

Name: charles sonia omotese

18/mhs02/057

Nursing science

Mhs

Food security

#### Executive Summary

MedNexus, Inc. (the company) is a medical device development company that has designed and patented medical devices which it plans to produce and market. A magnetic muscle stimulator/field generator has been designed with the participation of leading medical personnel and biomedical engineers. One patent is initially incorporated.

#### Allopathic Medicine

One market addresses the unanswered need of atrophy prevention/treatment in conditions resulting in patient immobilization for greater than two weeks. After two weeks of immobilization, the average muscle loses over 30% of its mass, resulting in an increased time to complete recovery. A new and innovative design, dubbed the MedStim system, has been created to answer this need for an effective, easy-to-use atrophy prevention/treatment device. The number of indications for this device is expected to rise as further research on the benefits of pulsed magnetic fields unfolds. For example, pulsed field magnetism has recently been shown in controlled studies to be an effective treatment in accelerating the healing of skeletal fractures.

The market for magnetic stimulation devices in allopathic medicine is existent, but in the embryonic stages and subject to explosive growth once the technology proves cost-effective. This potential market has reached an estimated 4.2 million patients in the United States. The new and innovative device designed to target this market has been named the MedStim system.

#### Alternative Medicine

Another market addresses an unanswered need in the alternative medicine market for a device which will provide a more powerful and consistent therapeutic magnetic field. Dynamic magnetic field therapy (the treatment of soft tissue with variable magnetic pulses) is currently thought to have beneficial effects on circulation, immune system function, wound healing, etc., in the alternative healthcare sector and these effects are thought to be proportional to the strength of the magnetic field generated. The new and innovative design created to answer this need for a more powerful therapeutic magnetic field in alternative medicine has been named the TheraMag system. This market is in existence and is expected to have the potential of approximately 40 million customers in the United States on our starting date.

#### Technology

Patent applications on the company's first market entries have been filed using a patent agent specializing in biomedical device patents. MedNexus' technology utilizes the principal that a

current in a coil will generate a magnetic field which will, in turn, generate a current in any conductive material within this field. This model is currently effectively applied in diagnostic studies in which single nerves are stimulated with magnetism for diagnostic purposes alone. Using this model, and considering the human nerve to be the conductive material, MedNexis has developed an electromagnetic device which will painlessly stimulate human muscles to contract. Applications of this technology are numerous, with the following devices being those initially marketed:

MedNexis' patented device will be tailored to effectively stimulate muscle. This will require larger electrical currents, greater functionality, and a wider range of settings. This device will be marketed for mainstream, allopathic medicine

TheraMag- MedNexis' patented device will bathe tissue in a magnetic field without causing contraction of the muscle. This device will be marketed for alternative applications.

### Strategy

MedNexis will target the following two markets: allopathic and alternative medicine. In order to effectively distance the two products from possible negative connotations associated with alternative medicine in the field of allopathic medicine, the two devices will be given separate and distinct names: MedStim for the allopathic medicine device and TheraMag for the alternative medicine device.

MedStim will be distributed through channels dominated by large distributors and strategic association with these players will be key to gaining acceptance in this market. Furthermore, physicians will demand randomized, controlled study data, the production of which will be the focus of the bulk of MedNexis' early efforts in this market.

TheraMag will be distributed to alternative medicine centers which are less centralized and direct sales will also be possible. Less scientific proof is required by this market, and entrance will be immediate once the FDA issues an Investigational Device Exemption.

### Regulatory Issues

Through obtaining an Investigational Device Exemption and clearly labeling the product "For Investigational Use Only," FDA regulations will be satisfied and market entrance will be expedited. Acceptance of these products based on successful research results will drastically increase demand and allow for expansion to foreign markets

### Major Milestones

Animal stage Research and Development underway, early Year One.

Extend patent coverage to Australia, Europe and Canada, middle Year One

Human clinical trials underway, middle Year Two.  
Research studies published, end of Year Two.  
TheraMag for sale, end of Year One.  
MagnaStim for sale, labeled as 'For Investigational Use Only', end of Year Two.  
Profitability established by Year Four.  
Competitive Advantage

While the MagnaStim and TheraMag devices are effective and user-friendly, with multiple home healthcare applications, all the competing devices currently on the market are only partially effective or difficult and awkward to use for the recommended therapeutic treatment. MedNexis will use its patented designs to fill the need in the market for an easier to use, more effective magnetic stimulator/field generator.

## Financial

Based on detailed financial projections, if the company receives the \$750,000 in funding, it will operate profitably by Year 3. The company projects \$23.5 million in sales with a formidable net profit in Year 3, with projections based on penetration of less than 3% in any market segment.

