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MDI Instruments, Inc.
Business Plan
1997-2000

Creating A New Standard in Childrens’ Health Care

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MDI Instruments, Inc.
Business Plan
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1. Executive Summary

MDI Instruments is in the business of developing and marketing diagnostic health care products for both the professional and consumer markets. Highly focused on the execution of its current strategies, MDI management intends to become the market leader in the rapidly expanding home diagnostic segment of pediatric health care over the period of this Business Plan.

Founded in 1994, MDI has emerged in mid-1997 from being a start-up company focused on completing product development and obtaining FDA approval to a business which is consistently manufacturing and actively marketing its initial product. During this same time, a heavily experienced management team, which has consistently met its milestones on schedule and within budget, has been created.

MDI has developed two medical devices. The EarCheck PRO™ Otitis Media Detector for medical professionals was launched in late May, 1997. The EarCheck™ Middle Ear Monitor, a consumer product for parents, may receive FDA 510(k) marketing approval as early as September, 1997. Both EarCheck products screen for middle ear fluid that is frequently associated with ear infection (otitis media), a medical condition that has become epidemic in scope and each year afflicts millions of children worldwide resulting in billions of dollars in annual health care expenses.

On the basis of market research coupled with three years of clinical development, MDI management believes that it will achieve sales in excess of $100 million during the next five years.

MDI markets its professional products in the U.S. through medical distributors who sell to a targeted population of approximately 48,000 office-based pediatricians and 73,000 general and family practitioners. MDI has received initial orders from McKesson General Medical, the largest physician supply distributor in the U.S., and from School Health Supply Corporation, the U.S.’s largest distributor to school nurses. Management is currently negotiating for additional national and regional distribution. MDI’s U.S. distribution plan for EarCheck PRO for 1998 consists of three national and ten regional distributors.

MDI’s sales and marketing plan for the EarCheck monitor, its consumer product, consists of initial sales in 1997 through targeted specialty consumer catalogs followed in early 1998 by the addition of a limited number of upscale retailers. By Q3 1998, sales will begin in both national and regional pharmacy chains. The years 1999 and 2000 will see MDI’s EarCheck products roll out to the mass merchandiser and wholesale club channels as consumer market awareness and demand expands and additional products are introduced.

With FDA marketing approval, MDI is confident that it can transact initial stocking agreements totaling approximately $1 million with The Sharper Image, the leading U.S. consumer product catalog, and with The Right Start, one of the leading baby catalogs in the U.S.
Internationally, MDI will begin developing partnerships with medical supply distributors in core European countries with initial sales planned for Q4, 1998. Introduction of EarCheck PRO is planned in Japan for early 2000 through alliances with established medical distributors.

Product manufacturing, packaging and distribution of both the consumer and professional products have been outsourced to Key Tronic Corporation, a $250 million publicly-held corporation which has core competencies in high quality, high volume plastics and surface mount assembly.

MDI owns patented, proprietary technology that uses acoustic reflectometry to detect and monitor fluid in the middle ear. Presently MDI owns four U.S. and 10 foreign patents, with additional patents pending.

MDI has assembled a heavily experienced management team each of whom has brought a unique blend of corporate management background in medical and consumer products coupled with entrepreneurial management experience in early stage companies.

MDI is proceeding with raising an equity financing round of $7.5 million to be completed by October 1, 1997. The primary use of these funds will be to develop and execute both the professional and consumer marketing programs, expand the consumer and professional sales organizations, and develop enhanced disposables and the next generation products.

____________________ _______  _____________________________
Jack Derby , CEO     Geoff Jenkins, VP Operations

____________________ _______  _____________________________
Paul Kowalski, VP Sales    Sandra Kimball, VP Medical/Regulatory

__________________________
David Kunen, Director Engineering
2. The Otitis Media Market

During the 1990’s, otitis media has reached epidemic proportions in the U.S. and in a number of other geographies in the world. In the U.S., it is the most frequent reason for preschool child visits to pediatricians and family practitioners.

Prevalence of the Disease

Office Visits for Otitis Media

The Center for Disease Control determined that otitis media was the primary diagnosis in over 24.5 million doctor visits in 1990, an incidence that more than doubled between 1975 and 1990. This trend projects to over 30 million visits in 1995. Office examinations for otitis media in children under two years of age have more than tripled, and in the two to five year old age group they have more than doubled. Recent studies have linked this increasing incidence of otitis media to the rapid growth in group day care for young children.

It has been estimated that the total cost for the diagnosis and treatment of otitis media is between $3 and $4 billion annually. In a healthcare environment which is attempting to limit the use of antibiotics, over 25 million antibiotic prescriptions are written each year to treat it. Due to the chronic nature of otitis media, the number one childhood surgical procedure requiring general anesthesia is the insertion of tympanostomy tubes. Over 1 million of these procedures are performed annually.

Ear infection has significant impact on American families. The majority of children develop otitis media. By the age of three, 83% of children have experienced one or more episodes and 46% have had three or more.

The Causes of Otitis Media

In a healthy child, the middle ear is filled with air. Sound waves enter the ear canal, causing the eardrum to vibrate, allowing the child to hear normally. If the middle ear is filled with fluid (effusion), the vibration of the eardrum is restricted. This can result in temporary hearing loss.

Air in the middle ear travels through the Eustachian tube which connects the ear to the back of the nose. In young children, the Eustachian tube is shorter, wider and more horizontal than in adults. As a result, infected fluids from the nose may reach the middle ear more easily. This is
why children are more likely to have middle ear fluid which can lead to ear infections and why ear infections are a common result of upper respiratory infections among young children.

Medically, otitis media consists of two primary conditions. When middle ear fluid is infected, the condition is called Acute Otitis Media and is often accompanied by pain, fever and other symptoms. Fluid, which is always present when acute otitis media is diagnosed, may persist in the middle ear for weeks or months after the infection is cured.

When fluid is present in the middle ear without active infection, the condition is called Otitis Media with Effusion. This condition may be the result of a recovering ear infection or may be associated with an oncoming ear infection. Although otitis media with effusion does not generally cause symptoms such as pain and fever, it often impairs hearing. Otitis media with effusion, often referred to as the “hidden disease”, can be far more difficult to diagnose than acute otitis media because there may be no noticeable symptoms. Older children may recognize and complain of hearing problems but younger children are often not capable of this.

**The Consequences of Otitis Media**

The presence of middle ear fluid causes an average hearing loss of 25 decibels, the equivalent of a young child wearing ear plugs. Studies have shown that recurrent or prolonged middle ear fluid can cause impaired speech, language and cognitive development, as well as lack of coordination and impaired motor skill development in children. The chronic presence of fluid is the primary reason for the insertion of tympanostomy tubes which are designed to allow fluid to drain and pressure to equalize in the middle ear.

**The Diagnosis of Otitis Media**

Physicians typically rely on visual examination of the tympanic membrane with an otoscope. The diagnostic indicators of acute otitis media include the reddening of the tympanic membrane and visible fluid behind the eardrum. Unfortunately, reddening can be the result of causes other than ear infection, such as fever and crying, and fluid can be difficult to see. As a result, the otoscope is a highly subjective and imprecise method of determining the condition of the middle ear. Virtually all physicians own and use otoscopes. These devices typically cost between $300 and $500 and otoscopic examinations are not covered by third party reimbursement. Welch-Allyn is the market leader in otoscopes.

