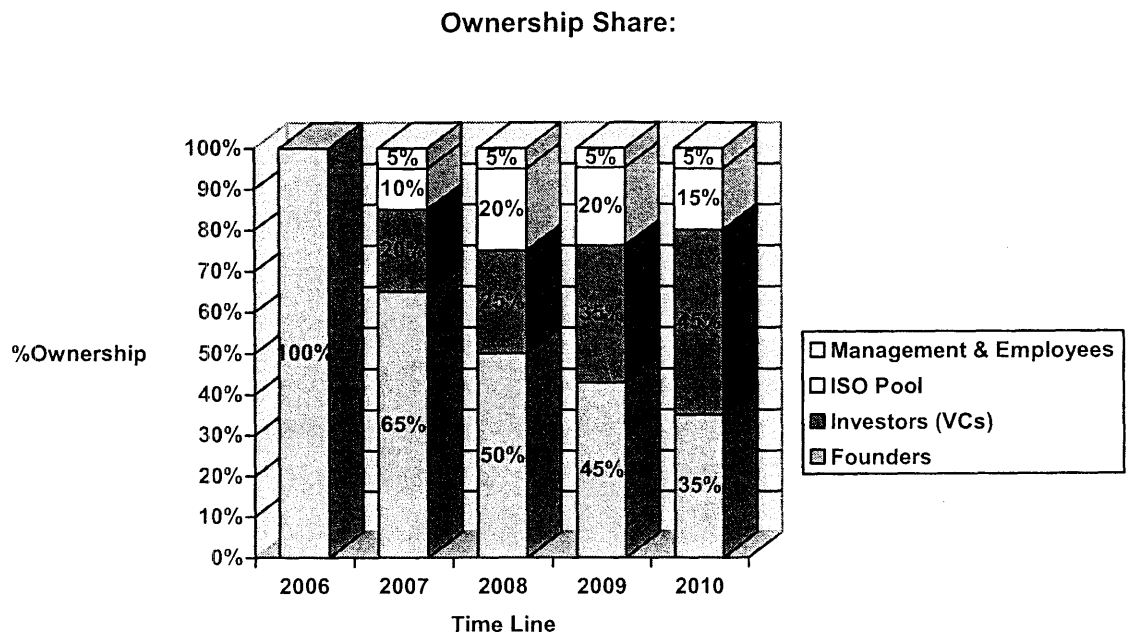


Figure 11 Ownership Distribution

5.9 InVivo Therapeutics™ Corporation Management Team

5.9.1 Operations Team

- Frank Reynolds, Chief Executive Officer & Founder
- Paul Mraz, Chief Operating Officer
- Yang (Ted) Teng: MD, Ph.D. Chief Science Officer & Founder
- Rajiv Saigal, Biomedical Engineering
- Konstantin Rozanov, Finance
- Michael Panos, Sales

5.9.2 Board Members

- Frank Reynolds,
- Bob Langer, Sc.D.
- Yang D. Teng, M.D., Ph.D.

5.9.3 Scientific Advisory Board

- Bob Langer, Sc.D.
- Yang D. Teng, M.D., Ph.D.
- Rajiv Saigal

5.9.4 Business Advisory Board

- Stan Lapidus, President & CEO of Helicos Biosciences Corporation
- Paul Mraz, Chairman & CEO of Angstrom Medica
- Arnoldo Hax, Ph.D.
- Pradeep Gupta,
- James Joseph Skeffington, Esq.
- Ramana Nanda,

5.9.5 Detailed Team Bios

Frank Reynolds, CEO, and Founder,

Mr. Reynolds is responsible for commercializing novel neurological science and technologies that were developed at Massachusetts Institute of Technology, Harvard Medical School, and Children's Hospital of Boston.