### Company Summary

MedNexis will research and develop biomedical devices, including the MedStim and TheraMag systems, to aid in the treatment of a variety of diseases. Its customers are patients afflicted with any condition resulting in muscular atrophy, as well as those patients interested in the proposed alternative benefits of magnetic therapy. The company is currently developing its patent-applied technology to final product and approval stage. It is also seeking to establish its corporate identity in the medical products field. The company's growth strategy involves the following objectives:

Complete the patent process.  
Establish corporate identity, brand names, trademarks.  
Set a clear business direction and both long-term & short-term goals to be achieved.  
Build staff and company infrastructure.  
Complete clinical trials and obtain FDA approval.  
Continue R&D and product development.  
Maintain market performance by linking remuneration packages for key personnel with the performance of the company through stock options and other salary schemes.

### 2.1 Company Ownership

The company will be incorporated in North Carolina. It will have authorized 15,000,000 ordinary shares and 150,000 preferred shares. The rights and privileges of these shares will be stated in the company's Articles of Incorporation.

The proposed share capital of the company prior to capital raising

Owner	Percentage of Shares Owned
Daniel Burnett	40%
Mike Marriott	20%

Nathan Wain 20%

Brian Bell 20%

The company is expected to raise seed capital of approximately \$750,000 prior to the commencement of its business operations. Additional working capital is anticipated and will be raised in year 2 of operations. Capital raising exercises are anticipated to be conducted in 2 portions (i.e. Year 0 and Year 2) raising approximately \$6.75 million in funds.

## 2.2 Start-up Summary

The key elements in the start-up plan for the company are:

The legal expense for filing all patent applications.

The establishment of a corporate identity.

The location of business.

Funding of working capital requirements, purchases of other equipment and assets deemed necessary for the principle operating activities of the company, and additional capital raising alternatives.

Salary for key managers and staff of the company.

Formulation of the strategic business plan.

Costs of raising capital through private placement

Approximately \$250,000 was raised from the founders of the company for these purposes. This funding will be available in early 2001 and these tasks have either been completed successfully or are in the final process of completion.

These are treated purely as start-up expenses and initial working capital by this plan. The \$250,000 is treated as cash-on-hand as of the start of this plan on January 1, 2001. The remainder of the start-up capital required, as well as capital required for the continuation of operations in the first 6 months will be provided by selling the shares via a private placement to key investors. The capital obtained through this fund-raising exercise is expected to provide an additional \$750,000 and the business plan calls for these funds to be infused for the purposes of operating the business, in accordance with this business plan.

Need actual charts? We recommend using LivePlan as the easiest way to create graphs for your own business plan. Create your own business plan

### START-UP FUNDING

Start-up Expenses to Fund \$168,000

Start-up Assets to Fund \$82,000

TOTAL FUNDING REQUIRED \$250,000

### Assets

Non-cash Assets from Start-up \$0

Cash Requirements from Start-up \$82,000

Additional Cash Raised \$0

Cash Balance on Starting Date \$82,000

TOTAL ASSETS \$82,000

Liabilities and Capital

Liabilities

Current Borrowing \$0

Long-term Liabilities \$0

Accounts Payable (Outstanding Bills) \$0

Other Current Liabilities (interest-free) \$0

TOTAL LIABILITIES \$0

Capital

Planned Investment

Daniel Burnett \$100,000

Nathan Wain \$50,000

Mike Marriott \$50,000

Brian Bell \$50,000

Additional Investment Requirement \$0

TOTAL PLANNED INVESTMENT \$250,000

Loss at Start-up (Start-up Expenses) (\$168,000)

TOTAL CAPITAL \$82,000

TOTAL CAPITAL AND LIABILITIES \$82,000

Total Funding \$250,000

Need real financials We recommend using LivePlan as the easiest way to create automatic financials for your own business plan. Create your own business plan

START-UP

Requirements

Start-up Expenses

Legal \$50,000

Stationery etc. \$500

Brochures \$3,000

Consultants \$3,000

Insurance \$3,000

Rent \$1,000

Research and development \$100,000

Expensed equipment \$6,500

Other \$1,000

TOTAL START-UP EXPENSES \$168,000

Start-up Assets

Cash Required \$82,000

Start-up Inventory \$0

Other Current Assets \$0

Long-term Assets \$0

TOTAL ASSETS \$82,000

Total Requirements \$250,000

2.3 Company Locations and Facilities

The company will initially be based in the Research Triangle Park area in North Carolina.

