Feel Better **LIVE BETTER**

About Restore Medical

Restore Medical develops, manufactures and markets innovative medical devices to treat sleep disordered breathing. The Company's proprietary Pillar®Palatal Implant System is the only FDA-cleared and CE Marked implantable palatal device to treat snoring and mild to moderate obstructive sleep apnea. The Pillar Palatal Implant System is sold throughout North America and various countries in South America, Europe and Asia. Restore Medical is located in St. Paul, Minnesota.

TO OUR STOCKHOLDERS:

"Helping people around the world to Sleep Better, Feel Better and Live Better" - Our mission guides everything we do at Restore Medical as we strive to become a global leader in the treatment of sleep disordered breathing.

Business & Market Overview

In May 2006, we made the transition from a private to a public company. We made the decision to raise equity capital to fund our growth initiatives based on the fact that sleep disordered breathing is a huge global market, and neither physicians nor patients were satisfied with traditional medical and surgical treatment options. Left untreated, chronic snoring and obstructive sleep apnea (OSA) can cause or contribute to serious health consequences, and both conditions negatively affect the quality of life for tens of millions of people. The ability to effectively address these unmet clinical and lifestyle needs is the enormous and exciting opportunity for Restore Medical.

Our novel and proprietary Pillar Palatal Implant System® provides physicians and their patients with a safe, proven and effective one-time, minimally-invasive treatment option for both chronic snoring and mild-to-moderate OSA. The Pillar Procedure® can be performed in a physician's office in approximately 20 minutes with minimal pain and discomfort. To date, physicians around the world have treated more than 20,000 patients with our Pillar Procedure.

While the fundamental business opportunity in the sleep disordered breathing market has been clear and compelling from the beginning of our Company, during 2006, we experienced the complex challenges of driving increased adoption of a new medical technology in a relatively young, dynamic and evolving market. I am very proud of the fact that we were able to quickly recognize and assess these development challenges and act rapidly and decisively to change the focus and execution of our sales strategy, including expanding and reconfiguring our sales force. While the implementation of these initiatives was disruptive and negatively impacted near-term sales and our stock price, I am confident these actions were essential to establish the foundation for our long-term growth.

Executive Leadership

A critical element of addressing these strategic and operating challenges is a management team with the experience, knowledge and talent necessary to achieve our growth objectives. We strengthened our executive ranks during 2006 and early 2007 with the addition of several individuals with significant experience in driving change and delivering results in office-based, self-pay medical device markets. The new members of our senior leadership team include Christopher Geyen, Senior Vice President and Chief Financial Officer; Craig Palmer, Senior Vice President of U.S. Sales; Michael Kujak, Vice President of Marketing; and, David Bremseth, Pharm.D., Vice President of Clinical, Regulatory and Quality Affairs.

Driving Revenue Growth

Revenue growth is our number one priority and we have defined and are executing five key operating strategies to drive increased Pillar Procedure utilization and sales in the U.S. during 2007:

Integrated Consultative Sales Approach

We are implementing an integrated consultative sales approach to assist and support physicians in targeted high-potential, high-volume accounts to grow their sleep disordered breathing practices and to increase their use of the Pillar Procedure. We are applying proven, successful strategies from fast-growing, self-pay medical device markets such as ophthalmology, dental implants and orthodontics, and are focusing our resources on physicians and their staff who are committed to proactively expanding their sleep disordered breathing practices.

Innovative Practice Support & Development

As part of our commitment to build strong partnerships with targeted, high-potential, high volume accounts, we have developed a variety of innovative practice development and support resources. The collateral, programs and tools driving this initiative are designed to train and educate physicians and their staff on how to move potential patients from being merely interested in a treatment for their snoring or OSA to choosing the Pillar Procedure. In addition, we offer our customers a variety of patient education materials to support their practices.

We also have developed and are implementing a series of targeted, cost-effective marketing outreach programs designed to help physicians attract interested patients into their practices. These programs include local consumer outreach initiatives such as direct-mail campaigns to patients within a physician's practice group, and local community health talks to discuss snoring and OSA treatment options in informal, educational settings. We also are collaborating with key physician customers to establish effective relationships with referring physicians and local sleep centers. These referral programs are designed to identify and treat snoring patients who typically are not considered candidates for treatments such as continuous positive airway pressure (CPAP), and for OSA patients who are unable to comply with their CPAP therapy.

Building on our Clinical Results

Data from 21 clinical studies involving nearly 700 patients have consistently demonstrated the safety, efficacy and sustained results of the Pillar Procedure to treat snoring and mild-to-moderate OSA. Manuscripts reporting data from eight OSA clinical studies and eight snoring clinical studies have been published or accepted for publication in peer-reviewed medical journals. In September 2006, the compelling clinical results of the first evidence-based-medicine Level 1 prospective, randomized, blinded, placebo-controlled OSA clinical study of the Pillar Procedure were reported at the annual meeting of the American Academy of Otolaryngology (AAO), and the manuscript has been submitted for publication. Enrollment is complete in two additional prospective, randomized, Pillar OSA placebo studies, and we expect manuscripts reporting data from these studies will be submitted for publication in 2007.

Collectively, this body of clinical data clearly validates the efficacy and sustained outcomes from the Pillar Procedure, and is an important element of our consultative Pillar Procedure practice development and support programs. With this large and increasing body of clinical data as a foundation, our physician discussions have expanded from using the Pillar Palatal Implant System as a stand-alone treatment for chronic snoring and OSA, to an effective first-line palatal treatment that can be used stand-alone, or in combination with other procedures to treat multi-level upper airway obstruction.

Obtaining Reimbursement Coverage

We made significant progress during 2006 in our efforts to obtain OSA reimbursement coverage for the Pillar Procedure. Effective October 1, 2006, the Centers for Medicare and

Medicaid Services (CMS) granted the Pillar Procedure a "New Technology Ambulatory Payment Classification Designation" (New Tech APC), and established an $850 payment for Pillar Procedures performed on Medicare patients in an outpatient setting, while allowing physicians to bill separately for their fees. Following issuance of this New Tech APC, Wisconsin Physician Services, the regional Medicare carrier for Minnesota, Illinois, Michigan and Wisconsin, implemented the first positive reimbursement coverage policy for the Pillar Procedure and established a $1,140 payment for Pillar Procedures performed on Medicare patients in physicians' offices.

We will continue to seek positive OSA coverage policies for the Pillar Procedure from other regional Medicare and private insurance payers during 2007, although we believe other Medicare carriers and fiscal intermediaries will wait until the placebo-controlled studies described above are published before making a decision on OSA coverage policies for the Pillar Procedure. We plan to ask the AAO to file an application with the American Medical Association for an OSA Pillar Procedure CPT Code at the AAO annual meeting in September 2007. We expect the Pillar Procedure will remain a self-pay procedure when used to treat chronic snoring.

New Product Development

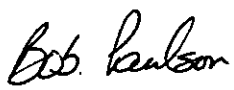
We believe accelerated growth of the sleep disordered breathing market will be driven, in part, by an increase in combination or staged procedures to effectively treat multi-level upper airway obstruction that can cause chronic snoring and OSA. Our current research and development efforts are focused on expanding our product portfolio through the development of a minimally invasive device to treat tongue-base collapse, which is the second most common contributor to OSA after the soft palate. In addition, we are evaluating opportunities to further improve the clinical performance of our Pillar Palatal Implant System. As a result of our ongoing research and development efforts, we continued to broaden and strengthen our patent portfolio during 2006; Restore Medical now has 41 issued U.S. patents and 17 pending patent applications covering a range of product designs, materials and applications to treat sleep disordered breathing.

Longer term, we will evaluate and assess opportunities to expand our product portfolio by developing, licensing or acquiring other products or technologies that will help physicians improve both the diagnosis and the treatment of sleep disordered breathing.

Growth Market with Tremendous Potential

While the development of the sleep disordered breathing market will require significant and continuing investment, we have put the foundation in place for building a strong and growing business in the treatment of snoring and OSA. Restore Medical is well-positioned to provide comprehensive and effective clinical and business solutions to address the needs of physicians, patients and their bed partners in the dynamic and growing sleep disordered breathing market for years to come.

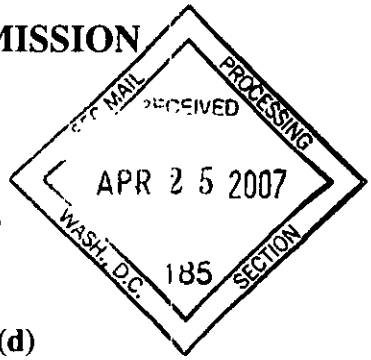
On behalf of my colleagues at Restore Medical and our board of directors, we appreciate your continued support.



J. Robert Paulson, Jr.
President & CEO
Restore Medical, Inc.

April 2007

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549



Form 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2006

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Commission file number 000-51998

Restore Medical, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**41-1955715**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

2800 Patton Road
St. Paul, Minnesota 55113
(651) 634-3111
(Address and zip code of principal executive offices and registrant's telephone number, including area code)

Securities Registered pursuant to Section 12(b) of the Act:

Common Stock, $0.01 par value	**Nasdaq Global Market**
(Title of each class)	*(Name of each exchange on which registered)*

Securities Registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statement incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act (check one):

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☑

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

The approximate aggregate market value of the registrant's common stock, $0.01 par value, held by non-affiliates of the registrant (based on the closing sales price of the common stock as reported on the Nasdaq Global Market) on June 30, 2006 was approximately $73,764,000.