Industry research suggests that approximately half of pediatricians own tympanometers, a traditional objective tool for detecting middle ear fluid. These devices utilize positive and negative pressure to measure the compliance of the eardrum. Tympanometry requires an air tight seal and pressurization of the ear canal which can be painful to the child. Among infants aged 3 months to two years, where otitis media is most prevalent, up to 28% will not tolerate tympanometry. The market leader in tympanometer sales is also Welch-Allyn. Prices range from $2,300 to $3,500. Tympanometry tests are generally reimbursed by third-party payers.

Although otoscopes and tympanometers are relied upon to detect otitis media in the presence of other symptoms, physicians currently have no tools to easily screen children for early detection of middle ear fluid or to precisely monitor the resolution of fluid after an episode of acute otitis media. Leading experts in the field of pediatric infectious disease have identified three areas where improved diagnostic products could aid physicians in the proper diagnosis and treatment of otitis media.
The need for objective testing...
“The annual cost for diagnosis and treatment of otitis media is between $3 and $4 billion annually. Not only is it the most diagnosed illness in children, it is the most over and misdiagnosed illness as well. Visual otoscopy greatly contributes to the over-diagnosis as redness of the tympanic membrane can be caused by a variety of factors, including fever and crying. An objective, confirmatory test could reduce the time and money associated with unnecessary treatment and misdiagnosis.”
Dr. George McCracken
Professor of Pediatrics
University of Texas
Chief Editor, Pediatric Infectious Diseases

The need for screening...
“Many children who never exhibit any symptoms of acute otitis media still suffer from fluid in the middle ear and the negative effects such fluid has on their hearing, speech and cognitive development. It is vital that physicians examine every child for middle ear effusion not only during episodes of infection, but also during every well-child visit.”
Dr. Jerome T. Combs
Medical Director, Pediatric Group, Hospital of Saint Raphael
Associate Professor Department of Pediatrics
Yale New Haven Medical School

The need for monitoring treatment...
“About 70% of children still have fluid in the middle ear after a ten day course of treatment with even the most potent of antimicrobial agents. At four weeks, 40% of children have fluid, at eight weeks that figure drops to 20%, and at twelve weeks 10% still show signs of remaining fluid. Whenever fluid fills the middle ear, there is some loss of hearing. Because of the impact even moderate hearing impairment can have on speech, language and cognitive development in young children, it is imperative to correctly monitor prolonged time spent with middle ear effusion.”
Dr. Jerome O. Klein
Vice Chairman for Academic Affairs, Department of Pediatrics
Boston University School of Medicine
Co-author: Otitis Media in Infants and Children.

At present there is no objective device or procedure to help parents identify middle ear disease at home. Instead, parents rely on signs such as fever, ear pain, fussiness and pulling on the ear to determine the need for a doctor visit. Parents are often unsure about differentiating these symptoms from other problems, such as teething pain, which do not require a visit to a physician. Importantly, after the acute symptoms of an ear infection are relieved by antibiotic treatment, parents are unable to monitor the resolution of middle ear fluid which can lead to chronic problems.

MDI’s work with consumer focus groups confirms that many parents are looking for a device to help them identify the problem at home. Consumer otoscope products are readily available at retail pharmacies and purchased by an unknown number of parents. Despite this fact purchasers usually admit that for the most part they have no idea what they are looking at.
The Health Care Environment

Fueled by increasing health care costs and the resulting societal pressures for policy changes to control rising costs, the health care environment continues to rapidly evolve toward more cost efficient and streamlined delivery systems. This has resulted in important changes in the consumer health care marketplace.

First, it has propelled a rapidly growing market for home diagnostic and screening instruments. In 1997, Frost & Sullivan called home diagnostics “one of the most promising markets in health care”. This market is forecasted to expand rapidly over the next five years driven by three significant trends.

1. A dramatic shift to preventative medicine and capitated health care programs, and a rapid decline in traditional indemnity health care insurance are compelling health care providers to look for improved and more cost effective methods to care for patients.

2. The growth in public service awareness campaigns has increased consumer involvement in illness prevention and at-home monitoring of medical conditions. Consumer acceptance of home testing has led to dramatic growth in retail sales of blood sugar, blood pressure, pregnancy, cholesterol and other home diagnostic products.

3. The miniaturization of electronics and breakthroughs in non-invasive and less-invasive, easy to use products have created expanded consumer options to conduct health screening at home. These products and services have empowered consumers to assist in their own wellness and have enabled them to more effectively communicate the status of their health to their health care providers.

Second, a better informed consumer, combined with increasing consolidation of health care providers, has led to increasing competition to gain and retain patients. As a result, health care professionals are more focused than ever before on positive treatment outcomes, patient satisfaction and overall quality of care.
3. The Market Opportunity for MDI

MDI has developed a patented technology for objectively detecting middle ear fluid. The EarCheck products are cost effective, accurate, simple to use and meet professional and consumer needs for the objective diagnosis, screening and monitoring of children for middle ear fluid.

The professional market for the product is substantial, consisting of over 125,000 primary care physicians and another 100,000 specialists and nurses who examine and treat children in various stages of the disease. Clinical research has confirmed that the EarCheck PRO instrument is as accurate as traditional devices costing two to three times more. And because the product is fast, simple to use and causes no patient discomfort it can become a widely utilized screening tool for pediatric physicians and nurses. The Company believes it can capture a significant portion of these markets.

With FDA marketing approval, the EarCheck monitor will be the first device available to consumers to detect middle ear fluid at home. The pervasive incidence of ear infection in the nation’s 17 million households with children aged six and under, and the fact that the disease can have long term consequences in the development of language, cognitive and motor skills, result in a significant and long term market for the EarCheck monitor. The product is designed for use during acute episodes to help parents determine when to visit the doctor, as well as for the monitoring of fluid after antibiotic treatment and regular at-home screening of children for middle ear disease. The Company believes it can achieve significant penetration of households with young children.

The current retail environment for home diagnostics provides a ready opportunity to establish retail distribution of the EarCheck product. There are currently over 70,000 retail pharmacies in the United States including independent and chain drugstores, and pharmacies in mass merchandisers and grocery chains. The explosive growth of the home health and consumer diagnostics in these pharmacies, including pediatric products such as the Thermoscan tympanic ear thermometer, create an environment conducive to gaining wide spread distribution and support for a new diagnostic product that addresses a pervasive and currently unmet consumer need.

The current health care environment in the U.S. and other developed nations is conducive to the successful introduction of cost effective products which improve health care both in physician offices and at home. The EarCheck product meets these criteria and is being introduced at a time when physicians, consumers and retailers are embracing such products.
4. **Company History and Organization**

**History**

MDI’s original technology was invented by John Teele, a sonar expert, and his brother, David Teele, M.D. in the early 1980’s using the principles of Acoustic Reflectometry. Dr. Teele, while a practicing pediatrician at Boston University Medical Center, recognized the need for a device that would accurately detect middle ear fluid. As a result, he and his brother developed a non-invasive medical device and received their first patent in 1984. In 1986 a second patent was issued as a continuation and improvement patent. After licensing the technology to two other early stage companies whose efforts failed due to underdeveloped products, virtually non-existent marketing and a unit price of $2,000, in July 1993, the Teele family granted these patents to Boston University.

MDI was founded in January, 1994, by the principals of Boston University’s venture capital organization, Community Technology Fund, as a means of commercializing the technology both in the physician market, where the Teeles had previously focused, and to explore the much larger consumer market where ear infections resulting from middle ear fluid had become epidemic in preschool children.

In 1994 MDI began the process of improving the original instrument and developing consumer applications for the acoustic reflectometry technology. An improved method for data analysis that did not rely on precise user technique, along with the identification of less costly components, provided the opportunity to develop a version of the instrument for parents to use at home.