In view of the strategic plan to contract with a third party for all manufacturing requirements, the facilities needed will be mainly offices for personnel and storage space for inventory. After Year 5, when the market for our products reaches our anticipated milestone, the company will explore the feasibility of constructing its own manufacturing facilities.

#### Products

MedNexis will initially market its MedStim system to the atrophy prevention/treatment market, while the TheraMag system will be marketed to the alternative medicine market. The primary differences between these two products will be the amplitude and frequency of the magnetic field generated and the programmability/capability of the logic controllers. The amplitude of the magnetic field generated by the TheraMag system will be significantly less than that generated by the MedStim system in order to avoid functional stimulation of the underlying muscles. The frequency of stimulation, though, will be greater in the TheraMag system in order to provide a more consistent therapeutic magnetic field desired for alternative medicine applications.

Both systems will be sold in two parts, the programmable logic controller (LC), which will generate the electrical impulses, and the array of overlapping coils (AOC), which will generate the magnetic fields. The AOC will be available in multiple designs, each of which will contain the signature overlapping coils and will be simple to apply. Every design will be available in multiple sizes to accommodate patients of various dimensions. The technology used in these products is the subject of a patent which is currently in the application process.

### 3.1 Product Description

A detailed and technical description of both the MedStim and TheraMag systems follows:

#### Therapeutic Magnetic Field Generators: The MedStim and TheraMag Systems

**Applications:** The prevention/treatment of muscular atrophy in conditions resulting in immobilization and the generation of a non-stimulatory magnetic field for alternative medical therapy purposes.

**Scope:** This innovation applies to both stimulatory and non-stimulatory magnetic field generation used in the treatment of a variety of diseases and ailments. The MedStim and TheraMag systems are two-component devices designed to deliver a powerful magnetic field to the subcutaneous tissue. The logic controller (LC) generates the electrical current impulse through powerful capacitors and the array of overlapping coils (AOC) provides the necessary pathway for the current to generate the desired magnetic field.

#### Current Technology:

##### Atrophy Prevention/Treatment

Currently bulky, difficult to use technology exists which provides for therapeutic, functional stimulation of musculature using magnetic induction of neural impulses. These devices, though,

consist of only a single focus of stimulation and must be manipulated by a trained, experienced user in order to effect a useful therapy. The main limitations of the existing magnetic stimulation devices are:

Inability to treat multiple muscle groups, or even adequately treat a single muscle group, without a highly skilled, trained operator manipulating the device throughout the lengthy process.

Inconsistent treatment regimens which are time intensive and costly due to the necessary continued presence of the trained operator.

Limited effectiveness due to lower ranges of both gauss (a rating of the strength of the magnetic field) and joules (a measure of the actual energy flowing through the coil).

There is also technology which stimulates musculature using transdermal electrical stimulation. Electrical stimulation is a well-developed field in sports medicine and this form of therapy is currently widely used. The main limitations to electrical stimulation are as follows:

Stimulatory levels of electricity are frequently painful and may result in contact burns.

Muscle groups that can be stimulated are restricted to those which are superficial and easily reached transdermally. Deep muscle groups cannot be stimulated without more powerful electrical impulses which cause significant discomfort. Due to this limitation, stimulation of superficial muscles is usually submaximal as well.

Alternative Medicine

There is currently technology for providing non-stimulatory magnetic fields for alternative medicine applications, but none with an overlapping series of coils activated by powerful capacitors. The main limitations of current non-stimulatory magnetic field generators are as follows:

Limited strength of magnetic field due lack of powerful field induction mechanism.

Inability to penetrate deeply throughout the treatment area due to discreet, nonoverlapping magnetic field generators of lesser power.

Difficulty of use due to constant manipulation of the single coil required to treat any significant region of the body.

MedNexis Technology:

In generating a magnetic field, impulses of electric current originating from the LC flow through the AOC in a predetermined sequence. The flow of electrical current through the coil induces a strong magnetic field (Faraday's Law), which in turn induces a current in motor neurons perpendicular to the magnetic field, causing involved muscles to contract. Sufficient muscle activity is induced to prevent atrophy of the muscle group affected. Therapeutic stimulation of peripheral motor neurons and muscle tissue for the prevention of atrophy and/or the augmentation of muscular mass may be clinically indicated for a variety of medical conditions including fractures immobilized beyond 2 weeks, Induced Paralysis for Mechanical Ventilation, Persistent Vegetative State, Traumatic Paralysis, and Guillain-Barre Syndrome. Potential indications now being

researched include: bone healing, preventing deep venous thrombosis, and increasing range of motion.