As of February 7, 2007, 15,557,155 shares of common stock, $0.01 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for its 2007 Annual Meeting of Stockholders are incorporated by reference in Part III of this Form 10-K.

Restore Medical, Inc.

Form 10-K

Table of Contents

This Annual Report on Form 10-K contains certain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical facts, are "forward-looking statements" for purposes of these provisions, including any projections of earnings, revenue or other financial items, any statement of the plans and objectives of management for future operations, any statements concerning proposed new product development, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as "may," "will," "expects," "plans," "anticipates," "estimates," "potential," or "continue" or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained herein are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct. Our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed below in Item IA "Risk Factors" and in other documents we file from time to time with the Securities and Exchange Commission, including our Quarterly Reports on Form 10-Q. Restore Medical, Inc. disclaims any intention or obligation to update or revise any forward-looking statements. Unless the context requires otherwise, references to "we," "us," "our" and "Restore" refer to Restore Medical, Inc.

PART I

Item 1. *BUSINESS*

Overview

We develop, manufacture and market our proprietary and patented Pillar® palatal implant system ("Pillar System"). The Pillar System is a simple, innovative, minimally invasive, implantable medical device used to treat sleep disordered breathing, which includes mild to moderate obstructive sleep apnea, or OSA, and habitual or socially disruptive snoring. During the Pillar Procedure, a physician implants three small, braided, proprietary polyester inserts into the muscle of the soft palate. These Pillar inserts, together with the body's natural fibrotic response to the implanted Pillar inserts, add structural support and stiffen the soft palate, thereby minimizing or eliminating the palatal tissue vibration that can cause snoring and the collapse that can obstruct the upper airway and cause OSA. We believe the Pillar Procedure is a safe, clinically effective, long-lasting and low-risk procedure with minimal pain or complications that offers significant benefits to both patients and physicians over other available treatment options.

As reported in the April 2004 Journal of the American Medical Association, it is estimated that one in five adults, or approximately 44 million people, in the United States suffers from mild OSA, and that one in 15 adults, or approximately 15 million people, in the United States suffers from moderate or more severe OSA. A significant number of these estimated 59 million people who suffer from OSA remain undiagnosed and many of those diagnosed with mild to moderate OSA may be reluctant to seek treatment given the less severe nature of their condition, the potentially negative lifestyle effects of traditional treatments, and the lack of awareness of new treatment options. Internationally, the aggregate number of people with OSA is estimated to exceed that in the United States, including approximately 20 million people in Western Europe, 57 million people in China, and 47 million people in India. OSA is a potentially harmful breathing condition caused by one or more obstructions of the upper airway during sleep. Individuals suffering from OSA experience frequent interruptions during sleep, resulting in excessive daytime sleepiness that can lead to memory loss, lack of concentration, depression and irritability. OSA also has been linked to more severe health consequences, including increased risks of cardiovascular morbidity, high blood pressure, stroke, heart attack and Type II diabetes.

In a separate report, the American Academy of Otolaryngology, or AAO, estimates that one in four adults, or approximately 55 million people, in the United States suffer from habitual snoring. Because most people who have OSA snore, the number of people with OSA overlaps significantly with the number of people

who snore. Snoring is a lifestyle issue that often negatively affects the quality of life for the individual who snores and his or her bed partner, often resulting in daytime sleepiness and irritability for both.

We currently market and sell our Pillar System to otolaryngologists (ear, nose and throat physicians, or ENTs) and to a limited number of oral maxillofacial surgeons, as a minimally invasive, clinically effective treatment for mild to moderate OSA and snoring. Our Pillar System has been both cleared by the United States Food and Drug Administration, or FDA, and received CE Mark certification from the European Commission for treatment of mild to moderate OSA and snoring. To date, more than 20,000 Pillar Procedures have been performed world-wide. Our goal is to have the Pillar Procedure recognized as the preferred minimally invasive treatment for the soft palate component of snoring and mild-to-moderate OSA. We also intend to establish the Pillar Procedure as the preferred alternative palatal treatment for individuals suffering from OSA who are unable or unwilling to comply with traditional treatments, including continuous positive airway pressure, or CPAP, or who seek a safe and clinically effective alternative to CPAP therapy for reasons of lifestyle, flexibility and convenience.

We were incorporated in Minnesota in November 1999 and reincorporated in Delaware in May 2004. Our principal executive offices are located at 2800 Patton Road, St. Paul, Minnesota 55113 and our telephone number is (651) 634-3111. Our website address is www.restoremedical.com.

Industry Background

Obstructive Sleep Apnea

OSA is a serious, potentially life-threatening condition that is far more common than generally understood. OSA occurs in all age groups and both genders. According to a report published in the April 2004 Journal of the American Medical Association, approximately 44 million people in the United States suffer from mild OSA and approximately 15 million people suffer from moderate or more severe OSA. Recent studies have linked OSA with increased risks of cardiovascular morbidity, high blood pressure, stroke, heart attack, Type II diabetes and depression. OSA typically causes excessive daytime sleepiness, resulting in memory loss, lack of concentration, slower reaction time that can cause difficulty driving or operating equipment and sexual dysfunction, such as impotence and reduced libido.

OSA occurs when air flow into or out of the nose or mouth is obstructed during sleep due to excess or relaxed tissue that collapses and blocks the upper airway with the effort of inhalation. When the airway becomes blocked, the brain detects a drop in blood oxygen content that causes a "physiological awakening" in order to tighten the muscles and tissues of the upper airway and allow normal breathing to resume. People with OSA may experience sleep disruptions several hundred times in one night, in many cases without being aware that they are waking up, thereby losing the ability to have the deep, restful sleep that is critical to good health. For most people, the soft palate and base of the tongue are primary contributors to upper airway obstruction, although blockages in the nasal airway and walls of the throat, including the tonsils, also affect significant numbers of people. Ingestion of alcohol or sleeping pills can increase the frequency and duration of breathing pauses in people with OSA. Obesity also can be a contributing factor to OSA when excessive amounts of tissue narrow or obstruct the upper airway, as can decreased muscle and tissue tone as a result of aging.

Symptoms of OSA include loud, frequent snoring, periodically gasping for breath or ceasing to breathe during sleep, resulting in excessive daytime sleepiness and fatigue. Not everyone who snores has OSA, and not everyone with OSA necessarily snores, although most do. Primary care physicians often fail to recognize OSA because signs of this sleep disorder can be missed or ascribed to other conditions, such as depression, thyroid problems, anemia or insomnia.

In addition to primary care physicians, ENTs, pulmonologists, neurologists, or other physicians who have specialized training in sleep disordered breathing may diagnose and prescribe treatment for OSA. Diagnosis of the cause of OSA is complicated because there can be many different reasons for disturbed sleep, as well as multiple areas of upper airway obstruction that contribute to OSA. While there are several tests available to accurately diagnose the presence of OSA, a sleep test, or polysomnography, often is required to determine its

severity. Sleep tests are most commonly administered in sleep labs and require an overnight stay. Although home sleep studies can be prescribed by a physician and self-administered by patients, these studies typically are not covered by health insurance.

The specific therapy recommended to treat OSA is tailored to the individual patient based on medical history, physical examination and the results of sleep tests. In addition to recommended lifestyle changes, treatment options for OSA traditionally have been limited to mechanical therapies or the surgical removal or scarring of tissue.

Mechanical Therapies

The most frequently prescribed and common treatment for OSA is CPAP. CPAP therapy requires the patient to wear a nasal or facial mask during sleep that is connected by a tube to a portable airflow generator which delivers air at a predetermined continuous positive pressure. The continuous positive pressure forces air through the nasal passages and keeps the tissue of the upper airway at the back of the throat open and unobstructed, essentially acting as a pneumatic stent of the upper airway during sleep. CPAP prevents upper airway closure while in use, but apnea or hypopnea episodes return when CPAP is stopped or used improperly. CPAP is not a cure for OSA, but a life-long therapy for managing OSA that must be used on a nightly basis. Non-compliance rates for CPAP are estimated to exceed 50% due to factors such as physical discomfort and claustrophobia resulting from use of the nasal or facial mask, nasal and facial irritation, uncomfortable sleeping positions, lifestyle changes, social factors and inconvenience. The reimbursed costs of the portable airflow generator and accessories required for CPAP therapy in the first year of use range from $1,200 to $2,500. The accessories, including hoses, masks and filters, must be periodically replaced at an annual reimbursed cost of approximately $350 to $500.