In December, 1995, MDI assembled a syndicate of venture capital investors to fund the Company through the completion of product development and into initial manufacturing, sales and marketing implementation and product launch.

To date, all of the milestones which had been established have been accomplished on schedule and within budget. Both EarCheck products have been fully developed. FDA marketing approval was received on schedule for the EarCheck PRO model in late May and marketing approval is slated for the consumer EarCheck model in September, 1997. Detailed 1997-1998 sales and marketing plans have been developed and are in the process of being executed. Manufacturing processes have been rationalized and product consistency is in place. A formal cost reduction program is also in place, and costs are being consistently reduced on schedule. Finally, an experienced management team with seasoned knowledge of early stage companies has been assembled.

**Organizational Structure**

As a result of bringing broadly experienced and field-tested management to MDI early in its development as a business, the Company structure has been developed on the basis of a virtual organization. As such, the organizational model that has been created is to have a small number of heavily experienced employee managers run each of the functional areas and to outsource, where practical, those functions which are not core to the sales and marketing process of the business.
At this stage, the primary business of MDI is executing the sales and marketing plans in both the professional and the consumer markets on a global scale. To develop the sales function, the Company has invested in experienced field management and will support them with extensive training and technology tools. Additionally, since a primary strategy of the business is to “Capture the Consumer” at all levels of customer service including order entry and technical assistance, management will continue to make investments in personnel and technology in these areas.

Marketing is equally core to the business. As a result of bringing heavily experienced management to the Company both at the departmental and board levels, MDI is moving to cost effectively create a significant impact in the market with its use of advertising, public relations, collateral materials and websites. Management will continue to build its core expertise in marketing both internally and with a selective use of experienced marketing consultants.

Outsourcing on a targeted basis will continue to be a primary strategy of MDI’s growth model as shown by the following current examples:

- **Key Tronic Corporation**, with production capacity in Spokane, Washington and Mexico, was selected as the outsourced partner for all manufacturing and distribution due to its history of high volume, high quality plastic molding, surface mount technology, and its warehousing and distribution expertise with retail customers. As a partner Key Tronic invested in the financing of MDI’s tooling.

- **Product Genesis Inc.**, an engineering and product development firm, located in Cambridge, Massachusetts, specializing in consumer products, provides the primary engineering functions for MDI. As a result, MDI is able to move rapidly from product concept to full manufacturability in very short periods and with great flexibility. As a partner, Product Genesis has made financial investments in MDI in exchange for a portion of its fees.

- **Capital Management Consulting**, a heavily experienced FDA and regulatory consulting firm located in Cambridge, Massachusetts, has enabled MDI to complete clinical trials and FDA submissions on an aggressive schedule and without any additional submissions.

  Capital Management’s expertise, coupled with MDI’s clinical and regulatory management has developed an open and extremely positive relationship with the FDA resulting in rapid on-time approvals.

- **Mainspring Marketing LLC**, located in San Diego, California, has provided MDI with the tactical experience of field-tested consumer product successes from Thermoscan, Interplak, Black & Decker, and Voice-It. As partners to MDI, the principals of Mainspring have made financial investments in MDI in exchange for a portion of their fees.

  Management has created a number of additional outsourced partnerships that bring specific functional expertise to MDI for defined periods of time.
5. **Product Technology and Patents**

MDI has developed a patented technology for the detection of middle ear fluid using the principles of acoustic reflectometry to measure the response of the eardrum to a pleasant sound stimulus. This technology is similar in theory to sonar.

The EarCheck instruments use an acoustic speaker to emit a tone into the ear canal in the range of 1.8 to 4.4 kilohertz at 80 decibels. The tympanic membrane vibrates some sound into the middle ear and reflects back the remaining sound, out of phase with the incident wave. The instrument’s built-in microphone picks up the reflected sound wave at the point of maximum cancellation and transmits it to the microprocessor, which analyzes the frequency spectrum. When the eardrum is vibrating normally, about half the sound is reflected back to the instrument and the echo is soft with a broad frequency spectrum, resulting in a wide spectral gradient angle. If the mobility of the eardrum is restricted by fluid, the reflected sound wave is louder with a narrower frequency spectrum, thus the Spectral Gradient angle is narrow. In addition to measuring the Spectral Gradient angle, the EarCheck instruments determine the probability of fluid present in the middle ear.

MDI has incorporated this core technology into two product lines designed to address the needs of the professional and consumer markets.

**Professional Products**

EarCheck PRO Otitis Media Detector is designed for the physician market and targeted for use by pediatricians, family practitioners and other medical professionals. This product incorporates the following features:

- LCD readout of the spectral gradient angle
- Interpretation chart showing probability of the disease (see chart in appendix)
- Ability to measure and store separate readings for right and left ear
- Capability to print graphic results for patient charting and reimbursement
- Battery operated for portability

The instrument requires the use of a disposable tip. These low cost tips will generate a growing revenue stream from the increasing universe of units in use.

The instrument can be used in conjunction with the EarCheck PRO Smart Base to print examination results including the Spectral Gradient angle, curve, and interpretation chart. The instrument utilizes an infra-red port to download results to the Smart base which can be connected to any standard parallel port printer.

The EarCheck PRO instrument and Smart Base provide health care practitioners with a number of important benefits. The instrument provides an objective determination of the presence of middle ear fluid in about 3 seconds. It is simple to use and is not technique dependent. The procedure is painless and does not require an air-tight seal or pressurization of the ear canal, making it very tolerable for patients. The EarCheck system is also cost effective. The instrument and base combined are priced at less than half the cost of a tympanometer and the examination is equally reimbursable.
Consumer Products

The EarCheck™ Middle Ear Monitor is designed for consumer use and targeted toward parents of children from 6 months to 10 years of age. Although the product uses the same technology as the professional instrument, it is designed as a screening, rather than a fully diagnostic instrument. The display indicators provide mothers with information about when to consult the doctor.

The consumer product requires the same disposable tip as the professional instrument, again providing recurring revenue from the installed base of units.

Patents

MDI has very strong proprietary protection for its EarCheck technology. The Company has four U.S. patents and 10 international patents issued, and additional international patents pending. The issued patents include very strong, broad protection of the core technology to detect pathologies of the ear, as well as specific protection of improvements to the technology that make it suitable for a consumer product. Additionally MDI owns a design patent for the devices.

Management understands the importance of intellectual property and has new patent applications pending for improvements under development, to not only protect the technology, but also to preempt competition. MDI has worked closely with its patent attorneys at Wolf, Greenfield and Sacks, to develop an intellectual property strategy that maximizes its proprietary protection.
6. Marketing and Sales

The incidence of ear infection and its associated impact on both physicians and families results in two key target audiences for the EarCheck and EarCheck PRO devices. The professional target audience for the EarCheck PRO instrument is primarily 125,000 pediatricians and family practitioners who specialize in the treatment of children and families and secondarily over 100,000 school nurses, otolaryngologists, allergists and emergency/urgent care physicians who see children in various stages of the disease. The consumer target audience for the EarCheck monitor is the 17.3 million U.S. families with children six and under.

Strategically, the marketing plan for EarCheck products has been designed to reach and penetrate both professional and consumer audiences and to leverage professional use and endorsement to build consumer sales. Professional, consumer and retail programs will work synergistically to maximize sales to both audiences.

**Strategic Schematic**

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**Professional Marketing and Sales Plan**

Although the largest unit sales potential for the product lies in penetrating consumer households, the physician market represents significant high margin sales potential for the EarCheck PRO instrument and the Smart Base. The physician market will also be the primary source of recurring replacement tip revenues and a persuasive source for consumer information and motivation to purchase for home use.