Prior to founding InVivo Therapeutics™, Mr. Reynolds was Director, Global Business Development for Siemens Corporation were he was responsible for new business revenue in 132 countries. At Siemens, I won numerous awards including the 2005 Global Presidential Sales Award, and he was a 2004 Top+ USA Strategy Award winner

for his initiatives in global sales force strategy and collaboration. Mr. was Founder and CEO of Expand The Knowledge, Inc from 1997-2002. In addition Mr. Reynolds has 10 years management experience primarily in healthcare related fields

Mr. Reynolds has been an Executive Board Member of the Ireland Chamber of Commerce of the United States since 1998. He is currently a candidate in the Sloan Fellows Program at the Massachusetts Institute of Technology and he is completing coursework at the Harvard Business School. He holds a M.S. in Technology Management Program from The Wharton School of Business and a M.S. in Engineering from the University of Pennsylvania. Mr. Reynolds also has a M.S. in Health Administration from Saint Joseph University, an M.S. in Management Information Systems from Temple University, an M.S. in Psychology from Chestnut Hill College, and he received his Bachelors of Science in Marketing from Rider University.

Paul Mraz: Chief Operating Officer

Mr. Mraz has been active in the medical Device and Life Sciences industry for over 15 years with a focus on medical devices for the spine. He has been involved in companies large and small with roles in executive management, product development, marketing, sales management and business development - all on a global basis.

Mr. Mraz currently serves as Chairman and CEO of Angstrom Medica, Inc., a biomaterials and medical device company located near Boston, Massachusetts (USA). Angstrom Medica is engaged in the development and commercialization of structural, nanocrystalline calcium phosphate based medical devices for the spinal, sports medicine, trauma and general orthopedics markets.

Prior to Angstrom Medica, Mr. Mraz was a principal of Link Spine Group Inc., a start-up company that developed the world's first total disc replacement for the lumbar spine and was acquired by Johnson & Johnson in 2003. Mr. Mraz was also a key management team member of three other early-stage medical device companies and his early experience includes positions at Figgie Medical Systems, Ortho Development Corporation (acquired by Japan MDM) and Marlow Surgical Technologies Inc. (acquired

by Cooper Surgical) as well as DePuy, Inc. and DePuy Spine (formerly AcroMed Corporation) - both acquired by Johnson & Johnson in 1998.

Mr. Mraz also currently serves as a Director of SuperDimension, Ltd. (Herzliya, ISRAEL), an emerging world leader in the minimally-invasive diagnosis and treatment of lung disease (e.g. cancer, emphysema) via interactive real-time guidance of endoscopic tools and bronchoscopy.

Mr. Mraz received a B.S. degree in Mechanical Engineering from Lafayette College and a M.S. degree in Mechanical Engineering and Biomechanics from Case Western Reserve University. Mr. Mraz holds six U.S. Patents for various medical devices and is an active advisor to numerous venture capital groups and other entrepreneurs in the medical device industry worldwide.

Yang (Ted) Teng: MD, Ph.D.- Chief Science Officer & Founder,

Dr. Teng studies molecular mechanisms that underlie or enhance experimental therapeutic strategies of neural stem cells for the frequent and challenging issues of experimental spinal cord injury (SCI) and neurodegenerative diseases that are clinically relevant. As a member of the Harvard Stem Cell Institute, he directs a team of investigators at CHB/BWH and VA Boston Healthcare System with primary focus on using polymer scaffolds to potentiate neural stem cell (NSC) mediated repair of the injured spinal cord through mitigating neurodegeneration and creating regeneration promoting environment. Dr. Teng has made significant contributions in understanding secondary injury mechanisms and respiratory dysfunction after experimental SCI. His team recently established the first animal SCI model showing chronic respiratory abnormalities.

They are continuing to develop new drugs into clinical applications to improve post-SCI respiratory function, and to test the potential of NSCs in reconstructing respiratory

centers. Dr. Teng's lab finished the first investigation of the respiratory dysfunctions in a murine model of ALS (Lou Gehrig's Disease). Their stem cell treatment has successfully doubled the longevity of the ALS mice. He and his collaborators in the past year discovered novel mechanisms that are accountable for augmenting therapeutic roles of human NSCs to treat a primate model of Parkinson's disease. They also initiated new study projects on examining and treating muscular and bone disorders resulting from SCI. His work on finding a new mechanism to treat SCI is included in the HMS dean's 2004 report. Dr. Teng has authored and co-authored 13 papers in 2003-2004.