Another mechanical therapy prescribed to treat OSA is a custom-fitted or prefabricated orthodontic-like device, or oral appliance, that is worn while sleeping. An oral appliance attempts to reposition the jaw and/or the base of the tongue to prevent the tongue from collapsing and obstructing the upper airway during sleep. Oral appliances typically are prescribed and fitted by a dentist or orthodontist, the vast majority of whom are not trained or certified in sleep medicine and who may prescribe oral appliances without the clinical experience or knowledge necessary to accurately diagnose OSA or the site(s) of obstruction causing OSA or snoring in their patients. While oral appliances can be helpful to those patients whose OSA is primarily the result of a collapse of the base of the tongue, they have not been proven to be effective for treating the palatal collapse or flutter addressed by our Pillar System. Oral appliances often are very uncomfortable and inconvenient, and many patients are unable to comply with the requirement of nightly life-long use. Periodic visits to adjust the appliance and dental rehabilitation are often required. The cost of oral appliances is not typically covered by third-party healthcare insurers, and the cost to patients can range between $500 and $2,000.

Surgical Procedures

Before the Pillar Procedure, the only options for palatal-based OSA patients who were not able to tolerate or comply with CPAP therapy were aggressive interventional palatal surgical procedures that permanently remove or scar tissue. Although there are several interventional procedures used to remove or destroy soft palate tissue that can cause upper airway obstructions, none of these surgical procedures is completely successful or without risks. The more invasive of these palatal surgical procedures are very painful, usually require post-procedure prescription narcotics to manage the pain, often result in potentially serious post-surgical complications which can involve hospital re-admission, usually result in lengthy recovery periods of up to two weeks, and are expensive to administer. Interventional procedures to scar or stiffen soft palate tissue often involve more than one treatment, and the scarring or stiffening that results from these procedures diminishes over time as scar tissue tends to remodel and lose stiffness. Other extremely aggressive surgical procedures to treat OSA include a variety of procedures intended to improve air flow through the back of the throat, such as procedures that detach and reattach soft tissues in the throat, advance the anchor point of a key tongue muscle, and advance and realign the upper and lower jaws.

Uvulopalatopharyngoplasty, or UPPP, currently the most common palatal surgical treatment for both OSA and snoring, uses a scalpel, electrocautery, coblation or other cutting technology to remove excess tissue at the back of the throat (tonsils, uvula, and part of the soft palate) under general anesthesia. The UPPP procedure is very painful, often requires an overnight hospital stay, sometimes requires hospital readmission to resolve complications, and typically involves a lengthy recovery period of up to two weeks. An analysis of 18 clinical studies published in February 1996 with the approval of the American Sleep Disorders Association, which included 497 patients who underwent a UPPP procedure to treat their OSA, reported a 38.2% improvement in the patients' respiratory disturbance index. In a separate analysis published in January 2005 by the American Laryngological, Rhinological and Otological Society of the early complications experienced by 1,004 patients who underwent a UPPP, the post-surgical complication rate ranged from 3.4% to 19.4%, including severe complications such as post-operative pulmonary embolism, respiratory complications, hemorrhaging and cardiovascular events. Although the incidence of long-term complications of the UPPP procedure is unclear, the most commonly reported long-term side effects include velopharyngeal insufficiency (a poor seal between the pharynx and soft palate causing a regurgitation of food and fluids when swallowing and adversely affecting speech), nasopharyngeal stenosis (a narrowing of the upper airway above the soft palate) and voice change. It is difficult to predict which patients will experience good clinical results following this procedure. The UPPP procedure generally is covered by third-party healthcare insurers after a patient has been unable to comply with CPAP therapy. The average reimbursed cost of a UPPP procedure ranges from $3,100 to $6,800, depending upon the geographic region in which the procedure takes place. If paid for out-of-pocket, the average cost of a UPPP procedure to the patient ranges from $9,600 to $16,400, depending upon the geographic region in which the procedure takes place and length of stay. Complications could result in additional costs.

Laser-assisted uvulopalatoplasty, or LAUP, is similar to UPPP but uses heat from a laser to destroy tissue of the soft palate. The LAUP procedure requires the use of expensive laser capital equipment and often involves multiple treatments. The clinical and economic benefits of using LAUP over UPPP have not been well established and, as a result, LAUP procedures are now performed less frequently. LAUP procedures are typically performed as an outpatient procedure or in the physician's office, and generally are not reimbursed by third-party healthcare insurers. The total out-of-pocket cost to the patient ranges from approximately $1,500 to $3,000, and multiple procedures may be required.

Radiofrequency ablation, or RF ablation, is a procedure that uses high frequency radio waves to stiffen the soft palate tissue through scarring, and/or reduce the volume of excess nasal turbinate and/or base of tongue tissue. RF ablation typically requires more than one treatment in separate visits to the physician for adequate results. RF ablation can be painful and uncomfortable, and the clinical effect of scarring the soft palate through ablation often is not permanent because the scar tissue tends to remodel over time and lose stiffness. RF ablation is most often performed in the physician's office and is generally not reimbursed by third-party healthcare insurers. FDA clearance for use of RF ablation to treat OSA is currently limited to base of tongue procedures. The total out-of-pocket cost to the patient ranges from $1,500 to $3,000, and often requires two or three treatments per site of obstruction.

Snoring

Habitual and socially disruptive snoring affects both the individual who snores and his or her bed partner, often causing daytime sleepiness and irritability for both. The average non-snoring bed partner loses approximately an hour of sleep each night as a result of his or her partner's snoring. Additionally, a recent survey of 1,008 adults whose partner experienced sleep-related problems, including heavy snoring, determined that 31% of the couples surveyed adjust their sleeping habits by sleeping apart, altering their sleep schedules or wearing ear plugs while sleeping.

The noisy sounds of snoring occur when air flows across the upper airway tissues of the nose or back of the mouth or throat (soft palate), causing relaxed or unstable tissue to vibrate. Although vibration of other parts of the upper airway may contribute to snoring, the soft palate is estimated to be a contributing factor to snoring in 90% or more of patients.

The diagnosis of snoring typically involves a consultation between the patient, his or her bed partner and the patient's primary physician, along with a physical examination of the patient's upper airway. The treating physician often is an ENT or other physician specializing in sleep disordered breathing. The physician typically discusses treatment alternatives with both the patient and his or her bed partner, because in many cases the bed partner is most affected by the patient's snoring.

Historically, the treatment options for snoring have been limited. Typically, the only options available to patients have been lifestyle changes, such as weight loss or sleeping position adjustment; unproven and clinically ineffective over-the-counter remedies, such as nasal strips; oral appliances, which frequently are ineffective; expensive, invasive and painful surgical procedures, such as UPPP or LAUP; or less-invasive procedures, such as RF ablation or sclerotherapy, which have not demonstrated sustained or long-term clinical efficacy.

Sclerotherapy is a procedure where a small amount of a sclerosing agent is injected into the soft palate and uvula. The sclerosing agent causes scarring via an inflammatory tissue response, which results in the shrinking and stiffening of tissue. Patients frequently must undergo multiple treatments to achieve the desired stiffening of the tissue. As with RF ablation, the results of sclerotherapy often are temporary as scar tissue tends to remodel over time and lose stiffness. Sclerotherapy treatments are performed in the physician's office and generally are not reimbursed by third-party healthcare insurers. The out-of-pocket price range of a single sclerotherapy procedure to the patient is approximately $350 to $500, and ongoing treatments are required.

All procedures or devices to treat snoring are viewed by third-party healthcare insurers as elective or cosmetic procedures, and are not reimbursed in the absence of a definitive diagnosis of OSA. The patient's out-of-pocket costs for these procedures can range from several hundred dollars for each sclerotherapy treatment to multiple thousands of dollars for a UPPP procedure. Although CPAP also may be offered as a therapy for habitual snoring, the costs are not reimbursable, and it is not commonly prescribed.

Our Solution — The Pillar Procedure

Our Pillar System treats the soft palate, which is the most common contributor to the upper airway obstruction and tissue vibration that causes OSA and snoring. We designed our Pillar System to address several essential clinical and physiological requirements. We wanted to preserve the normal function of the soft palate while producing a long-lasting physiological effect. Additionally, we wanted the Pillar inserts to provide a long-term clinical benefit using a procedure that was reversible and that used only well-known, well-understood biocompatible materials. We designed our Pillar System to stiffen and increase the structural integrity of the soft palate and to improve its response to airflow, without interfering with normal soft palate functions, such as swallowing or speech. The Pillar System can be used as a stand-alone treatment or in combination with other therapies.

During the Pillar Procedure, the physician uses topical and local anesthetics to numb the soft palate tissue, and then individually implants three Pillar inserts into the muscle of the soft palate at the junction of the hard and soft palate using our specially-designed, single-use delivery tool. Each precisely braided Pillar insert is approximately 18 mm (0.7 inches) in length and has an outer diameter of 2 mm (0.08 inches). We braid our Pillar inserts to our precise specifications from a polyethylene terephthalate fiber that has been used for many years in implantable medical products such as surgical sutures and heart valve cuffs. Each patient receives three Pillar inserts as part of the Pillar Procedure. The Pillar inserts are placed as closely as possible to each other without touching (approximately 2 mm apart) to achieve maximum stiffening.