Logic Controller- Requires both a powerful 40,000 microFarad capacitor and a 2:1 step-up transformer capable of generating 250 Volts for the MedStim system. A less powerful (and less expensive) 10,000 microFarad capacitor will be sufficient for the TheraMag system and a transformer will not be necessary. Both systems will require multiple discrete discharge channels so that coils in the AOC may be activated individually. A standard 110 Volt power source will be needed to generate the necessary electrical impulses. Any channel not being used for stimulation will be grounded to prevent electrical interference of the stimulated coil. The frequency and amplitude of stimulation will be determined by the Logic Controller console. (See Fig. 1, 2, and 3 in Appendix)

Array of Overlapping Coils- Each copper insulated coil in the series will be connected to a single channel on the Logic Controller. Current, will flow in through the logic controller with discharge of the capacitor then out through a grounded lead in the logic controller. The firing of individual coils will occur in a rapid, yet controllable, sequence and, in the case of the MedStim system, will result in the stimulation of motor neurons in the subcutaneous tissue perpendicular to the induced magnetic field. (See Fig. 1 and 4 in Appendix)

Clinical Advantages:

#### Atrophy Prevention/Treatment

The main clinical advantage of the MedStim system is that it is able to provide maximal stimulation of deep musculature without significant discomfort to the patient. This is in direct contrast to the frequently painful, submaximal electrical stimulation currently used. The LC is an easy-to-program device and the AOCs are easily applied in any environment, making them an attractive option in home health situations. Due to its ease of application and use, the MedStim system will provide a means of preventing, not just reversing, disuse atrophy with daily use on immobilized patients. Also, as additional indications arise for magnetic field therapy, the MedStim system will be in an ideal position to fill these needs due to its highly consistent, thorough generation of pulsed magnetic fields.

In summary, the clinical advantages of the MedStim system are:

Magnetic field generated is safe, comfortable, and effective, even in the stimulation of deep musculature.

Logic Controller is easy to program and operate, allowing for possible home health applications.

Array of Coils is easy to apply so as to provide effective, maximal stimulation of the underlying musculature with no need for a highly skilled operator once settings on logic controller are established.

Array of Coils can be used multiple times on a single patient, helping to make the device more cost-effective.

Flexibility of configuration of Array of Coils allows treatment of a variety of conditions including systemic processes, such as Guillain-Barre, and local processes such as isolated fractures.

Use of the MedStim system will result in a more rapid return to functionality for patients and will decrease subsequent Physical Therapy required after the period of immobilization. Due to these factors, implementation of the MedStim system is a cost-effective therapy.

Alternative Medicine

It is postulated, that there are less well-defined benefits to magnetic stimulation, such as increasing blood flow, activating the immune system, and promoting wound healing. This will allow entry of the TheraMag system into the alternative medicine market in an altered form in which maximum magnetic fields generated will be non-contractile to underlying musculature. The TheraMag system, though, will still be able to provide magnetic stimulation greater than any device currently available in the alternative medicine market in a more user-friendly fashion.

In summary, the clinical advantages of the TheraMag system are:

Flexibility and ease-of-use identical to the MedStim system.

Generation of dynamic magnetic fields with greater amplitude than existing devices in a systematic and controlled manner.

Competitive price structure

### 3.2 Competitive Comparison

Atrophy Prevention/Treatment

Current competition for the MedStim system consists mainly of the following devices: Neotonus' Neotone, MagStim's Model 200, 220, 250, and Quadropulse 500. These devices use pulsed magnetic fields to induce muscular contraction. The base cost of Neotone, MedStim's primary competitor, is \$20,000, while MagStim's model 200 starts at \$19,800. What these devices lack, though, is an easy-to-use, cost-effective means of inducing this contraction. Due to the fact that all of these devices employ a single, focused coil in inducing muscular contractions, they also require a skilled, trained user at the controls. While this may be practical for diagnostic purposes, which is the main use of the MagStim devices, it is not cost-effective for the treatment of atrophy, and it is surely not cost-effective for the prevention of muscular atrophy. In summary, the key advantages of the MedStim system over Neotonus' and MagStim's devices are:

Much easier to use and apply with possible applications in a home healthcare setting.

Allows for a more consistent therapy due to ergonomic wrap targeting key nerves and no requirement for a highly trained operator to constantly manipulate the device for adequate therapy.

Allows treatment of multiple sites in a sequential, timely fashion due to multiple ports on the logic controller and multiple coils stimulated by each port, as opposed to the single stimulatory coil of competing devices.