Dr. Teng continued his commitment to medical education. He lectured in the Harvard-MIT's Health Science & Technology graduate program, and grand rounds in the Departments of Neurosurgery, Physical Medicine & Rehabilitation, and SCI service at Harvard and VA. He's been devoted to the academic training of postdoctoral fellows, clinical trainees, and medical school students at Spaulding Rehabilitation Hospital, Children's Hospital Boston, Brigham & Women's Hospital, VA Boston Healthcare System and Harvard Medical school.

Administratively, Dr. Teng continues as the Director of the SCI research in the VA Boston Healthcare System, and as the coordinator of the academic programs for the VA national advanced SCI fellowship program. Nationally and internationally, Dr. Teng is a panel member for the brain disorder and clinical neuroscience study section of the NIH, and the motor neuron disease study section of the U.S. Army Medical Research and Materiel Command (USAMRMC), Department of Defense. He is an invited study section member on the grant review panels of the Health Research Board of the Ireland, the Swiss National Science Foundation, and the South Carolina SCI Research Fund. He also serves as panel and guest reviewers for academic journals including Exp Neurol, Nature Biotech, J Neurosci, J Neurochem, J Biomat App, Neurobiol Dis, Neurosci Lett, and Meth Find Exp Clin Pharmacol.

Dr. Teng, as the mentor and sponsor, received the 2004 ERF New Investigator Award from the Foundation for Physical Medicine & Rehabilitation and the American Academy of Physical Medicine & Rehabilitation.

Konstantin Rozanov, Finance and Accounting

Ph.D. candidate MIT-Sloan Dept of Economics, Finance, and Accounting. Consulting includes the banking, manufacturing, international investments sectors. Strong focus on accounting and controls

Michael Panos, Sales

Mr. Panos has excelled in various roles during his 10+ years with Stryker Corporation, a global medical device company with more than $5B in sales worldwide. He is currently charged with Northeast business development for products in the burgeoning spinal, neurological & ENT surgical device markets. Prior to this assignment, Mr. Panos has been recognized for his leadership & distinguished performance at Stryker Corporation as a Sales Manager (Northeast, 2003-2005); *as a* Sales Representative (Orlando, FL: 1998-2002); and in Product Management (Kalamazoo, MI: 1996-1997). He earned a B.S. in English (1993) and a M.Ed. (1994) from Boston College, where he was a scholarship football player. Mr. Panos currently resides in Boston.

Bob Langer, Sc.D. - Founder, Board of Directors, Scientific Advisory Board

Robert S. Langer is one of 14 Institute Professors (the highest honor awarded to a faculty member) at the Massachusetts Institute of Technology (MIT). Dr. Langer has written over 860 articles. He also has over 500 issued or pending patents worldwide, one of which was cited as the outstanding patent in Massachusetts in 1988 and one of 20 outstanding patents in the United States. Dr. Langer's patents have been licensed or sublicensed to over 100 pharmaceutical, chemical, biotechnology and medical device companies; a number of these companies were launched on the basis of these patent licenses. 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;1999-2002 Dr. Langer has received over 140 major awards. In 2002, he received the Charles Stark Draper Prize, considered the equivalent of the Nobel Prize for engineers and the world's most prestigious engineering prize, from the National Academy of Engineering. He is the also the only engineer to receive the Gairdner Foundation International Award; 65 recipients of this award have subsequently received a Nobel Prize. Among numerous other awards Langer has received are the Dickson Prize for Science (2002), Heinz Award for Technology, Economy and Employment (2003), the Harvey Prize (2003), the John Fritz Award (2003) (given previously to inventors such as Thomas Edison and Orville Wright), the General Motors Kettering Prize for Cancer Research (2004), the Dan David Prize in Materials Science (2005) and the Albany Medical Center Prize in Medicine and Biomedical Research (2005), the largest prize in the U.S. for medical research. In 2006, he was inducted into the National Inventors Hall of Fame. In 1998, he received the Lemelson-MIT prize, the world's largest prize for invention for being "one of history's most prolific inventors in medicine". In 1989 Dr. Langer was elected to the Institute of Medicine of the National Academy of Sciences, and in 1992 he was elected to both the National Academy of Engineering and to the National Academy of Sciences. He is one of very few people ever elected to all three United States National Academies and the youngest in history (at age 43) to ever receive this distinction.