The professional marketing plan is designed to quickly gain awareness and trial of the EarCheck PRO product among physicians who provide primary medical care to children and families. Key objectives of the plan are to:

- Penetrate 25% of core physicians (pediatricians, family practitioners and pediatric clinics) by year-end 1998
- Generate broad professional awareness and endorsement of home usage of the EarCheck monitor among patients.
Professional Sales Strategy

Professional sales will be accomplished through a combination of MDI sales employees and medical product distributors. MDI is developing partnerships with key national and regional medical product distributors to penetrate targeted professional end users. These distributors offer rapid and cost efficient coverage of medical offices, hospitals and clinics. Medical distributors typically have strong relationships with their customers which offers immediate market access for the EarCheck PRO instrument. These distributors also inventory product and manage order entry, shipping and collections directly with end users thereby reducing MDI’s potential operating costs.

In order to efficiently utilize limited internal sales resources while maximizing distributor commitment and focus, MDI initially sought one primary medical distributor to introduce the EarCheck PRO line on a short term exclusive basis. In June 1997, MDI signed McKesson General Medical (MGM) as its first national distribution partner. MGM is a leading U.S. medical product distributor with national presence through 32 distribution centers and 432 sales representatives. MGM has been granted a 120-day exclusive to represent the EarCheck PRO instrument to primary care physicians in return for a 3,500 unit commitment totaling $1.5 million. In addition, the Company has signed a one year exclusive distribution contract with School Health Supply Corporation, the leading medical distributor calling exclusively on the school nurse market.

By October 1997, MDI plans to expand distribution to include two other key national distributors, Physician Sales & Service and Bergen Medical. Combined with McKesson General Medical, these companies represent 45% of the market for primary care distribution. The Company also plans to add strong regional distributors in markets, such as the New York metropolitan area and New England, which are not sufficiently served by national distributors. In total, approximately 1,500 distributor sales representatives will be presenting the product in physician offices and clinics by year end 1997.

To manage these distributors, MDI employs District Managers experienced in selling medical products through distributors. At present, the Company has five District Managers who cover key markets in the Northeast, Mid-Atlantic, Mid-West, South and West Coast. These employees have been recruited from leading medical industry manufacturers including Becton Dickinson, Burdick, Welch-Allyn and Thermoscan. To further expand sales capacity in the professional market, the Company will add three District Managers in the next six months.
Pricing and Models

The EarCheck PRO instrument provides a significant price and value advantage over tympanometers. The entire system, including the Smart Base, can be purchased for less than half the price of a standard tympanometer. Based on an average diagnostic reimbursement of $20.00 per test, the system will pay for itself in about 40 tests.

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<th>Professional Product Line</th>
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<tr>
<td><strong>Product</strong></td>
</tr>
<tr>
<td>PEC-1 EarCheck PRO instrument</td>
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<tr>
<td>SB-1 Smart Base</td>
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<td>PT-300 Disposable tips (300)</td>
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Professional Communications

To rapidly build physician awareness, generate leads and insure high close rates in physician office calls, the Company has launched an aggressive professional marketing program. This program entails national public relations efforts, advertising in major medical journals, participation at key medical trade shows and conventions, direct mail and an extensive website for professional end-users.

Through its public relations agency in Chicago, the Company has implemented an Otitis Media Newsbank which provides regular updates to the medical and consumer press regarding the diagnosis and treatment of ear infection. The Newsbank is designed to position MDI as an expert in the disease and to cultivate press relationships prior the launch of the consumer model. The Newsbank has been distributing information since March, 1997. To insure that information provided through the Newsbank and other public relations programs is of the highest relevance to practicing physicians, the Company has named an editorial board consisting of three nationally known academicians and clinicians in the field of pediatric infectious diseases.

In addition to regular Newsbank releases, the Company will continue to disseminate product and technology updates to writers and editors. The objective of these programs is to cost efficiently generate awareness among target physicians and to leverage third-party endorsement of the product. In June 1997, the Company disseminated press kits to over 300 members of the press announcing FDA approval of the EarCheck PRO instrument. As a result of this effort, articles regarding the product are beginning to appear in the medical press. Additional releases targeted to medical, consumer and business media are planned for the consumer unit after FDA approval is granted.

In July 1997, the Company launched its professional advertising campaign. This campaign is designed to reach the universe of pediatricians and family physicians through consistent advertising presence in the leading professional journals. The introduction of the EarCheck PRO instrument is being supported by two page spreads designed to gain attention and to focus on the key product benefits that were determined through market research with physicians. To maximize efficiency and increase the frequency of advertising, the Company plans to follow the introductory campaign with single page ads. After FDA approval of the consumer product, the
Company will use similar single page ads to introduce the consumer product to physicians. All advertising includes a toll-free number and the Company’s website address to facilitate leads which will be forwarded to District Managers and distributor sales reps for follow-up.

Major medical trade shows and conventions provide the opportunity for the Company to cost effectively demonstrate its EarCheck products and present clinical support directly to thousands of physicians. The Company intends to exhibit at six medical conventions in 1997 which offer the potential to reach over 50,000 professionals in the fields of pediatrics, family practice, otolaryngology, speech and hearing and school nursing. The trade show schedule will be expanded in 1998 to thirteen shows reaching these and other professional targets.

Targeted direct mail programs are planned to physicians in high volume practices who treat large numbers of children with otitis media. This group is able to be identified without extensive field research because they are the most frequent prescribers of pediatric antibiotics. The mailings to them are designed to support distributor promotions and provide leads for field sales follow-up.

The Company has created an entertaining and educational website designed to provide on-line information about the Company’s products, answer frequently asked questions, provide on-line purchase registration and generate leads. The website address is: www.earcheckpro.com.

In order to carefully track its progress in penetrating professional targets and provide on-going leads to field sales individuals, the Company has also developed a database of the most frequent pediatric antibiotic prescribers. This computerized database has been provided to our District Managers who send regular updates and reports via modem to internal sales management.

**Clinical Program and Advisory Board**

The Company will continue to build a solid clinical foundation for its professional communications programs. Toward this end the Company has created a Medical Advisory Board consisting of leading practitioners, researchers and academicians in the field of pediatric infectious diseases. Members of this board include nationally recognized experts in the field of otitis media. Their backgrounds are shown under the “Management and Advisors” section of this business plan.

The Medical Advisory Board counsels the Company regarding the latest trends and research in the treatment and diagnosis of otitis media, aids the Company in designing clinical protocols to substantiate claims, advises the Company on product improvements, coordinates clinical research activities and acts as spokesmen for the Company at professional meetings and in public relations efforts. Their involvement has already begun to establish a high degree of credibility for the Company among practicing physicians.

**Consumer Sales and Marketing Plan**

The consumer market represents the largest long term revenue potential for the Company. The EarCheck monitor will be the first product available to parents to detect and monitor middle ear fluid. Initial consumer research has shown a high level of interest in the product.

Because otitis media is most prevalent in young children, the primary consumer target for the EarCheck monitor is defined demographically as households with children six years of age and
under. There are currently over 17 million such households in the U.S. and the market is continually “refreshed” by 4 million new births per year.

The Company has completed an extensive analysis of the income, education and lifestyle characteristics of the universe of households with young children and, through this analysis, has identified the geographic concentration of 5.4 million families which constitute the primary initial target for the EarCheck monitor. This analysis has been used to define key markets and zip codes for professional sales efforts and to identify high potential retail distribution opportunities. It will also be utilized in the development of consumer advertising programs in 1998 and beyond.