The implantation of the Pillar inserts into the soft palate tissue triggers the body's natural fibrotic response to injury and the introduction of foreign bodies, which stimulates tissue growth into and around the inserts, resulting in a fibrotic tissue encapsulation of the implant. The proprietary surface texture of the Pillar inserts promotes this tissue in-growth, serving to anchor the Pillar inserts in the soft palate. In addition to the structural support provided by the inserts themselves, this natural fibrotic response into and around the implants further stiffens the soft palate tissue, effectively acting to "extend the hard palate," and thereby reducing or eliminating the soft palate tissue flutter that causes snoring and the retropalatal collapse that can obstruct the airway and cause OSA.

The reported commercial complication rate for the Pillar Procedure, with more than 20,000 procedures performed to date, is less than 1%. The most commonly reported complication is the partial extrusion of a Pillar insert, which typically occurs as the result of an insert being implanted too shallow or too deeply in the soft palate tissue. In the event of a partial extrusion, the physician simply removes the partially extruded insert and replaces it with a new Pillar insert.

We believe the Pillar Procedure offers the following significant advantages over other current treatment options:

- *Clinically effective, long-lasting treatment.* In multiple clinical studies, the Pillar Procedure has demonstrated comparable or superior clinical outcomes compared to more invasive palatal surgical procedures that involve the permanent removal or destruction of tissue. Our procedure has demonstrated sustained clinical benefits over time, as compared to the clinical benefits of surgical procedures that ablate and destroy palatal tissue, which often diminish over time as scar tissue tends to remodel and lose its stiffness.

- *Low-risk procedure with minimal pain, complications and inconvenience.* The Pillar Procedure involves minimal pain and has a reported commercial complication rate of less than 1% with few post-procedure side effects. Invasive surgical procedures, such as UPPP, that permanently remove soft palate tissue are painful, involve recovery periods of up to two weeks and have reported substantially higher complication rates of 3.4% to 19.4%. For CPAP users with mild to moderate OSA who are unable or unwilling to comply with their CPAP therapy and suffer from palatal obstruction, the Pillar Procedure offers a one-time, permanent treatment alternative that could alleviate the nightly burden of wearing an uncomfortable and inconvenient mask.

- *Uses local anesthetic, not general anesthesia.* Physicians use only topical and local anesthetics to perform the Pillar Procedure, rather than the general anesthesia required for more invasive surgical procedures, resulting in fewer complications and a significantly shorter recovery period.

- *In-office procedure that takes approximately 20 minutes.* The Pillar Procedure is a one-time procedure that typically is performed in the physician's office. Patients typically resume their normal diet and activities the same day without the need for an overnight hospital stay or prescription pain relievers. Invasive surgical procedures often entail a recovery period of up to two weeks and prescription narcotics to manage the pain. Other surgical procedures that scar or ablate tissue usually require multiple treatments involving repeat visits to the physician.

- *Economic benefits to patients, physicians and payors.* For patients, the Pillar Procedure is a relatively low-cost, one-time treatment solution with no recurring expenses. For physicians, the Pillar Procedure is a simple, easy-to-learn, minimally invasive, in-office procedure with clinical proven and sustained benefits for patients suffering from mild to moderate OSA and chronic snoring. The Pillar Procedure can be a profitable in-office procedure for physicians, and can offer a cost-effective alternative to more invasive and risky procedures with higher complication rates or procedures which have not demonstrated long-term clinical benefits. For patients and payors, our procedure combines quality outcomes with reasonable costs.

The Pillar Procedure was cleared by the FDA for snoring in December 2002 and for mild to moderate OSA in July 2004. Our Pillar System also received CE Mark certification from the European Commission for snoring in May 2003 and mild to moderate OSA in December 2004.

Our Strategy

Our goal is to have the Pillar Procedure recognized by the market as the preferred minimally invasive, in-office treatment of the soft palate for patients suffering from mild to moderate OSA and snoring. We intend to establish the Pillar Procedure as the preferred alternative treatment for individuals who suffer from chronic snoring as well as those individuals who are unable or unwilling to comply with CPAP therapy or who seek a safe and clinically effective alternative to CPAP therapy for reasons of lifestyle flexibility and convenience. To

achieve these goals, we must successfully develop the market for the Pillar Procedure in the United States and internationally. We are undertaking the following key growth strategies and related tactics:

- increase physician and patient awareness of the Pillar Procedure over other treatment options for patients suffering from sleep disordered breathing;
- work closely with our physician customers to implement practice support programs that help increase the number of patients who are referred to, or self-refer to, their sleep disordered breathing practices, and to train physicians and their staff in the education and treatment of these patients;
- continue our efforts to establish adequate and appropriate third-party healthcare insurance coverage and reimbursement for use of the Pillar Procedure to treat mild to moderate OSA;
- sponsor and participate in additional clinical studies that seek to further validate the clinical effectiveness of the Pillar Procedure as a stand-alone treatment for mild to moderate OSA and snoring or in combination with CPAP therapy to treat other areas of upper airway obstruction that cause OSA and snoring, and further expand the FDA-cleared indications for use of the Pillar Procedure; and
- proactively explore the development of new products and technologies that would allow us to effectively treat other areas of upper airway collapse.

Sales and Marketing

U.S. Sales and Marketing Strategies

We employ a direct sales force in the United States which has increased from 12 field representatives at the beginning of 2006 to 20 field representatives at December 31, 2006. The direct sales force is primarily focused on marketing and selling our Pillar System to ENTs, and to a lesser extent, oral maxillofacial surgeons who treat patients suffering from sleep disordered breathing. We have worked closely with our physician customers to implement practice development and support programs that help increase the number of patients suffering from sleep disordered breathing who are referred to, or self-refer to, their practices. These practice development programs include the creation and implementation of local physician and prospective patient sleep disordered breathing education programs, as well as customized local advertising, public relations, and sleep disordered breathing information initiatives to promote physician practices to potential patients.

In addition to programs focused on our current and potential physician customers, we are developing marketing programs targeted to potential consumers and their bed partners. We will continue to execute marketing programs to increase awareness of our Pillar System as a clinically effective, minimally invasive treatment of the soft palate for individuals suffering from mild to moderate OSA and snoring. These programs will include local and regional marketing programs to drive patient self-referrals and working closely with physicians to generate referrals from sleep centers and sleep medicine physicians, as well as from primary care physicians.

International Sales Strategy

We currently market our products in 27 countries outside the United States through independent distributors in North and South America, Asia Pacific, Europe, the Middle East and South Africa. We have entered into multi-year distribution agreements with each of these international distributors. Under the terms of each of our international distribution agreements, we ship our products to our distributors upon receipt of purchase orders from these distributors. Each of our independent distributors has the exclusive right to sell our Pillar System within a defined geographic territory. Many of these distributors also market and sell other medical products, although contractually they are not permitted to sell products directly competitive with our Pillar System. Our independent distributors purchase our Pillar System from us at a discount to our United States list price and resell our Pillar System to physicians, hospitals or clinics in their respective geographic territories. The end-user price of our Pillar System in each country is determined by the distributor and/or local physicians and varies from country to country.

Clinical Studies

To date, 21 clinical studies have been completed in which the clinical safety and efficacy of the Pillar Procedure has been evaluated and assessed on a total of 689 patients, including patients who were part of both separate 90 day and long-term follow-up studies. Eleven clinical studies have been completed on 445 patients to evaluate the Pillar Procedure for the treatment of mild to moderate OSA. Ten clinical studies have been completed on 244 patients to evaluate the Pillar Procedure to treat snoring. We believe the individual and collective results of these clinical studies demonstrate that the Pillar Procedure is a safe and effective treatment for the palatal component of mild to moderate OSA and snoring.

Obstructive Sleep Apnea

All of the Pillar Procedure OSA clinical studies have utilized the apnea-hypopnea index (AHI), as determined by a clinical-based polysomnography (PSG) during an overnight sleep study to measure and document the severity of patients' clinical sleep disturbances both prior to and subsequent to receiving the Pillar Procedure. Eight OSA clinical studies have been completed in which the manuscripts have been published in peer-reviewed medical journals, accepted for publication in peer-reviewed medical journals, or have been submitted for publication and are undergoing the peer-review process. These studies include the results of the first evidence-based-medicine Level 1 prospective, randomized, blinded, placebo-controlled clinical study of the Pillar Procedure, which was reported by the American Academy of Otolaryngology at its annual meeting in September 2006.

The collective results of these studies report that between 66% and 81% of patients demonstrated a clinically and statistically significant decrease in their AHI between their baseline PSG and the PSG administered 90-days following the Pillar Procedure. Between 21% and 45% of these patients achieved the classical ENT surgical definition of "clinical success" (a reduction in AHI $\geq$ 50% and an absolute AHI $\leq$ 20). In two of these studies, clinical investigators followed patients out to twelve and fifteen months, respectively, and 77% to 81% of the patients continued to demonstrate a sustained clinically and statistically significant decrease in their AHI, along with a comparable level of classical ENT surgical clinical success.

The reported commercial complication rate for the Pillar Procedure, is less than 1%, with the primary complication being the relatively insignificant partial extrusion of a Pillar insert. In contrast to the more severe and sometimes permanent nature of complications resulting from more invasive palatal surgical procedures, a physician remedies a partially extruded Pillar insert by simply removing the insert and replacing it with another Pillar insert.