Forbes Magazine (1999) and Bio World (1990) have named Langer as one of the 25 most important individuals in biotechnology in the world. Discover Magazine (2002) named him as one of the 20 most important people in this area. Forbes Magazine (2002) selected Langer as one of the 15 innovators world wide who will reinvent our future. Time Magazine and CNN (2001) named Langer as one of the 100 most important people in America and one of the 18 top people in science or medicine in America. Parade Magazine (2004) selected Langer as one of 6 "Heroes whose research may save your life." He has served, at various times, on 15 boards of directors and 30 Scientific Advisory Boards of such companies as Wyeth, Alkermes, Mitsubishi Pharmaceuticals, Warner-Lambert, and Momenta Pharmaceuticals Dr. Langer has received honorary doctorates from the ETH (Switzerland), the Technion (Israel), the

Hebrew University of Jerusalem (Israel), the Universite Catholique de Louvain (Belgium), the University of Liverpool (England), the University of Nottingham (England), Albany Medical College, the Pennsylvania State University, Northwestern University and Uppsala University (Sweden). 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.

Rajiv Saigal- Founder and Scientific Advisory Board

Rajiv will receive his Ph.D. from the medical engineering/medical physics program at the Harvard–MIT Division of Health Sciences and Technology. As a National Science Foundation Graduate Research Fellow in Dr. Robert Langer's lab, his primary research interests are in neural engineering, electrically conductive biomaterials, and spinal cord injury.

Rajiv received a B.Sc. in Electrical Engineering summa cum laude from the Georgia Institute of Technology in 2000 and was named Mr. Georgia Tech for outstanding service, leadership, and scholarship. He received a M.Sc. in biomedical engineering from Aalborg University (Denmark) in 2002, completing a thesis project on intraspinal microstimulation with Dr. Vivian Mushahwar.

InVivo Business Advisory Board

Stan Lapidus, President & CEO of Helicos Biosciences Corporation

Mr. Lapidus is an experienced life-science entrepreneur. Helicos is his third life-science start-up. In 1995 he founded EXACT Sciences Corporation (NASDAQ: EXAS), an applied genomics company that develops and markets non-invasive, DNA-based methods for early detection of colorectal and other common cancers. He served as President from 1995 through 2000 and Chairman of EXACT Sciences' Board of

Directors from 2000 through 2005. He continues to serve as a board member. Prior to EXACT, Mr. Lapidus founded Cytyc Corporation (NASDAQ:CYTC) and was President and CEO from 1987 through 1994. In addition to his entrepreneurial activities, Mr. Lapidus holds academic appointments in the Pathology Department at Tufts University Medical School and MIT's Sloan School of Management. He earned a BSEE from Cooper Union. He has served as a trustee of Cooper Union since 2002. Mr. Lapidus holds 29 issued patents.

Arnoldo Hax, Ph.D. - Alfred P Sloan Professor of Management MIT-Sloan

Arnoldo C. Hax is the Alfred P. Sloan Professor of Management at the Sloan School of Management of the Massachusetts Institute of Technology. Dr. Hax served as Deputy Dean of the Sloan School from 1987 through 1990. He is currently the Director of the Track in Strategic Management and Consulting at Sloan School.

He received his M.S. at the University of Michigan and his Ph.D. at the University of California, Berkeley. Prior to joining M.I.T. in 1972, he was a member of the faculty at the Harvard Business School and a senior consultant for Arthur D. Little, Inc.

He has published extensively in the fields of strategic planning, management control, operations management, and operations research. He has participated in a great many executive programs at M.I.T., in many U.S. universities and corporations, and in most countries in Europe, in Latin America, and in Asia-Pacific.

In addition, Dr. Hax has wide consulting experience, both in the United States and abroad, where he has consulted with Synthes, Capitol One, General Motors, Motorola, Digital Equipment Corp., Siemens, Unilever, P&G, Castrol, Waste Management, ABB Asea Brown Boveri, DMK-China among others. He has assisted several Fortune 500 companies in the development of formal strategic planning process. He has been granted a Dean's Award for Excellence at the Sloan School of Management, M.I.T.