**Retail Distribution Strategy**

The Company intends to distribute its consumer product through retail channels serving its target consumer audience. Retail distribution expansion will be carefully managed to insure that consumer demand exists to generate successful retail sell-through of the product and to maximize our margin potential by distributing through high margin retailers before expanding into lower margin classes of trade. Toward this end, a scheduled retail rollout will occur over the first three years of introduction as follows:

- **1997:** Upscale catalog retailers
  - Children’s catalog retailers
- **1998:** Upscale and children catalog expansion
  - Chain drugstores
  - Drug wholesalers and independent pharmacies
- **1999:** Mass merchant pharmacies
  - Warehouse club pharmacies
  - Catalog showrooms
  - Children’s discount retailers

Product placement will be primarily in the pharmacy departments of the retail channels identified. This placement is in keeping with merchandising trends for home diagnostics and provides ideal visibility for parents filling antibiotic prescriptions for their children.

The Company has identified the following distribution objectives for the period 1997 through 1998:

- Gain placement in premier specialty retail catalogs featuring innovative new products and reaching upscale families in Q4 1997
- Expand distribution to chain drug and important independent pharmacies with the objective of securing at least 5,000 retail outlets by year end 1998.
- Utilize retailer merchandising and advertising programs to create consumer awareness and demand.

Based on existing management relationships with *The Sharper Image*, the leading U.S. specialty product catalog retailer and *The Right Start*, a leading baby product catalog retailer, the Company is confident that both retailers will be highly interested in the product. With FDA approval, the Company intends to transact short term exclusives with these customers to encourage aggressive advertising and in-store merchandising programs to begin in Q4 1997.
The Company will utilize a combination of experienced internal retail sales management and independent manufacturer’s representatives to gain and manage retail distribution. Manufacturer’s reps offer the Company existing expertise and immediate access to key retail customers and buyers. Because these organizations work on a percentage of sales, they allow the Company to match expenses with sales and minimize the internal resources required for sales training and personnel management. In May 1997, the Company began conducting interviews with manufacturer’s representatives who met its established criteria including new product introduction experience, established relationships with identified retailers, superior administrative systems for customer service and proven expertise in the development and execution of sales programs. Through these interviews the Company has identified qualified representatives in each geographic region in the U.S. These representatives will be brought on board as distribution expansion demands. To achieve full national coverage, the Company anticipates negotiating standard contracts with approximately 15 rep organizations employing approximately 60 field sales individuals.

In preparation for retail expansion in 1998, the Company intends to hire a retail sales manager in Q4 1997.

Pricing and Models

The Company will initially market two configurations of the EarCheck monitor. One model is designed for high margin retail distribution, the other for general distribution in lower margin customers. These differentiated models are designed to individually address these customers’ specific profit objectives and thereby increase our distribution and their support for our products. In addition, disposable tips will be packaged and offered for retail sale.

<table>
<thead>
<tr>
<th>Model</th>
<th>Contents</th>
<th>Anticipated Retail</th>
</tr>
</thead>
</table>
| EC-2 for high margin retailer classes of trade | - EarCheck monitor  
- 25 disposable tips  
- Batteries  
- Storage bag | $129.99 |
| EC-1 for general distribution | - EarCheck monitor  
- 5 disposable tips | $99.99 |
| T-20 for all distribution    | - 20 disposable tips      | $7.99              |

Initial retail pricing for the EarCheck monitor is consistent with introductory pricing of other successful home diagnostics, particularly the Thermoscan tympanic thermometer which was targeted at a similar audience. In the absence of alternatives, the Company expects little price resistance on the part of early adopters.

Consumer Communications Plan

The Company intends to aggressively build consumer awareness and demand for the EarCheck monitor through a combination of consumer public relations programs, highly targeted consumer advertising, physician office displays and literature and cooperative advertising programs with major retail customers. The objectives of these programs are:
• Achieve a conservative 0.6% penetration of households with children six and under by year-end 1998. This goal entails achieving sales through retail channels of approximately 103,000 units by year-end 1998.

• Achieve 30% aided awareness of the product in target, upscale households with children six years of age and under by year-end 1998 as measured by awareness surveys.

The Company plans to conduct an impactful consumer public relations campaign upon FDA approval. This program is designed to cost effectively educate and inform parents about the management of ear infections and introduce the EarCheck monitor to them through credible third-party sources.

Consumer advertising is planned to begin with the expansion of distribution into chain drug channels in Q3 1998. The Company plans to implement a highly targeted and cost efficient print campaign aimed at reaching mothers with small children. Advertising efforts will be expanded in 1999 to support increased distribution. All consumer advertising will include a toll-free number consumers can call to locate the nearest retailers stocking the EarCheck monitor.

A variety of consumer displays and literature will be provided to physicians and pharmacists. These materials will be designed to reach mothers when ear infections are top-of-mind, at the doctor’s office and at the pharmacy counter.

All consumer communications will provide access to additional information through the Company’s toll-free number and a consumer oriented website.

The Company will leverage retailer merchandising and advertising programs through a cooperative advertising program. This program is designed to fund EarCheck monitor ads in retail circulars and to promote in-store merchandising including demonstrations and displays. Cooperative advertising funds will be accrued based on retailer purchases, and specific programs will be developed with each account.

Retailers who have pharmacies present a unique opportunity to expand endorsement of the EarCheck product through their pharmacists and among local physicians. MDI will implement pharmacist education programs to encourage product recommendations by these trusted professionals. The Company plans to develop joint direct mail programs with retail partners using their existing databases of high prescribing doctors. Consumer programs, such as prescription bag inserts, will be also be implemented at store level.

**Partnership Programs**

The Company intends to pursue partnership opportunities which will serve to quickly and cost efficiently accelerate awareness and demand by leveraging the resources of non-competitive, but related, companies and organizations.

Pharmaceutical companies marketing pediatric antibiotics provide an opportunity to extend clinical research programs utilizing the EarCheck PRO instrument. MDI management has begun approaching leading pediatric pharmaceutical companies to encourage usage of the product in research for new otitis media drugs. Preliminary discussions have also been initiated.
to explore the potential of using the EarCheck PRO instrument as a detailing incentive by pharmaceutical sales reps.

Managed care organizations (MCO) are in a position to mandate the usage of products among participating physicians and to potentially recommend, reimburse or subsidize a patient purchase. MDI has initiated exploratory meetings with several MCO’s to determine the potential of such programs for the EarCheck PRO and EarCheck products. Although the implementation of such programs typically have very long lead times, the Company believes there is significant long term potential for developing MCO programs.

Through its public relations agency, the Company has also held preliminary discussions with the Alexander Graham Bell Association for the Deaf. This organization focuses on improving consumer education regarding hearing health. Although this program would be largely non-commercial, the Company believes increased consumer understanding of the causes and consequences of ear infections will have a positive impact on its long term business.
7. New Markets and New Products

International

The primary sales focus for MDI in 1997 and 1998 will be in North America. Objective number one is to successfully penetrate the U.S. market, gain endorsement of the U.S. medical community and establish awareness and value among U.S. consumers. Objective number two is to leverage this knowledge and success into international markets.

Canada

Canada is the eleventh largest economy in the world and fourth largest in per capita GNP and per capita consumption of medical devices. The professional and consumer product line introductions in Canada will lag behind their respective U.S. introductions by approximately six months and be accomplished through the same distribution strategies as in the U.S.

MDI will recruit one independent sales representative to introduce the professional product line through Canadian medical distributors beginning in September, 1997. MDI will develop its distribution partnerships, focusing on the expanding populations of British Columbia, Alberta, and Ontario. Agreements will be explored with Ingram & Bell, Medical Mart Supplies, Dufort & Lavigne, Futurmed and BC Stevens. Professional sales are projected to be 5% of the previous year’s U.S. professional sales. This relatively small number results from the heavily subsidized and government managed professional health care system which is not as robust as that in the U.S.