Snoring

Manuscripts from eight clinical studies reporting the clinical safety and efficacy of the Pillar Procedure to treat snoring have been published in peer-reviewed medical journals. Two additional clinical studies on the use of the Pillar Procedure to treat snoring have been completed and the corresponding manuscripts reporting the clinical results have been submitted for publication and are currently undergoing the peer review process. A third clinical study presented in September 2006 at the annual meeting of the American Academy of Otolaryngology reported follow-up results at three years post-treatment. The reported clinical results at 90 days, one year, and three years post-treatment demonstrate a decrease in snoring intensity of between 32% and 66%. Bed partner satisfaction with the decrease in patients' snoring intensity was reported between 67% and 100% at ninety days, and maintained at between 70% and 80% at one and three years. We are not aware of peer-reviewed published clinical data that has reported comparable or superior results from any other snoring treatment.

Additional Clinical Studies

A recently completed clinical study, as well as the manuscript reporting on a retrospective clinical study that was published in 2006, evaluated OSA patients suffering from multi-level upper airway obstruction and reported on the effectiveness of the Pillar Procedure to treat the soft palate in combination with surgical procedures to treat nasal obstruction. The manuscript reporting the results of this recently completed clinical

study has been submitted for publication and is undergoing the peer-review process. Patient enrollment is complete on two additional evidence-based Level 1 blinded placebo studies involving approximately 122 patients at four centers, and the investigators are in the process of completing patient follow-up and preparing manuscripts, which we expect to be submitted for publication by peer-reviewed medical journals.

We recently initiated or are involved in additional post-market evidence-based-medicine Level 1 prospective, randomized studies to further validate the efficacy of the Pillar Procedure in the treatment of mild to moderate OSA, and potentially expand the approved indications of use for the Pillar Procedure. One of these studies is designed to evaluate the effectiveness of the Pillar Procedure in patients who are not compliant with their CPAP therapy, and will assess whether the combination of a soft palate stiffened with Pillar implants will make CPAP therapy more tolerable and improve patients' CPAP compliance. Another clinical study has been initiated to evaluate the use of a fourth or fifth Pillar implant for patients who have not been able to achieve a satisfactory outcome for snoring with just three Pillar inserts. A pilot study presented at the Annual Meeting of the American Academy of Otolaryngology in September 2006 reported that 26 of the 31 patients involved achieved a satisfactory reduction in snoring intensity and bed partner satisfaction after receiving a fourth or fifth Pillar insert. We also are evaluating additional clinical studies to evaluate the use of the Pillar Procedure to treat the soft palate in combination with procedures to treat other areas of upper airway obstruction causing OSA. We will continue to work with leading, independent physician investigators to conduct these clinical studies, and will endeavor to facilitate the publication of the data derived from these clinical studies in peer-reviewed medical journals, as well as presenting this data at key scientific and medical meetings.

Third-Party Reimbursement

Generally, patients who undergo the Pillar Procedure pay for the procedure out-of-pocket without third-party reimbursement. Treatments for snoring are deemed elective cosmetic surgery and are not reimbursed by third-party healthcare insurers. The use of the Pillar Procedure as a treatment for snoring will remain a self-pay procedure. We believe the number of Pillar Procedures performed to treat snoring will continue to increase as patients pay for the Pillar Procedure out-of-pocket, and that the Pillar Procedure will continue to be an effective and profitable in-office treatment snoring treatment for our physician customers.

Certain therapies for the treatment of OSA, including CPAP and UPPP, generally are covered by third-party healthcare insurers, and we are seeking to obtain third-party reimbursement for individuals who elect to undergo the Pillar Procedure to treat their mild to moderate OSA. Obtaining coverage will depend, in large part, on publication of additional, peer-reviewed clinical literature demonstrating the effectiveness of the Pillar Procedure in treating patients suffering from mild to moderate OSA. As discussed above, there are several manuscripts for completed clinical studies which are undergoing the peer review process, and well as additional clinical studies underway, that we anticipate will further demonstrate the clinical effectiveness of the Pillar Procedure to treat the soft palate component of mild to moderate OSA.

An important step in obtaining reimbursement is securing appropriate Current Procedural Terminology, or CPT Codes, which are administered by the American Medical Association, or AMA. CPT codes are used by all payors, including Medicare, to adjudicate claims and to reimburse for certain healthcare services, particularly physician fees. The AMA has an annual process to create new CPT codes, whereby physician societies are responsible for applying to the AMA for new CPT codes. We are working in collaboration with the American Academy of Otolaryngology — Head and Neck Surgery, or AAO-HNS, to provide the information necessary to support the creation of a distinct CPT code for the Pillar Procedure. We intend to use the data from three prospective, randomized, placebo-controlled clinical studies of our Pillar System currently underway in the United States and Europe, along with the data from the clinical studies described above, to support our future application for a Pillar Procedure CPT code. We believe these clinical studies will not only support the creation of a distinct CPT code for the Pillar Procedure, but also will supplement the published data from our previous clinical studies validating the clinical efficacy of the Pillar Procedure in treating the palatal component of mild to moderate OSA.

Effective October 1, 2006, the Centers for Medicare and Medicaid Services, or CMS, granted a New Technology Ambulatory Payment Classification Designation, or New Technology APC, for the Pillar System.

The New Technology APC provides a billing and payment mechanism for the Pillar Procedure when performed in the hospital outpatient setting. CMS created a distinct HCPCS Level II code for the Pillar System for billing and payment purposes. The New Technology APC provides a national average payment amount of $850 to the hospital to cover the cost of the Pillar implants and facility fees. Physicians bill for their professional fees associated with the Pillar Procedure separately.

Also effective October 1, 2006, Wisconsin Physician Services (WPS) began to include the Pillar Procedure as a covered in-office treatment for OSA for Medicare patients who meet certain conditions. WPS establishes medical policy for Medicare physician services in Minnesota, Illinois, Michigan and Wisconsin, and is the first regional Medicare carrier to grant coverage for the Pillar Procedure. WPS is in the process of determining the payment that will apply to this new Pillar Procedure coverage policy.

Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In most markets, there are private insurance systems as well as government-managed systems. As with regulatory approval to sell the Pillar Procedure in international markets, it is the responsibility of each distributor to obtain any government and third-party payor reimbursement for the Pillar Procedure in the respective country. Many international markets have government managed healthcare systems that control reimbursement for new products and procedures. Market acceptance of our Pillar System will depend on the availability and level of reimbursement in international markets targeted by us.

Research and Development

We are continuing our efforts to develop and introduce clinically relevant improvements and enhancements to our current Pillar System, including the use of materials or agents that could further enhance the clinical efficacy of the Pillar implant mechanism and further improve the ease-of-use of our Pillar System. We also are evaluating a number of different device designs that would allow us to leverage our technology and patent portfolio to treat base of tongue obstructions that can cause OSA.

We incurred research and development expenses of approximately $3.0 million, $1.9 million, and $2.3 million for the years ended December 31, 2006, 2005 and 2004, respectively. We anticipate that we will continue to make significant investments in research and development as we explore opportunities to leverage the Pillar technology.

Intellectual Property

Our success will depend in part on our ability to obtain and defend patent protection for our products and processes, to preserve our trade secrets and to operate without infringing or violating the proprietary rights of third parties. To date, we have been granted 37 United States patents that we believe provide us with broad intellectual property protection for our Pillar System, related concepts and a wide variety of implants, tools and applications. Our patent coverage includes a wide array of devices, designs and materials implanted in the soft palate and other areas of the upper airway to induce tissue fibrosis and stiffening. We also have 21 additional pending U.S. patent applications. In addition to our U.S. patents and applications, our technology is covered by 16 issued international patents, 20 pending foreign patent applications.

We also register the trademarks and trade names through which we conduct our business. To date, we have registered the trademarks "Pillar" and "Restore Medical." In addition to the United States, we have trademark registrations or pending applications for our name and mark in China, the European Union, Indonesia and Singapore.

In addition to our patents, we rely on confidentiality and proprietary information agreements to protect our trade secrets and proprietary knowledge. These confidentiality and proprietary information agreements generally provide that all confidential information developed or made known to individuals by us during the course of their relationship with us is to be kept confidential and not disclosed to third parties, except in specific circumstances. The agreements also specifically provide that all inventions conceived by the individual relating to our technology, in the course of rendering services to us, shall be our exclusive property.

Manufacturing

We manufacture our Pillar System in our leased facility in St. Paul, Minnesota. We perform all final assembly, including manufacturing our Pillar inserts, assembling the parts for our Pillar delivery tool and inserting our Pillar inserts into the delivery tool in our facility. We outsource the plastic injection molding of our delivery tool. We make our Pillar inserts in our facility using our proprietary material braiding process. In addition, we perform all packaging, labeling and inspection in-house. We use our FDA and EU compliant production and quality systems and processes in performing all of our operations. We use our own proprietary production floor control system software to electronically generate manufacturing work instructions, track product-build status, establish lot control records and maintain operator training records. We follow lean manufacturing principles to provide high-quality, low-cost production of our Pillar System.