Pradeep Gupta, Managing Partner of WireFree Ventures

Pradeep is a Sloan Fellow 2006, and his experience as a successful entrepreneur along with his financial expertise is invaluable to InVivo's strategic planning initiatives. Pradeep has spent his entire career in Silicon Valley, where he has established key relationships that drive his business initiatives today. Pradeep founded Object Stream Inc, in 1997 and sold the firm to Cisco in 2001 for $180M. In 2001, he was Founder & CTO of Cambria Corporation where he commercialized DARPA research and raised the necessary capital to hire a CEO and 22 employees while establishing a strategic alliance with AT&T. Pradeep is well connected to the venture base in Silicon Valley and is the Managing Partner of WireFree Ventures in San Francisco, Ca. Pradeep has guided venture firm investment and he is a member of the Board of Vinewyck where he guides corporate strategy and strategic partnerships.

James J. Skeffington, Esq.,

James provides InVivo Therapeutics™ will a broad range of legal guidance. James J. Skeffington, Jr. is a 2006 Fellow in the Sloan Fellows Program for Innovation and Global Leadership at the MIT Sloan School of Management. Prior to becoming a Sloan Fellow, Skeffington was an attorney at Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., where he practiced all aspects of corporate and transactional law including registered public offerings, mergers and acquisitions, venture financing and general business counseling. Skeffington also advised public company clients with respect to corporate governance matters, including compliance with the Sarbanes-Oxley Act of 2002. Skeffington has been a Trustee of Children's Hospital Boston since 2002. He is also a Trustee of the Adopt-A-Student Foundation, an initiative founded in 1990 to provide tuition for low-income high-school students. Jim serves on the Executive Committee of the Fulton Professional Group, an alumni network that awards scholarships to certain needs-based students at Boston College. In 2002, he received Boston College's Annual Rising Star Award for his various development efforts. Skeffington received his B.A. from Boston College, an M.Litt. in Management, Economics and Politics from

University of St. Andrews in Scotland, and a J.D. from Georgetown University Law Center.

Ramana Nanda

PhD candidate in Entrepreneurial Finance at MIT's Sloan School of Management. His research is in the area of entrepreneurial finance. Prior to starting his PhD at MIT, Ramana was project manager in the London and New York offices or Oliver, Wyman & Company, a strategy consulting firm focused on the financial services industry. Ramana has a BA and MA in economics, from Trinity College, University of Cambridge.

5.10 Conclusion

We will establish ourselves as the market leader for spinal cord injury repair. In addition to the high humanitarian benefits we will provide patients, we will deliver strong financial results with profits exceeding $185,000,000 by 2015. Our assumptions for both revenue and costs are conservative and built on firm logic, so we have a high degree of confidence that we can not only achieve the financial projections, but also exceed our forecasts. Achieving each milestone event will bring great value to our shareholders, and key to achieving our milestones will be our strong management team, We have a team of experienced entrepreneurs, and scientists who have an solid history of success

Chapter 6: The InVivo Integrative Strategic Framework

We started with a vision statement that identified how InVivo positioned ourselves, and we completed our analysis of InVivo's value proposition to customer segments, bundle of competencies, mission of our business, the strategic agenda, financial evaluation and our management team.

Figure 10 identifies the building blocks that we used to develop our organizational strategy. Each component has a logical fit into each other as the strategy builds to form a firm foundation for InVivo's Growth.