In the fall of 1998 sales will begin in selective chain drugstores and independents and will coincide with launches to the same classes of trade in the U.S. Canadian retail sales are projected to be 10% of the previous year’s U.S. retail sales.

Europe

The European Community is the largest economic block in the world and four of the top eight country economies in the world are in Europe. MDI plans to enter the core European countries in Q4 1998 with the EarCheck PRO instruments adapted for European sale. Otitis Media is a rapidly increasing disease in Great Britain, Germany, Italy, and the Scandinavian countries. Since the tactical approach of introduction will be with European distributors on a country by country basis, this timetable will allow the necessary completion of TUV and ISO regulatory filings. In the interim, a European sales manager will join MDI in December, 1997 to begin the task of identifying specific distributors and promotional strategies.

Management recognizes that although European consumers are becoming increasing health conscious, they only spend on average 6% of their total expenditures on health care compared to 16% in the U.S. As a result, the consumer introduction of EarCheck instruments will purposefully lag behind the introduction of the professional EarCheck PRO instrument by a full year to assure sufficient time for physician penetration and resulting endorsements.
Japan

Japan is the second largest economy in the world and has the most concentrated population centers of any developed country. Otitis media has become epidemic in Japan as working mothers increasingly enter the economy and daycare use expands. MDI plans to enter the professional Japanese market in late 1998 or early 1999 through a well-established distributor such as Shenogi or Terumo that will both pave the path for regulatory approvals and serve as the primary sales channel for EarCheck PRO instrument. With consumer health care expenditures at 10% of total expenditures and comprehensive health care provided by the government, Japan should represent a significant opportunity for MDI. At the same time, given the relatively closed distribution channels and regulatory requirements in Japan, management does not expect that consumer sales will begin until the year 2000.

Additional Markets

There are significant niche opportunities for additional EarCheck professional product expansion during the next three years. School nurses represent an immediate niche market as do other health care professionals involved in the diagnosis and treatment of auditory and language problems. MDI currently has a distribution agreement with School Health Supply Corporation to distribute its EarCheck PRO instrument to school nurses. Efforts in this will be expanded during 1998 and 1999. Similarly, day care centers represent an additional opportunity for product sales and consumer awareness building programs since children in these environments have a higher incidence of the disease.

New EarCheck Claims

From preliminary research and clinical trials, MDI knows that the EarCheck instruments identify conductive hearing loss due to the presence of middle ear effusion (fluid). Furthermore, it is an accepted medical fact that middle ear fluid negatively impacts hearing. More importantly, hearing loss in children who are developing speech and language skills may cause intellectual and developmental delays and problems. Early identification of hearing problems in children is an important focus in child health care and child development.

Validation trials to date were designed to expedite FDA marketing approval. MDI will substantiate claims for the EarCheck instruments to identify conductive hearing loss in clinical trials scheduled for Q4, 1997. Validation of a claim for conductive hearing loss identification will result in a new marketing claim that will expand the utility and broaden the markets for the EarCheck instruments.

New Products

MDI is committed to maintaining its lead in acoustic reflectometry and expanding the technology’s applications in differentiating progressively subtle variations in middle ear conditions through an ongoing program of product development and controlled clinical studies. Management believes that there is significant opportunity to expand the diagnostic claims of the technology through increasingly sophisticated analysis of the Spectral Gradient angle. The following section outlines the current plans of management. The specifics of the actual product features will be dependent on additional market research and analysis of customer needs.
MDI’s new product strategy is focused on the following four components:

1. Develop enhancements to the existing products and technology.
2. Expand the menu of physiological test functions available on the current product platform.
3. License complimentary products and technologies which can be sold into the same markets.
4. Expand the use of disposable components and create subscription services.

MDI plans to begin the development of a second generation of professional and consumer EarCheck instruments during the second quarter of 1998. It is anticipated that these products would be launched in Q3 1999, incorporating a number of enhancements including, smaller overall unit size, a small and more disposable tip, and expanded memory for storage of multiple readings.

There is also the potential to incorporate electronic data transfer capabilities into the consumer unit. This MDI *Smart Link* technology would allow a parent to transfer the retained ear measurement data over a standard telephone or the Internet directly into the pediatrician’s office. Utilizing this data, the physician would be able to print out a Spectral Gradient graph and interpret the results more completely and store the data for future comparisons.

Alternatively, MDI will evaluate the development of a data warehousing subscription service (*Smart Vault*), which would act as a convenient intermediary between the consumer and the physician’s office. *Smart Vault* would provide the consumer with one nationwide 1-800 number to download their EarCheck data. The *Smart Vault* system would receive, store, and convert the EarCheck data into a Spectral Gradient format which could be retrieved by the patient’s physician at will. There is also a potential for trending and providing the physician with sophisticated analysis of the data.

By late 2000, MDI plans to introduce new EarCheck instruments into the professional and consumer markets which would incorporate both acoustic reflectometry and ear-based temperature measurements. Beyond the single-step convenience of combining these two distinct functions into a single product, the temperature data will be analyzed in conjunction with the device’s acoustic reflectance data to provide an improved screening and diagnostic reading since elevated temperature is one of the key indicators of ear infection. Other menu expansion options include pulse and oxygen concentration.

MDI has begun a formalized program to seek out and acquire or license complimentary products and technologies which could be sold into the same pediatric and consumer market categories as the EarCheck product line. The ongoing search and evaluation program targets industry, government and university sources. Product concepts are evaluated for potential market impact, uniqueness, utility, cost and consumables content.
8. Operations

MDI’s operational tactics follow its organizational strategy of investing in those functions which are core to its business growth. Other functions are outsourced to corporate partners that provide MDI with greater speed and flexibility, and reduce the need for capital investments. To this end, management has decided that it will continue to outsource manufacturing and engineering.

Manufacturing

Key Tronic Corporation was chosen as the manufacturer of the EarCheck products because of its core competencies in high volume production, high quality plastics, surface mount technology and the fact that it distributes high volume products to retail customers. As volume increases in 1998, existing production will shift from the Spokane, Washington facility to Key Tronic’s plant in Mexico, and our new products will be made in the Spokane facility. During 1999, high volume production will begin in Taiwan as a second source. MDI’s manufacturing management is experienced in outsourcing internationally and specifically in Taiwan and mainland China.

Engineering

Management will continue to outsource product development and basic engineering services, although proprietary expertise for the essential software algorithms and patented acoustic reflectometry technology will remain a core competency internally. Product Genesis was chosen as the initial outsourcing partner for the current EarCheck products which allowed MDI to bring the units to market with much greater speed and improved manufacturability.

Management has achieved consistency in the production processes, and has begun a formal cost reduction program for its EarCheck products. This project which will be ongoing through 1997 and into the first half of 1998, is being managed jointly with Product Genesis and Key Tronic.

Regulatory

MDI management has developed an open relationship with the FDA which has resulted in obtaining approval for its EarCheck instrument on-time and without additional submissions. Although MDI will continue to use Capital Management as its outsourcing partner for conducting its clinical trials and assisting in preparing its 510(k)s, the expertise of QA/QC, clinical requirements and medical affairs will remain resident as core expertise within MDI.