Competition

We believe that our competitive success will depend primarily on our ability to effectively create market awareness and influence increased clinical acceptance and adoption of our Pillar System by physicians and patients. The market for the treatment of sleep disordered breathing has attracted a high level of interest from various companies in the medical device industry. Our primary competitors include companies that offer CPAP and other therapeutic devices designed to treat OSA and snoring. Respironics, Inc. and ResMed Inc. are the leading competitors in the CPAP market, collectively accounting for an approximately 80% market share. Fisher & Paykel Healthcare Corp., Nellcor Puritan Bennett (a subsidiary of Tyco) and Vital Signs, Inc. are also competitors in the CPAP market. We also compete against companies offering radiofrequency-based ablation devices such as Gyrus ACMI and ArhtroCare and against traditional surgical procedures often recommended by ENTs and other surgeons who specialize in treating OSA and snoring. Additionally, we are aware of several development-stage companies that are attempting to develop new products or technologies that may be designed to treat other areas of airway obstruction that cause OSA.

Many of our competitors and potential competitors have substantially greater capital resources than we do, including larger and more experienced research and development staffs and facilities. In addition, most of our competitors and potential competitors have substantially greater experience than we do in researching and developing new products, testing products in clinical trials, obtaining regulatory approvals and manufacturing and marketing medical devices. These competitors may be in a stronger position to respond quickly to new technologies and may be able to undertake more extensive marketing campaigns. Our failure to demonstrate the clinical efficacy and cost-effective advantages of our products over those of our competitors could adversely affect our business and results of operations.

Government Regulations

United States

Our Pillar System received FDA 510(k) clearance in December 2002 for the treatment of socially disruptive snoring and was commercially introduced for snoring in April 2003. During the next 15 months we undertook clinical trials to substantiate the use of our Pillar System to treat patients suffering from mild to moderate OSA, and received a 510(k) clearance from the FDA in July 2004 for this indication.

Our Pillar System is regulated in the United States as a medical device by the FDA under the federal Food, Drug and Cosmetic Act, or FDC Act. Pursuant to the FDC Act, the FDA regulates the research, testing, manufacture, safety, labeling, storage, record keeping, advertising, distribution and production of medical devices in the United States. Noncompliance with applicable requirements can result in warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant pre-market approval for devices and criminal prosecution.

The FDA's Premarket Clearance and Approval Requirements. Unless an exemption applies, each medical device we wish to distribute commercially in the United States will require either prior clearance under Section 510(k) of the FDC Act from the FDA or acceptance of a premarket approval, or PMA, application by the FDA. Medical devices are classified into one of three classes — Class I, Class II, or

Class III — depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. Devices deemed to pose lower risks are placed in either Class I or II, which requires the manufacturer to submit to the FDA a premarket notification requesting permission to commercially distribute the device. This process is generally known as 510(k) clearance. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in Class III, requiring premarket approval. The Pillar Procedure is a Class II device.

510(k) Clearance Pathway. When a 510(k) clearance is required, we must submit a premarket notification to the FDA demonstrating that our proposed device is substantially equivalent to a previously cleared and legally marketed 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of a PMA application. By regulation, the FDA is required to respond to a 510(k) premarket notification within 90 days of submission of the application. As a practical matter, clearance often takes significantly longer. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. If the FDA determines that the device, or its intended use, is not substantially equivalent to a previously-cleared device or use, the FDA will place the device, or the particular use, into Class III, which requires premarket approval.

Premarket Approval (PMA) Pathway. A PMA application must be submitted to the FDA if the device cannot be cleared through the 510(k) process. The PMA application process is much more demanding than the 510(k) premarket notification process. A PMA application must be supported by extensive data, including but not limited to technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device.

After a PMA application is submitted and the FDA determines that the application is sufficiently complete to permit a substantive review, the FDA will accept the application for review. The FDA has 180 days to review an "accepted" PMA application, although the review of an application generally occurs over a significantly longer period of time and can take up to several years. During this review period, the FDA may request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with quality system regulations. New PMA applications or PMA application supplements are required for significant modification to the manufacturing process, labeling and design of a device that is approved through the PMA process. Premarket approval supplements often require submission of the same type of information as a PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application and may not require as extensive clinical data or the convening of an advisory panel.

Clinical trials are almost always required to support a PMA application and are sometimes required for 510(k) clearance. In the United States, these trials generally require submission of an application for an Investigational Device Exemption, or IDE, to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specific number of patients unless the product is deemed a non-significant risk device eligible for more abbreviated IDE requirements. Clinical trials for significant risk devices may not begin until the IDE application is approved by the FDA and the appropriate institutional review boards, or IRBs, are present at the clinical trial sites. Clinical trials must be conducted under the oversight of an IRB at the relevant clinical trial sites and in accordance with the FDA regulations, including but not limited to those relating to good clinical practices. Patients' informed consent that complies with both the FDA requirements and state and federal privacy regulations is also required. The FDA or the IRB at each site at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the benefits. Even if a trial is completed, the results of clinical testing may not demonstrate the safety and efficacy of the device, or the results may not be equivocal or may otherwise not be sufficient to obtain approval of the product. Similarly, in Europe the clinical study must be approved by the local ethics

committee and in some cases, including studies with high-risk devices, by the Ministry of Health in the applicable country.

We are required to provide information to the FDA on death or serious injuries alleged to have been associated with the use of our medical devices, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur. In addition, the FDA prohibits an approved device from being marketed for unapproved applications. If the FDA believes that a company is not in compliance, it can institute proceedings to detain or seize products, issue a recall, enjoin future violations, and assess civil and criminal penalties against the company, its officers and its employees. Failure to comply with applicable FDA regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

Regulations regarding the manufacture and sale of our products are subject to change. We cannot predict what impact, if any, such changes might have on our business, financial condition or results of operations.

International

We received CE Mark certification from the European Commission for the snoring indication and the OSA indication in May 2003 and December 2004, respectively. International sales of our products are subject to regulatory requirements that vary widely from country to country. The European Union has adopted rules which require that medical products receive the right to affix the CE Mark, an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. As part of the CE compliance, manufacturers are required to comply with the ISO series of quality systems standards.

We plan to continue to leverage the FDA clearance and CE Mark certification for OSA and snoring indications in support of other regulatory filings outside the United States, and provide regulatory dossiers to international regulatory agencies, as required. Our Pillar System is currently approved for sale in the following countries in the Asia Pacific region: China, Singapore, Australia, South Korea, Hong Kong, the Philippines, Malaysia, Brunei, Thailand, Indonesia, Vietnam and Cambodia, and applications have been filed or are in process in several other countries in the region. Our Pillar System is also approved for sale in the following countries in the Middle East: Israel, Turkey, Bahrain, Qatar and the United Arab Emirates. Additional countries will be added to the registration process as distributors are selected. The regulatory review process varies from country to country, and we cannot provide assurance that such approvals will be obtained on a timely basis or at all.

Product Liability and Insurance

The development, manufacture and sale of medical products entails significant risk of product liability claims and product failure claims. We have conducted relatively limited clinical trials and clinical studies to date, and we do not yet have, and will not have for a number of years, sufficient clinical data to allow us to measure the long-term risk of such claims with respect to our products. We face an inherent business risk of financial exposure to product liability claims in the event the use of our products results in personal injury or death. We also face the possibility that defects in the design or manufacture of our products might necessitate a product recall. Although, to date, we have not received any product liability claims nor have we had any recalls, there can be no assurance that we will not experience losses due to product liability claims or recalls in the future. We currently maintain product liability insurance with coverage limits of $5.0 million per occurrence and $5.0 million annually in the aggregate, although we do not have sufficient experience to confirm whether the coverage limits of our insurance policies will be adequate. Product liability insurance is expensive, may be difficult to obtain and may not be available in the future on acceptable terms, or at all. Any claims against us, regardless of their merit or eventual outcome, could have a material adverse effect upon our business, financial condition and results of operations.

Employees

As of December 31, 2006, we had a total of 67 employees, consisting of 31 employees in sales and marketing, 12 employees in research and development (including regulatory and clinical affairs), 11 employees in operations and quality assurance, and 13 employees in general and administrative functions. All of these employees are located in the United States.

From time to time we also employ independent contractors, consultants and temporary employees to support our operations. None of our employees are subject to collective bargaining agreements. We have never experienced a work stoppage and believe that our relations with our employees are good.

Seasonality

We believe that holidays, major medical conventions and seasonal vacations taken by physicians, patients and patient families may have a seasonal impact on our sales. We continue to monitor and assess the impact seasonality may have on demand for our products.