The only other main field of competition for the MedStim system is the alternative electrical stimulation technology, which is considered less effective. To summarize, the key advantages of the MedStim system over electrical stimulation are:

Magnetic field generated is safe, comfortable, and effective, even in the stimulation of deep musculature.

Logic Controller is easy to program and operate, allowing for possible home health applications with leasing of the system.

Array of Coils is easy to apply so as to provide effective, maximal stimulation of the underlying musculature.

Array of Coils can be used multiple times on a single patient, helping to make the device more cost-effective.

Flexibility of configuration of Array of Coils allows treatment of a variety of conditions including systemic processes, such as Guillain-Barre, and local processes such as isolated fractures.

Alternative Medicine

The TheraMag system is also a new innovation whose competition will include currently existing alternative medicine magnetic field generation devices. Key advantages of the TheraMag system over these devices are:

Flexibility and ease-of-use identical to the MedStim system.

Generation of magnetic fields with greater amplitude than existing devices in a systematic and controlled manner.

### 3.3 Sourcing

Primary raw materials needed for MedNexis products are as follows:

Electrical components (capacitor, wiring, etc) for Logic Controller and Arrays of Coils.

Molds for external console of Logic Controller.

Material for wraps in which induction coils will be placed.

All of these components are easily sourced and multiple suppliers have been identified. MedNexis will establish business relationships with these suppliers to be negotiated for preferred pricing structures without compromising quality standards. Two viable manufacturers have been identified: Colorado MedTech in Boulder, CO and JCD Manufacturing in Nashville, TN. Both companies specialize in manufacturing electronic medical equipment.

### 3.4 Technology

A patent has been authored and filed for the MedStim and TheraMag systems. This patent takes into account both offensive and defensive postures in its claims. Opinions of legal counsel are strong that MedNexis' patent applications are enforceable and defensible.

Care has been taken to file all potential claims of the invention in order to protect it from possible competition from other technologies.

All patent application documents will be made available for examination by potential investors. Trademark applications are in process on the names MedStim, TheraMag and MedNexis. No conflicts or other use of these names has been found in an initial search.

### 3.5 Future Products

Plans for future development by MedNexis include new concepts and technologies to be created by the company. For example, the company intends to expand its MedStim line by introducing more specialized products that offer highly technical users more sophisticated features, such as advanced logic controllers that provide enhanced control and generate detailed patient data relative to current and past treatments. These units will also incorporate more durable componentry.

Additionally, the company will expand its TheraMag line by developing new products tailored to specific consumer segments, as well as alternative medicine providers such as wellness centers. In addition, MedNexis may seek to acquire technologies developed by other companies and individuals to strategically achieve market penetration and additional business for the company, once it attains sufficient capitalization to do so. It is the objective of MedNexis to both innovate and market its products to other potential market segments and geographical regions. Once an industry reputation has been achieved and marketing channels are feasible, expansion into other medical device areas should be highly rewarding.

#### Market Analysis Summary

The market for our two-component device currently consists of two key market sectors:

The healthcare field for the prevention and treatment of muscular atrophy; and

The alternative medicine field for the application of potentially therapeutic, non-stimulatory magnetic fields.

The potential healthcare market sector consists of patients with diseases that result in immobilization of musculature for any length of time. The alternative health market consists of those patients who believe in the therapeutic effects of non-contractile magnetic fields.

The two key factors influencing discussion of MedNexis, Inc.'s markets are as follows:

The prevalence of conditions in which the MedStim system would be indicated.

The size and growth of the alternative medicine magnetic stimulation market in which TheraMag will compete.

#### 4.1 Market Segmentation

Currently there are two main markets for our two-component device: healthcare applications for the prevention/treatment of muscular atrophy (MedStim) and alternative medicine applications in which the device will be used for the potentially therapeutic benefits of non-contractile magnetic field stimulation (TheraMag).

In estimating the sale of logic controllers, obsolescence and machine failure are the only reasons for the replacement of the devices. Due to wear and tear, we have assumed a useful life of 2 years for each logic controller and in our projections, we have also assumed that the logic controllers are replaced after their useful life has expired. Due to the multiple configurations of AOCs, the sale of AOCs is expected to be approximately five AOC's per LC.

#### U.S. Market

The U.S. market will be the initial target market. This market can be broken down into the two main

applications: (1) Prevention and Treatment of Muscular Atrophy and (2) Alternative Medicine Applications.