Customer Services

The functions of customer service, order entry, and technical support represent strategic expertise to be developed within MDI. The importance of the customer at the physician, retailer and consumer levels is critical to MDI’s growth. Through the use of customer satisfaction measurement systems and database technology tools, MDI plans to “capture the customer” throughout their experience with EarCheck products.
9. Management and Advisors

Management

Jack Derby, CEO
Prior to forming Derby Management in 1990, Jack’s background included positions as CEO of Mayer Electronics Corporation, President of CB Sports, President of Litton Industries Medical Systems, CEO of Datamedix Corporation and President of Becton Dickinson Medical Systems. Jack is extremely active in the New England entrepreneurial community. He is currently and has been an active board member in a number of emerging companies. He was instrumental in restructuring the Board of the MIT Enterprise Forum (www.mitforum-cambridge.org) where he has held the position of Chairman of the Forum. Additionally, he has been the Vice Chair of the Smaller Business Association of New England (www.sbane.org). During 2004, Jack was the recipient of Smaller Business Association of New England’s “Pro Bono Publico Award” for his significant contributions to the entrepreneurial community. Currently, he is Chairman of the Association for Corporate Growth (www.acgboston.org), a Director of The Associated Industries of Massachusetts (www.aimnet.org), and a Director at Brainshark Corporation, Hybricon Corporation and Beacon Hospice.

Geoffrey H. Jenkins, Vice President of Operations. From 1991 to 1997, Geoff served as Vice President of Operations for MediSense Inc., a $270 million international developer, manufacturer, and marketer of medical diagnostics. He was responsible for the Company’s domestic and international manufacturing operations which included the production of high volume disposables (biosensors) and diagnostic instrumentation. (MediSense was acquired by Abbott Laboratories in May of 1996). Geoff joined MediSense as a start-up in 1984 as the Director of Electronic Development. In 1987 he became Vice President of U.S. Operations. From 1981 to 1984, he was Project Director for Sontek Industries, Inc., a manufacturer of medical products. Geoff has an engineering degree from Clarkson University.

Sandra Kimball, Vice President, Medical and Regulatory Affairs founded MDI Instruments in 1994 and served as its CEO and President and a Director through March, 1995. Sandra presently serves as Vice President of Medical and Regulatory Affairs. She is also responsible for exploring future business development partnerships with pharmaceutical firms, managed care organizations and the licensing offices of leading technology universities and teaching hospitals. Prior to joining MDI, Sandra was Managing Partner of Dental Design, a privately held dental technology company, specializing in products and services to the dental industry. Sandra received her BS from the University of Massachusetts, Amherst, and her MBA from Northeastern University.

Paul J. Kowalski, Vice President of Sales. From 1991 to 1996 Paul was promoted through the ranks of the sales organization at Thermoscan, Inc. where he most recently served as Director of Sales. Prior assignments included District Manager, Western Regional Manager and Director of North American sales where Paul was responsible for $25 million in medical and a sales staff of 25 people. From 1986 to 1991 Paul was the Northeast District Manager for Dental Research Corporation, manufacturers of the Interplak Plaque Removal Instrument. He holds a BS in Business Management from Keene State College and an MBA from the University of Hartford.

David A. Kunen, Director of Engineering. Prior to joining MDI, David was Director of
Programs at Product Genesis, Inc., an engineering and product development consulting firm in Cambridge, MA where he worked from 1993-1997. For the last year at Product Genesis, David was Project Manager for the EarCheck project under a contract with MDI Instruments. David’s other responsibilities at Product Genesis included supervision of the electrical and software engineering staff. From 1991-1993, David was a management consultant with The Boston Consulting Group where he focused on health care consulting. He worked closely with John Deere Company to help start a Deere-owned and managed HMO for employees and retirees. From 1985-1989, David worked as a software engineer in the Missile Systems Division of Raytheon Company. David has a BS in Electrical Engineering from Yale University, an MS in Electrical Engineering from Stanford University, and an MBA from the Harvard Business School.

Betsy A. Winsett, Principal, Mainspring Marketing. Mainspring Marketing is a consulting firm specializing in start-up companies, and Betsy is serving as Vice President of Marketing on an interim basis. From 1990 to 1996, Betsy was a founding officer and the Vice President of Marketing for Thermoscan, Inc. During her tenure at Thermoscan, she designed the medical and consumer marketing and distribution strategies that grew this entrepreneurial, privately-held company to over $115 million in sales. A recapitalization in 1994 and an acquisition of Thermoscan by Gillette in 1995 resulted in $190 million in returns to the investors. Betsy joined Thermoscan from the Black & Decker Household Products Group where she worked from 1983 to 1989 as Product Manager. Betsy began her marketing career at The Hoover Company in 1972. Betsy has a BS from Miami University and an MBA from Kent State University.

Medical Advisory Board

Charles D. Bluestone, M.D., received both his Bachelor of Science and Medicine degrees at the University of Pittsburgh. Dr. Bluestone is the Clinical Associate Professor of Otolaryngology at the University of Pittsburgh School of Medicine and Chief of the Otolaryngology Service at Children’s Hospital of Pittsburgh. In 1972, Dr. Bluestone became the first full-time Director of the Otolaryngology Department at Boston City Hospital and Professor of Otolaryngology at Tufts University School of Medicine. While in Boston, he became the Acting Program Director of the joint Tufts and Boston University Otolaryngology residency program and was appointed as a faculty member at Boston and Harvard Universities. He currently is the Director of the Pittsburgh Otitis Media Research Center at Children’s Hospital of Pittsburgh and the University of Pittsburgh School of Medicine. Dr. Bluestone has been the author or co-author of over 400 articles, chapters and books, related to pediatric otolaryngology.

Jerome T. Combs, M.D., FAAP, is the leading expert in the clinical and technical applications of acoustic reflectometry in pediatrics. Dr. Combs is the Medical Director of the Hospital of Saint Raphael Pediatric Group and is a Clinical Assistant Professor of Pediatrics at Yale New Haven Medical School. He has a special interest in otitis media and has published numerous articles on middle ear disease and Acoustic Reflectometry.

Jerome O. Klein, M.D., is the Vice Chairman for Academic Affairs of the Department of Pediatrics at Boston University’s School of Medicine. Formerly, he was the Director of the Division of Pediatric Infectious Diseases and Director of the Maxwell Finland Laboratory for Infectious Diseases, Boston City Hospital. Previously, Dr. Klein was Chief of Infectious Diseases at Franciscan Hospital for Children, Associate Pediatrician at Brigham and Women’s Hospital, Lecturer/Associate Professor of Pediatrics at Harvard Medical School and Associate
Pediatrician, Massachusetts General Hospital. Dr. Klein has published over 250 articles on infectious and pediatric diseases.

George H. McCracken, Jr., M.D., is a Professor of Pediatrics, University of Texas Southwestern Medical School at Dallas, Texas, and Chief Editor of The Pediatric Infectious Disease Journal. Since 1993, Dr. McCracken has held the distinction of the Sarah M. and Charles E. Seay Chair in Pediatric Infectious Diseases at the University of Southwestern Medical School. Dr. McCracken is also on the Board of the National Foundation for Infectious Diseases, Associate Editor, Report of The Committee on Infectious Diseases (The Red Book), and on the Editorial Boards of Developmental Pharmacology, and Therapeutics, and antimicrobial Agents and Chemotherapy. Dr. McCracken is a leader in the field of pediatric infectious diseases and has published over 350 articles on infectious and pediatric disease.