Executive Officers of Restore

Our executive officers are as follows:

Name	Age	Position
J. Robert Paulson, Jr.	50	President, Chief Executive Officer and Director
Christopher R. Geyen	36	Senior Vice President and Chief Financial Officer
Craig G. Palmer	57	Senior Vice President of U.S. Sales
David L. Bremseth, Pharm. D.	47	Vice President of Clinical Affairs
Paul J. Buscemi, Ph.D.	60	Vice President of Research and Development
Michael R. Kujak	42	Vice President of Marketing
Philip E. Radichel	63	Vice President of Information Systems
John P. Sopp	43	Vice President of Operations

J. Robert Paulson, Jr. was appointed President, Chief Executive Officer and a director of our company in April 2005. Prior to joining us, Mr. Paulson served as Chief Financial Officer and Vice President of Marketing for Endocardial Solutions, Inc. from August 2002 until January 2005 when it was acquired by St. Jude Medical, Inc. From 2001 to June 2002, Mr. Paulson was the Senior Vice President and General Manager of the Auditory Division of Advanced Bionics Corporation, and between 1995 and 2001, Mr. Paulson served in various capacities at Medtronic, Inc., including Vice President and General Manager of the Surgical Navigation Technologies business unit; Vice President of Corporate Strategy and Planning; and Director of Corporate Development. Mr. Paulson currently serves on the board of directors of two publicly held medical device companies, MedicalCV, Inc. and Vascular Solutions, Inc. Mr. Paulson received a Bachelor of Arts in Accounting, Economics and Political Science from Luther College; a Master of Business Administration from the University of St. Thomas and his Juris Doctorate from Vanderbilt University School of Law.

Christopher R. Geyen was appointed Chief Financial Officer of our company in March 2006 and was appointed Senior Vice President and Chief Financial Officer in February 2007. Prior to joining us, Mr. Geyen served as Chief Financial Officer and Vice President for Acorn Cardiovascular, Inc. since 2003. From 1999 to 2003, Mr. Geyen was the Chief Financial Officer, Vice President, Secretary and Treasurer of Urologix, Inc., where he also served as the Controller from 1998 to 1999. Previously, Mr. Geyen held positions as Controller at SurVivaLink Corporation and as a Senior Auditor for Ernst & Young, LLP. Mr. Geyen received a Bachelor of Arts in Business Administration and Accounting from the University of St. Thomas and is a Certified Public Accountant.

Craig G. Palmer has served as Vice President of U.S. Sales for our company since September 2006 and was appointed Senior Vice President of U.S. Sales in February 2007. Prior to joining us, Mr. Palmer was Vice President of Sales at ev3 from July 2003 until March 2006. From April 2002 until July 2003, Mr. Palmer held the position of Vice President of Sales at Urologix. From January 2000 until December 2000, Mr. Palmer was

Vice President of Sales at Image Guided Neurologics. From 1997 through January 2000, Mr. Palmer performed sales and marketing consulting with SurVivaLink Corporation and MaxMed. Mr. Palmer also held sales and sales management positions at Scimed/Boston Scientific from August 1989 through July 1997, including five years as Vice President of Sales. Prior to joining Scimed/Boston Scientific, Mr. Palmer held various sales, sales management and marketing positions at American/Baxter Edwards Laboratories and Jelco/Critikon divisions of Johnson & Johnson. Mr. Palmer received a Bachelor of Arts in Mathematics from St. John Fisher College in Rochester, NY.

David L. Bremseth, Pharm.D., joined us as Vice President of Clinical Affairs in December 2006 and took over responsibility for Quality and Regulatory in February 2007. Prior to joining us, Dr. Bremseth served as the Vice President of Clinical, Regulatory and QA for Celleration, Inc. since February 2001. From 1998 to 2001, Dr. Bremseth was the Senior Director of Clinical Affairs for Antares Pharma (formerly Medi-Ject Corporation), from 1996 until 1997 he was Director of New Medicine Development with Orphan Medical, Inc. and from 1995 to 1996 he was Associate Director of Clinical Affairs for LecTec Corporation. Dr. Bremseth was Director of Clinical Affairs for Pharmaceutical Research Associates, a contract research organization, from 1992 to 1995 and a Clinical Scientist at Parke-Davis Pharmaceuticals from 1989 to 1992. Prior to that he was assistant professor at the North Dakota State University College of Pharmacy from 1987 to 1988. He received a Bachelor of Science in Pharmacy from North Dakota State University in 1983, a Doctor of Pharmacy from The Ohio State University in 1985, and completed research fellowships in Pharmacokinetics and Drug Development in 1987 and 1989, respectively.

Paul J. Buscemi has served as our Vice President of Research and Development since joining us in October 2005. From 1998 to October 2005, Dr. Buscemi was Director of New Technology at Advanced BioSurfaces, Inc., where he designed and tested a novel minimally invasive implant to treat osteoarthritis of the knee. He also has served as a consultant to international biomedical firms including Medtronic, Upshire-Smith, Becton Dickenson and UpJohn Pharmaceuticals, as well as several entrepreneurial companies in the Twin Cities area involved in device design, coatings and drug delivery. Dr. Buscemi received a Bachelor of Arts in Physics and Applied Mathematics, a Master of Science in Material Science, and a Ph.D. in Bioengineering and Biomedical Science from the University of Florida, Gainesville.

Michael R. Kujak has served as our Vice President of Marketing since January 2007. Prior to joining us, Mr. Kujak was Group Manager, Marketing at American Medical Systems from April 2004 until January 2007. From January 2000 until March 2004, Mr. Kujak held the position of Vice President of Sales and Marketing at AmericasDoctor. Prior to joining AmericasDoctor, Mr. Kujak held various sales, sales management and marketing positions at Connetics, Interneuron Pharmaceuticals, Vencor and Hoffmann-LaRoche. Mr. Kujak received a Bachelor of Sciences in Chemistry and Physics from the University of South Dakota and is currently enrolled in the Executive Master of Business Administration program at the University of St. Thomas in Minneapolis, MN.

Philip E. Radichel has served as our Vice President of Quality and Information Systems from October 2005 through December 2006 and continues to serve as our Vice President of Information Systems. From November 2002 to October 2005, Mr. Radichel was our Director of Quality Assurance and Information Systems. From February 2002 to November 2002 he was a Vice President at Venturi Development Inc. Mr. Radichel was also Systems Manager at Integ Incorporated from December 1996 to February 2002. Mr. Radichel received a Bachelor of Science in Electrical Engineering from the University of Minnesota.

John P. Sopp has served as our Vice President of Operations since April 2004 and was our Director of Operations from December 2002 to March 2004. From February 2002 to November 2002, Mr. Sopp served as a Vice President of Venturi Development, Inc. From 1995 to 2001, he served as Production Manager and Senior Molding Engineer with Integ Incorporated. Prior to that he held a position with SIMS Deltec. He also held engineering positions at UFE Incorporated, a custom injection molding company, and General Dynamics. Mr. Sopp received a Bachelor of Science in Mechanical Engineering from the University of Minnesota and a Masters Degree in Manufacturing Systems from the University of St. Thomas.

Our Corporate Information

Our principal executive offices are located at 2800 Patton Road, St. Paul, Minnesota 55113, and our telephone number is (651) 634-3111. We make our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K available free of charge through the investor relations page of our website at www.restoremedical.com, as soon as reasonably practicable after we electronically file such material with (or furnish such material to) the Securities and Exchange Commission. Our reports filed with the SEC are also available at the SEC's website at www.sec.gov. Our Code of Conduct is also available on our website. The information on, or that may be accessed through, our website is not incorporated by reference into this report and should not be considered a part of this report on Form 10-K.

Pillar® and the Restore Medical logo are registered trademarks of Restore Medical, Inc. This report on Form 10-K contains other trade names and service marks of Restore and of other companies.

Item 1A. *RISK FACTORS*

Our business, financial condition or results of operations could be materially adversely affected by any of the risks and uncertainties described below. Additional risks not presently known to us, or that we currently deem immaterial, may also impair our business, financial condition or results of operations. You should consider carefully the risks and uncertainties described below and all the other information contained in this Annual Report on Form 10-K, including our financial statements and related notes. The market price of our common stock could decline due to any of these risks and uncertainties.

Risks Relating to Our Business and Industry

We will not be successful if our Pillar System is not adopted for the treatment of snoring or mild to moderate obstructive sleep apnea.

The first commercially available product based on our proprietary palatal implant technology is our patented Pillar System. Our success depends both on the medical community's acceptance and adoption of our Pillar System as a minimally invasive treatment for individuals suffering from mild to moderate OSA and socially disruptive and habitual snoring. Currently, a relatively limited number of ENTs and oral maxillofacial surgeons regularly perform the Pillar Procedure. We cannot predict how quickly, if at all, the medical community will accept our Pillar System, or, if accepted, the extent of its use. For us to be successful, our physician customers must:

- believe that the Pillar Procedure offers meaningful clinical and economic benefits as compared to the other surgical and non-surgical procedures or devices currently being used to treat patients suffering from mild to moderate OSA or snoring;
- use our Pillar System to treat individuals suffering from mild to moderate OSA or snoring either as a stand-alone treatment or in combination with procedures to treat other areas of upper airway obstruction, and achieve acceptable clinical outcomes in the patients they treat;
- believe patients will pay for the Pillar Procedure out-of-pocket; and
- be willing to commit the time and resources required to modify the way in which they currently treat, or have historically treated, patients suffering from mild to moderate OSA and snoring.