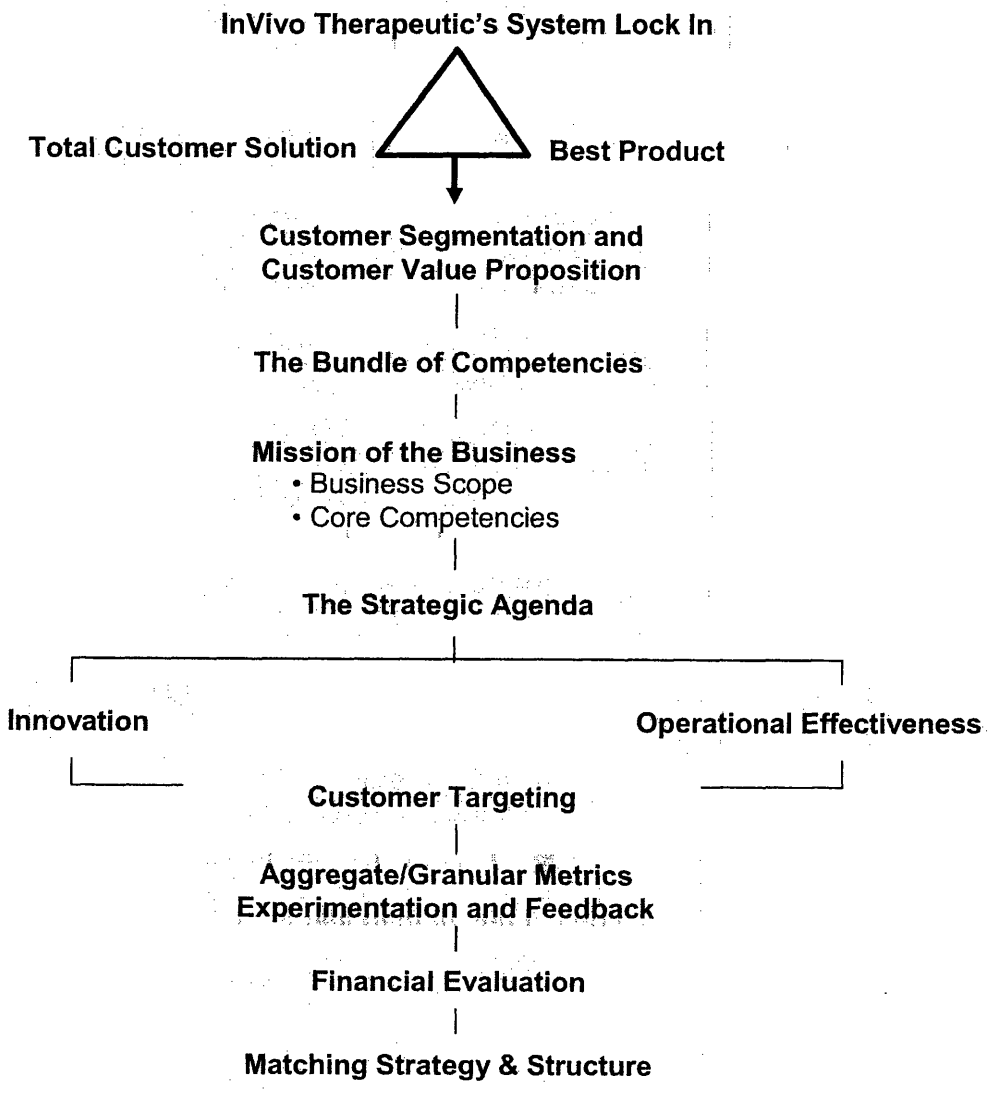


Figure 12 InVivo's Integrative Strategic Framework

Our process to creating this integrated strategic framework has been a detailed and thorough approach. We have explored our options with the necessary breadth and depth of knowledge to ensure we will not only effectively get our first product to market, but that we also provide our shareholders with a maximized return on investment.

At the heart of our strategy is our strategic intent. We have defined our strategic intent through a top-down approach from the CEO to the production engineers. It is rare to have a CEO suffer from a disease with the impact that a SCI has from a humanitarian and financial viewpoint. Our strategic intent comes loud and clear our CEO every day, and we will commercialize the first treatment for spinal cord injury repair. Our triangle is an effective tool for describing a meaningful strategic position. We are certain that we can obtain system lock-in and therefore have 4 of our 7 segments positioned between the total customer solution, and system lock-in. We have stated our mission and it is based on our core competencies, and incorporates a clear understanding of our business scope. We formed a concise strategic agenda based on all of the information that we have collected. We support our agenda be focusing InVivo's resources on innovation, customer targeting, and operational effectiveness. In the end our financial performance will determines whether or not we are a success, so we have identified 6 granular metrics to provide an assessment for how we are meeting shareholders objectives.