Board of Directors

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Betsy A. Winsett
Principal
Mainspring Marketing
1330 El Camino Real
Del Mar, CA 92014

Jack Derby
CEO, MDI Instruments, Inc.
10. Finances

The financial projections indicate steady revenue growth from approximately $5M in 1997 to $70M in 2000, a four year period. Profitability is projected in 1998, with operating income growing to 20% of revenues in 2000. An equity infusion of $7.5M is assumed during the fourth quarter of 1997, reflecting conversion of all notes outstanding plus additional cash investment. Operating cash flow is expected to become positive in 1998, offset by working capital investment exceeding $3M. In the year 2000, cash flow from operations will first exceed investment in working capital and debt payments.

The financial information below should be read in conjunction with the full financial projections for the years 1998 - 2000, which are included for review following this section. The financial projections were prepared based upon management’s combined experience, sales history of less than one full quarter and an assumption that timely approval will be received from the FDA for the consumer EarCheck monitor. The financial projections represent management’s estimates based upon information known and assumed at the time the projections were prepared.

**Statements of Operation Summary**

Revenue projections indicate a compound annual growth rate exceeding 135% for the three-year period subsequent to 1997. The projections grow from 1997 sales of $5.3M to sales of $69.6M in the year 2000. Gross margins erode slightly over the projection period, from a starting point of 71.4% to an ending point of 65.8%. The gross margin projections reflect the expected seasonality of the product, and an increasing percentage of sales arising from the consumer market, which generates lower price points and margins than the professional market.

Cumulative losses are projected to total approximately $9.85M through the third quarter of 1998; the projections indicate that the fourth quarter of 1998 will be the first quarter of profitability. Operating profitability is projected to increase to 20% of revenues for the year 2000, equivalent to approximately $14M. The financial projections reflect the full use of available net operating loss carryforwards during the second quarter of 2000, causing income tax expense of $3M to initially be recorded in that year.

**Balance Sheet Summary**

Net receivables will grow to approximately $18.2 by the end of the projection period, conservatively assuming 90 days as the average collection period. Given the Company’s expected gross margins, the balance sheet projections indicate that working capital needs are expected to be self-funded beginning in the year 2000. The Company is expected to utilize its short-term line of credit for approximately three quarters in late 1999 and early 2000, peaking at $6.3M in borrowings at the close of 1999. All working capital debt is projected to be repaid by mid-2000.
Net working capital is projected to approximate $18.5M at the close of 2000, indicating a current ratio of 2.9X. Given the nature of the Company’s business and outsourcing efforts, it is projected that non-current assets will not be significant to total assets. Current assets are projected to approximate 96% of projected total assets of $29.1M at the close of the year 2000. The balance sheet assumes that a portion of fixed asset expenditures will be financed by capital leases. Total stockholders’ equity is expected to increase from $5.8M at the close of 1998 to $19.2M at the close of 2000.

Cash Flow Summary

MDI projects an equity infusion of approximately $7.5M in late 1997, including the conversion of outstanding bridge loans. No further equity rounds are projected. For a period of approximately three quarters, the Company is projected to borrow on its working capital line, but the required borrowings are significantly less than the capabilities to then be in place. In 2000, MDI is projected to repay all outstanding debt, except capital lease balances, and be self-funding from that year forward. For the year 2000, net operating cash flow before capital items is projected to be approximately $8.8M, representing a cash conversion rate of 82% of net income and 11% of net revenues.

Current Funding Requirement

The Company requires equity financing in the amount of $7,500,000.

The expected round of funding will allow the Company:

- Support deeper market penetration by the EarCheck PRO;
- Aggressively launch the consumer version in selected channels;
- Develop and implement on-going marketing programs;
- Recruit, hire and train field and corporate sales personnel;
- Develop the corporate infrastructure necessary to support product development and sales and marketing activities;
- Continue research and development to introduce additional products;
- Fund required investment in inventory and trade receivables, net of short-term borrowings;
- Fund required fixed asset expenditures, net of capital lease proceeds.

The anticipated equity investment of at least $7.5M is expected to allow the Company to finance operations for approximately eighteen months. In 1999 the Company is expected to utilize a bank line of credit to further finance working capital investment. By mid-year 2000, the Company is expected to be self-funding with all short-term borrowings repaid. The Company does not anticipate a need for further equity financing beyond this expected round.
Use of Initial Funds

Cash-usage results may differ significantly from the Company’s expectations reflected in this business plan, based upon timing of activities, future product FDA approvals and market introductions, commitments received or not received, facts and circumstances not known to management at the time of preparation of this document and unforeseen opportunities that may arise and be worthy of investment. Therefore, the estimates set forth below should be considered to be approximations based upon the facts, circumstances, assumptions and choices currently known and reflected in this business plan. Based upon the assumptions reflected in the financial projections, an equity investment of at least $7.5M would be expended in the following areas in 1998 and the first half of 1999:

- Marketing and public relations programs to support product launches: $ 7,500,000
- Product research and development activities: $ 4,500,000
- Establish and support the sales organization: $ 5,375,000
- Fund initial working capital investment: $ 2,150,000
- Corporate infrastructure and other operating costs: $ 6,100,000
- Fixed asset expenditures, net of lease proceeds: $ 850,000

$26,475,000

Of course, a significant portion of the above funding requirement will be provided by gross margin on projected sales, which is expected to total approximately $22,375,000 over the six-quarter period. Also, a portion of the equity funding amount will be applied to convert approximately $1.85M of bridge loan financing provided in 1997 by current investors.
Four - Year Financial Summary

The following summarized financial data has been extracted from the projections.

<table>
<thead>
<tr>
<th></th>
<th>1997</th>
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<td>NBV of Fixed Assets</td>
<td>201</td>
<td>606</td>
<td>923</td>
<td>1,048</td>
</tr>
<tr>
<td>Total Assets</td>
<td>7,603</td>
<td>9,710</td>
<td>20,125</td>
<td>29,147</td>
</tr>
<tr>
<td>Total Debt</td>
<td>193</td>
<td>374</td>
<td>6,895</td>
<td>892</td>
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<tr>
<td>Net Equity</td>
<td>5,449</td>
<td>5,812</td>
<td>8,371</td>
<td>19,163</td>
</tr>
<tr>
<td>Operating Cash Flow (Deficit)</td>
<td>(4,517)</td>
<td>722</td>
<td>3,083</td>
<td>11,662</td>
</tr>
<tr>
<td>Investment in Working Capital</td>
<td>(1,492)</td>
<td>(3,002)</td>
<td>(10,648)</td>
<td>(1,863)</td>
</tr>
<tr>
<td>Investment in Fixed Assets</td>
<td>499</td>
<td>764</td>
<td>841</td>
<td>995</td>
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<tr>
<td>Net Cash Flow Before Capital Items</td>
<td>(6,523)</td>
<td>(2,357)</td>
<td>(8,407)</td>
<td>8,779</td>
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<tr>
<td>Total Ending Headcount</td>
<td>27</td>
<td>56</td>
<td>91</td>
<td>117</td>
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11. Appendices

- Product Specification Sheets
- Marketing literature
- Definitions

**Acute otitis media:** Rapid onset of signs and symptoms of acute infection in the middle ear.

**Conductive hearing loss:** An impedance of sound transmission to the inner ear primarily caused by middle ear effusion.

**Ear infection:** The layman’s term for the earache associated with otitis media.

**Middle ear effusion:** The fluid resulting from otitis media. The effusion can result from either acute otitis media or otitis media with effusion. Fluid may persist in the middle ear for weeks to months after an episode.

**Otitis media:** Inflammation of the middle ear.

**Otitis media with effusion:** Inflammation of the middle ear in which a collection of fluid is present in the middle ear space without signs of acute illness.

**Otoscopy:** Use of an otoscope which is a device that contains a light source and lens to look directly at the tympanic membrane.

**Tympanometry:** A test of tympanic membrane compliance and middle ear pressure.