#### Prevention and Treatment of Muscular Atrophy Market

Prevalence of medical indications for use of the MedStim system in the U.S. are as follows:

All Fractures 9,600,000  
Induced Paralysis for Mechanical Ventilation 963,000  
Persistent Vegetative State 106,000  
Paralysis of one or more Extremities 2,430,000  
Guillain-Barre Syndrome 3000  
Source: National Center for Health Statistics- 1997

The estimated percentages of these patients that are treatable with the MedStim system are as follows:

Fractures 10%  
Mechanical Ventilation 75%  
All others 100%

Using this data, and assuming both that hospitals will require one unit of the programmable logic controller and five arrays of coils per ten patients treated, the potential annual U.S. market for the MedStim components in 2001 is projected to be: 421,825 LCs and 2,109,125 AOCs.

Although there has been little activity to date in this sector, Neotonus has developed a magnetic device for urological uses that has gained FDA approval and has been received by allopathic practitioners. In the fourth quarter of 1999, the company sold 73 systems vs. just one during the same period in the previous year. The number of patient treatments performed on this installed base increased over 70% from third quarter 1999 to fourth quarter 1999. More than 20,000 treatments have been administered through January 2000. In October 1999, Neotonus received \$7.3 million in a second round of venture capital funding, bringing its total funding to \$12.2 million.

#### Alternative Medicine Market

The current U.S. market for alternative medicine applications is growing rapidly. Total visits to alternative medicine providers increased 47.3% from 427 million in 1990 to 629 million in 1997. Expenditures during this period increased 45.5% and is estimated at \$21.2 billion in 1997, with at least \$12.2 billion paid out of pocket, exceeding out-of-pocket expenditures for all U.S. hospitals. Further growth is anticipated as U.S. insurers offer more and more alternative medicine programs and benefits. Moreover, in 1994, there were 59,000 licensed alternative medicine practitioners in chiropractic, oriental medicine (acupuncture and herbal medicine), and naturopathy (Health Affairs 15(3), Fall 1996, pp. 226-238.).

Additionally, 15 million adults took prescriptions concurrently with alternative medicine remedies.

The potential market for energy therapy devices, of which magnetism is the most popular, is 40 million (source: JAMA Vol 280, No 18, pp 1571-1573). Conservatively, assuming only 20% of these consumers would employ magnetism as their source of energy therapy, the size of the market for magnetism in alternative medicine is approximately 8 million consumers. Assuming less leasing in the alternative medicine industry and more out-of-pocket purchases, we expect to sell 1 LC for every 5 patients and conservatively estimate one AOC per patient. The potential size of the U.S. market under these assumptions is 1.6 million LCs and 8 million AOCs per year.

## Insurance Concerns

While some health plans and self-insured employers, as well as Medicare, voluntarily cover, or are considering covering alternative medicine, some states have issued mandates. For example, a law in New York that went into effect on January 1, 1998, requires insurers to cover up to 15 chiropractic visits per year. Altogether, in early 1995, 41 states reportedly required private insurers to offer chiropractic, either as a rider or mandated as a benefit services (National Journal Group, Inc., "Access/Quality/Cost - Alternative Treatments: Acceptance is Increasing," American Health Line, January 30, 1995). Additionally, according to Oxford Health Plans, 8 states currently mandate that insurers offer acupuncture treatments.

Of all 50 states, Washington state has had the most extensive mandate. A law that took effect on January 1, 1996, requires health plans to provide access to licensed providers of alternative health care. It states that all categories of providers will be given equal treatment by insurance companies. The law initially mandates that, in every health plan, insurers must cover visits to chiropractors, acupuncturists, naturopaths, and other alternative care providers. However, after 12 of the state's largest insurers challenged the mandate, a federal judge ruled that the mandate was preempted by the Employee Retiree Income Security Act of 1974 (ERISA). In turn, the ruling was changed so that the mandate applied only to state-regulated health plans. As of April 1998, an appeal by the state was pending (National Journal Group, Inc., "Statelines - Washington: Insurance to Cover Alternative Medicine," American Health Line, December 18, 1995, National Journal Group, Inc., "Statelines - Washington: Insurers Challenge Alternative Care Mandate," American Health Line, January 10, 1996, National Journal Group, Inc., "Statelines - Washington: Insurers Freed from Alternative Care Mandate," American Health Line, May 8, 1997).