6.1 Value Proposition to Customer Segments

The seven dimensions are products, services, customers in segment, channels, end users, complementors to the segment, and unique opportunities for us to align with the segment. We then identify the value we will offer our customers. The sources of that value are the set of experiences that we provide our customers, the set of "value delivery systems"[19] needed to provide the experiences, and the value appropriation for both the customer and for InVivo Therapeutics

6.2 InVivo's Bundle of Competence to achieve objectives

InVivo has many competencies that on their own add great value, but when we bundle them into an integrative strategic framework we will create an unshakeable bond with our customers. We focus our competencies on the customer at all times. We will provide the best product, a total customer solution, and lock the into our system. In this section we will identify our competencies and the system that will ensure our customers and InVivo benefit from varying combinations.

6.3 The Mission

InVivo's mission is clear, we intend to be the dominant exchange in the SCI repair market. However, if we are to attain and then maintain a dominant position we need to keep our internal organization focused our product Scope, services scope, customer scope, end-user scope, channel scope, complementor scope, geographic scope, unique competencies.

InVivo's Mission Statement

Providing innovative neurological treatments for the Spinal Cord Injury patient through a network of global healthcare professionals

- Through patented materials and processes to treat in-cord spinal injuries
- Utilizing world class research from MIT and Harvard
- Providing multiple modalities of treatment to treat the physical deficits and to improve quality of life issues
- Delivering pharmaceutical solutions to enable the healing process
- Exploring new combinations of treatment options to maximize outcomes
- Moving research from the lab to the physicians black bag
- Creating an unmatched web based InVivo information portal for the clinician, patient, and interested parties

- Focused determination to provide a continuum of care and treatments from point of injury through the period of recovery and healing

6.4 The Strategic Agenda For InVivo

Our strategic agenda is comprised of four components- strategic thrusts, managerial accountability, business processes, and performance. To We studied the market to fully understand the demand side of the business, and we have studied the category market segment to fully understand the supply side, and as a result we are now able to identify the action-oriented issues that collectively capture the totality of the tasks needed to implement our mission and the desired strategic positioning of our business.

6.5 Financial Evaluation

We will begin to capture mindshare in 2007. We expect CE Mark in 2009 and FDA approval in 2010. We are forecasting $16M for revenue in 2010. We are forecasting revenue of $89.6M in 2011. We will expand sales effort for 2012 and we forecast $203.4M in 2012. We expect global revenues for 2013 to be $447.6M and global revenues in 2014 to be $502.8M. We will be focused on low cost production, and we have a solid manufacturing plan. We will have a strong profit position and earn our first profit in 2011.

InVivo has a two fold exit strategy. We believe that we will be an extremely attractive target for a number of companies in this space, since our product is extremely complementary to existing products in the market. There are 8 main players in this market: Medtronic, Johnson &Johnson, Synthes, Kyphon, Biomet, Stryker, Zimmer, Abbott Spine, Nuvasive, that account for 88.9% of the market share. As can be seen from the recent acquisition of Link-Spine by Johnson & Johnson, the valuations in the spine medical device market are to the range of 5X-6X Revenues. Given our projected revenues over the next several years, protected by our patents, we expect that a number of companies will be very interested in our product. To further this end, we have Bob Langer, and Stan Lapidus on our advisory board, and we have already had

indications of interest in our product from Synthes, and Medtronic. We also believe that there will be high demand from the public markets if we were to IPO. Given that we expect to have positive earnings by 2011, this should position us well for either a successful acquisition or an IPO within the next 5-7 years.

6.6 Conclusion

Our process to creating this integrated strategic framework has been a detailed and thorough approach. We have explored our options with the necessary breadth and depth of industry knowledge to ensure we will not only effectively deliver our first product to market in 2010, but that we also provide our shareholders with a maximized return on investment.

At the heart of our strategy is our strategic intent. We have defined our strategic intent through a top-down approach from the CEO to the production floor. InVivo will be led by a passionate and driven CEO and in the end we will bring the first Neuro-Tissue engineered device to market for the treatment of spinal cord injuries.

We will not fail the spinal cord injury patient.

Endnotes

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