Need actual charts? We recommend using LivePlan as the easiest way to create graphs for your own business plan. Create your own business plan

## MARKET ANALYSIS

YEAR 1 YEAR 2 YEAR 3 YEAR 4 YEAR 5

Potential CustomersGrowth

CAGR

U.S.- Atrophy Prevent/Treat 5% 4,218,250 4,429,163 4,650,621 4,883,152 5,127,310 5.00%

U.S.- Alternative Medicine 5% 8,000,000 8,400,000 8,820,000 9,261,000 9,724,050 5.00%

Other 0% 0 0 0 0 0 0.00%

Total 5.00% 12,218,250 12,829,163 13,470,621 14,144,152 14,851,360

5.00%

Need real financials We recommend using LivePlan as the easiest way to create automatic financials for your own business plan. Create your own business plan

#### 4.2 Target Market Segment Strategy

Our Market Segment Strategies will be tailored to the targeted markets as follows:

##### Muscular Atrophy Prevention Market

Our primary markets in this segment are large medical institutions (i.e. universities, regional hospitals, and HMOs) that are more likely to purchase our products in large volumes due to the frequency of new patients. The key in this market is to gain acceptance of the MedStim system as a cost-effective therapeutic device among healthcare providers. Our strategy involves "push" tactics at the outset, in which we hope to establish our MedStim System as the standard instrumentation used in key/renowned medical institutions for the treatment of muscular atrophy. As our products gain acceptance among medical institutions, a "pull strategy" will result, leading to demand of our products by other medical institutions. Initial sales of our products will primarily be through demonstrations and introductions made by our marketing personnel to medical institutions. Upon gaining market acceptance, the products may be sold on proprietary websites, leading to penetration of a larger market segment.

##### Alternative Medicine Market

The primary market for this segment will be individuals who subscribe to the effectiveness of non-contractile magnetic field stimulation. This is a highly fragmented market that is naturally segmented both by ailment type and preferred alternative remedy. More recent research investigated the characteristics of persons who have used alternative medicine. First, individuals with college or graduate degrees were found to be more likely to use alternative medicine than those with high school education or less. Second, individuals reporting serious health problems were more likely to use alternative medicine than healthier individuals. Furthermore, the majority of individuals who used alternative medicine did so largely because they viewed these practices as being compatible with their own values, beliefs, and philosophy toward life and health, not because they were dissatisfied with conventional medicine (JAMA 279 (19), May 20, 1998). Subscribers source related information and products largely at the local level, but with the proliferation of the internet have been able to effectively access pertinent information. We plan to use existing channels to access the 40 million alternative medicine users. Direct consumer sales will be encouraged by targeting alternative healthcare forums and the consumers themselves. Catalog and website sales will be the main channels of distribution for the TheraMag system.

#### 4.2.1 Market Needs

There is a large unfulfilled need for devices that prevent atrophy of the musculature in today's large health care facilities. While outpatient care is the fastest growing segment of the healthcare industry, there is still a large percentage of patients each year who require extended hospitalization time. Atrophy of the musculature of such patients can seriously impede recovery time for such patients, and raise the costs of overall health care.

In addition, there are a significant number of individuals who suffer from paralysis of one form or another. With the current research in genome and DNA promising the possibility of curing such conditions, many patients with such conditions need to prevent serious muscle decay from occurring if they wish to eventually lead normal lives.

Finally, there are those individuals who desire alternative methods of seeking good health and solving existing medical problems. The use of magnetism in alternative medicine has been around for decades, and more and more people are using non-traditional methods as the popularity of such practices becomes more mainstream.

#### 4.3 Industry Analysis

Our Industry Analysis is based on each individual market segments and breaks down as follows:

##### Muscular Atrophy Prevention Market

The reason the market for atrophy treatment/prevention devices is untapped is due to the lack of any user-friendly devices. The existing devices in the market, both Neotonus' and MagStim's products, are difficult and awkward to use, requiring intensive training and skilled operation for an effective therapy. While the trend in healthcare is expected to be towards magnetic stimulation for treatment/prevention of muscular atrophy, these devices are not expected to capture significant market share for the following reasons:

Difficult and expensive to use with cost-intensive, skilled medical personnel required to operate effectively.

Awkward to use and inconsistent stimulation due to the single focused coil requiring constant manipulation.

Further inefficiency in the treatment of multiple muscle groups due to the single focus of magnetic stimulation.

Atrophy is currently treated using electrical stimulation. Electrical devices, though, cannot penetrate deeply enough to affect important musculature. Magnetism has been shown to penetrate much more deeply than the current electrical stimulation, and much less painfully.

Magnetic stimulation also has potential indications that do not overlap those of electrical stimulation. Due to its painless nature, magnetic stimulation can be used more frequently and over a larger area of the body a disease, such as Guillain-Barre, would require virtually full-body stimulation of key muscle groups. This would not be treatable with painful electrical stimulation but can be treated using magnetism. Many of the potential indications for muscular atrophy prevention, therefore, are not currently encompassed in the available electrical stimulation industry data.

In summary, the healthcare industry can be expected to experience a trend towards magnetic stimulation for the following reasons:

Much less painful than electrical stimulation at submaximal thresholds and no risk of burn at

contact sites.

Penetrates much more deeply than electrical stimulation.

More frequent indication than electrical stimulation.

#### Alternative Medicine Market

The alternative medicine industry is experiencing phenomenal growth in many arenas. Magnetic stimulation is no exception. Industry estimates for potential markets incorporate current magnetic field applications and projected growth of these fields. This market will likely provide less resistance to entry than the data-intensive muscular atrophy prevention market.

The alternative healthcare market has experienced a trend towards use of magnetic stimulation because of the proposed beneficial effects on circulation, immune system function, and wound healing.

##### 4.3.1 Industry Participants

To date, the company is not aware of any products that provide therapeutic care that is as cost effective as the MedStim or TheraMag systems.

#### Prevention and Treatment of Muscular Atrophy

The only significant competitors in the therapeutic functional magnetic stimulation field are Neotonus and MagStim. As detailed earlier, each of these companies produces a device with a single stimulatory coil which requires intensive, skilled operator involvement. Even with a skilled operator, treatments are lengthy (greater than 15 minutes per muscle group) and inconsistent because constant manipulation is required to effect the desired result. These devices are more suited to the diagnostic field, in which MagStim has captured the majority of market share due to this fact. These devices, though, are not tailored to therapeutic application of magnetic fields.

Medtronic Dantec, Digitimer, and Schwarzer GmbH are also involved in the magnetic stimulation business, but have only produced devices for diagnostic purposes to date. Nihon Kohden produces diagnostic stimulators, which are sold only in Japan.

#### Alternative Medicine Applications

Major companies competing in the alternative medicine magnetic therapy field include: BioFlex, Tectonics, Nikken, MagnetRelief, Homedics, BMI, and Sota Instruments. Only Sota Instruments has a dynamic magnetic therapy device, the Magnetic Pulser, which functions through induction of a magnetic field through a conducting coil. This device, though, consists of only a single coil and, therefore, will not cover a large region without constant manipulation. Also, this device is significantly weaker than the TheraMag system.

All other products are either static magnets or not similar enough to the TheraMag device to compete directly.

#### 4.3.2 Distribution Patterns

Distribution patterns in the healthcare industry are such that the large buying groups dictate what products are used for certain conditions throughout their sphere of influence. Thus, our products could be mandated or forced out for thousands of patients due to endorsements by their health plan or hospital group. Others recommend several alternatives which require physician education and intervention, similar to pharmaceuticals.

In the alternative medicine industry, patients frequently choose their own therapy and method of treatment. Due to this fact, this industry will require a much more intensive advertising campaign than would be recommended for the healthcare industry. In addition, the company expects to penetrate this market through direct marketing of our products on our proprietary websites.

#### 4.3.3 Competition and Buying Patterns

In the medical industry, product cost in and of itself is not paramount. However, the effectiveness of the device is a major consideration for medical practitioners. The product must deliver performance as promised in order to effectively treat the patient with the desired results. It will be imperative to have data showing the cost-effectiveness of the MedStim system. More rapid recovery, and thus less missed work, and reduced physical therapy costs are the key economic parameters.

In the alternative medicine arena, more emphasis is placed on anecdotal accounts, and advertising will be crucial for the TheraMag system. Beneficial trial results, though, could also prove highly favorable for TheraMag sales.

MedNexis will succeed based upon the capability of its product in the healthcare industry and the positioning of its product in the alternative medicine industry. After initial market resistance to any new product, MedNexis' product can grow to dominate two market segments: the market for prevention and treatment of muscular atrophy and the market for magnetic therapy in alternative medicine. Both are large and growing markets.

#### Regulatory Issues

While it is expected that FDA approval will be gained quickly based on the approval of similar devices, MedNexis' products will be produced and marketed prior to this approval. By clearly labelling the device "For Investigational Use Only," MedNexis will be able to market and sell the device to interested parties prior to FDA approval. An example of such expedited market entrance can be seen with the laser vision correction procedure LASIK. Prior to its approval by the FDA in Winter of 1999, LASIK had been performed on 900,000 patients through labeling the laser as "For Investigational Use Only." We hope to similarly expedite market entrance.

Once FDA approval is obtained for MedNexis' products, the market is expected to expand dramatically and entrance into foreign markets will be possible. At this stage, as well, it is expected that insurance companies will begin reimbursing for magnetic therapy, greatly increasing demand for MedNexis' products. There is past precedent in 510k approvals (in an average of 3 months) in documented cases.