Studies have shown that a significant percentage of people who suffer from OSA remain undiagnosed and therefore do not seek treatment for OSA and that many of those diagnosed with mild to moderate OSA may be reluctant to seek treatment given the less severe nature of their condition, the potentially negative lifestyle effects of traditional treatments and the lack of awareness of new treatment options. If we are unable to increase public awareness of the prevalence of OSA or if the medical community is slow to adopt, or fails to adopt, the Pillar Procedure as a treatment for individuals suffering from mild to moderate OSA and snoring, we would suffer a material adverse effect on our business, financial condition and results of operations.

We expect to derive substantially all of our future sales from a single product.

Currently, our only product is our Pillar System. We expect that our Pillar System will account for substantially all of our sales for the foreseeable future. Because the Pillar Procedure is different from current surgical and non-surgical treatments for mild to moderate OSA and snoring, we cannot assure you that physicians will perform the Pillar Procedure and that demand for our Pillar System may decline or may not increase as quickly as we expect. Also, we cannot assure you that the Pillar Procedure will compete effectively as a treatment alternative to other more well-known and well-established therapies, such as CPAP, or other more common palatal surgical procedures. Since our Pillar System currently is our only product, decreased or lower than expected sales would cause us to lose all or substantially all of our revenues.

We have incurred losses and we may not be profitable in the future.

Since we commenced operations in 1999, we have incurred net losses primarily from costs relating to the development and commercialization of our Pillar System. As of December 31, 2006, we had an accumulated deficit of $72.0 million, which includes the non-cash deemed dividend of $20.8 million from the revision of preferred stock conversion prices in conjunction with our IPO. We expect to continue to increase our investment in our sales and marketing and research and development activities and, therefore, we expect to incur net losses through at least 2008. This business strategy may not be successful, and we may not become profitable in any future period. If we do become profitable, we cannot be certain that we will be able to sustain or increase profitability on a quarterly or annual basis.

Our future operating results are difficult to predict and may vary significantly from quarter to quarter, which may adversely affect the price of our common stock.

Our limited history of sales of our Pillar System, together with our inability to predict how quickly, if at all, the medical community will accept our Pillar System, or, if accepted, the extent of its use, make the prediction of future operating results difficult. You should not rely on our past revenue growth as any indication of future growth rates or operating results. The price of our common stock likely will fall in the event our operating results do not meet the expectations of analysts and investors. Comparisons of our quarterly operating results are an unreliable indication of our future performance because they are likely to vary significantly based on many factors, including:

- the demand for and acceptance of our Pillar System to treat mild to moderate OSA and snoring by both physicians and patients;
- the success of alternative therapies and surgical procedures to treat individuals suffering from sleep disordered breathing, and the possible future introduction of new products and treatments for sleep disordered breathing;
- our ability to maintain current pricing for our Pillar System;
- the expansion and rate of success of our direct sales force in the United States and our independent distributors internationally;
- the successful completion of current and future clinical studies, the presentation and publication of positive outcomes data from these clinical studies and the increased adoption of the Pillar Procedure by physicians as a result of this clinical study data;
- actions relating to ongoing FDA and European Union, or EU, compliance;
- the size and timing of orders from physicians and independent distributors;
- our ability to obtain reimbursement for the Pillar Procedure for the treatment of mild to moderate OSA in the future from third-party healthcare insurers;
- the willingness of patients to pay out-of-pocket for the Pillar Procedure for the treatment of snoring and, in the absence of reimbursement from third-party healthcare insurers, for the treatment of mild to moderate OSA;

- unanticipated delays in the development and introduction of our future products and/or an inability to control costs;
- seasonal fluctuations in revenue due to the elective nature of all sleep disordered breathing treatments, including the Pillar Procedure; and
- general economic conditions as well as those specific to our customers and markets.

Further clinical studies of our Pillar System may adversely impact our ability to generate revenue if they do not demonstrate that our Pillar System is clinically effective for currently specified or expanded indications or if they are not completed in a timely manner.

We have conducted, and continue to conduct, a number of clinical studies of the use of our Pillar System to treat patients suffering from mild to moderate OSA and snoring, including prospective, randomized, placebo-controlled studies, as well as clinical studies that are structured to obtain clearance from the FDA and the EU for expanded clinical indications for use of our Pillar System.

We cannot assure you that these clinical studies will continue to demonstrate that our Pillar System provides long-term clinical effectiveness for individuals suffering from mild to moderate OSA or snoring, nor can we assure you that the use of our Pillar System will prove to be safe and effective in clinical studies under United States or international regulatory guidelines for any expanded indications. Additional clinical studies of our Pillar System may identify significant clinical, technical or other obstacles that will have to be overcome prior to obtaining clearance from the applicable regulatory bodies to market our Pillar System for such expanded indications. If further studies of our Pillar System indicate that the Pillar Procedure is not a safe and effective treatment of mild to moderate OSA or snoring, our ability to market our Pillar System, and to generate substantial revenue from additional sales of our Pillar System, may be materially limited.

Individuals selected to participate in these further clinical studies must meet certain anatomical, physiological and other criteria in order to participate in these studies. We cannot assure you that an adequate number of individuals can be enrolled in clinical studies on a timely basis. Further, we cannot assure you that the clinical studies will be completed as planned. A delay in the analysis and publication of the positive outcomes data from these clinical studies, or the presentation or publication of negative outcomes data from these clinical studies, including data related to approval of our Pillar System for expanded indications, may materially impact our ability to increase revenues through sales and negatively impact our stock price.

Our business and results of operations may depend upon the ability of healthcare providers to achieve adequate levels of third-party reimbursement.

Generally, patients pay for the Pillar Procedure entirely out-of-pocket, whether the patient is being treated for OSA or snoring. Third-party healthcare insurers typically consider any snoring treatment to be an elective cosmetic procedure, and do not cover payment for such procedures. We believe that all treatments for snoring, including the Pillar Procedure, will continue to be considered elective procedures, and therefore, procedures for which patients will pay out-of-pocket. Our ability to generate revenue from additional sales of our Pillar System for the treatment of snoring may be materially limited by the fact that it is unlikely that it will ever be covered by a third-party healthcare insurer.

The cost of treatments for OSA, such as CPAP, and most surgical procedures generally are reimbursed by third-party healthcare insurers. The Pillar Procedure is currently reimbursed for the treatment of OSA on a very limited basis, and may in the future lose the reimbursement coverage that is currently available and/or fail to qualify for any additional reimbursement for the treatment of OSA. Our ability to generate revenue from additional sales of our Pillar System for the treatment of OSA may be materially limited by the extent to which reimbursement of the Pillar Procedure for the treatment of mild to moderate OSA is available in the future. In addition, third-party healthcare insurers are increasingly challenging the prices charged for medical products and procedures. In the event that we are successful in our efforts to obtain reimbursement for the Pillar Procedure, any changes in this reimbursement system could materially affect our ability to continue to grow our business.

Reimbursement and healthcare payment systems in international markets vary significantly by country and reimbursement for the Pillar Procedure may not be available at all under either government or private reimbursement systems. If we are unable to achieve reimbursement approvals in international markets, it could have a negative impact on market acceptance of our Pillar System and potential revenue growth in the markets in which these approvals are sought.

Our products and manufacturing activities are subject to extensive governmental regulation that could prevent us from selling our Pillar System or introducing new and/or improved products in the United States or internationally.

Our products and manufacturing activities are subject to extensive regulation by a number of governmental agencies, including the FDA, the European Union, or the EU, and comparable international regulatory bodies. We are required to:

- obtain clearance from the FDA, the EU and certain international regulatory bodies before we can market and sell our products;
- satisfy all content requirements for the labeling, sales and promotional materials associated with our Pillar System and the Pillar Procedure; and
- undergo rigorous inspections of our facilities, manufacturing and quality control processes, records and documentation.

Compliance with the rules and regulations of these various regulatory bodies may delay or prevent us from introducing any new models of our Pillar System or other new products. In addition, government regulations may be adopted that could prevent, delay, modify or rescind regulatory clearance or approval of our products.

We are required to demonstrate compliance with the FDA's and EU's quality system regulations. The FDA and the EU enforce their quality system regulations through pre-approval and periodic post-approval inspections by representatives from the FDA and the designated notified body for the EU, respectively. These regulations relate to product testing, vendor qualification, design control and quality assurance, as well as the maintenance of records and documentation. If we fail to conform to these regulations, the FDA or the EU may take actions that could seriously harm our business. These actions include sanctions, including temporary or permanent suspension of our operations, product recalls and marketing restrictions. A recall or other regulatory action could substantially increase our costs, damage our reputation and materially affect our operating results.

Our products are currently not recommended by most pulmonologists, who are integral to the diagnosis and treatment of sleep breathing disorders.

The majority of patients being treated today for OSA, domestically and internationally, are initially referred to sleep centers by their primary care physicians. Sleep centers primarily are staffed by pulmonologists, neurologists and psychologists (collectively, "sleep medicine physicians"), who typically administer a polysomnography, or overnight sleep study, to diagnose the presence and severity of OSA. If an individual is diagnosed with OSA or snoring by a pulmonologist, the sleep medicine physicians typically prescribe CPAP as the therapy of choice. Sleep medicine physicians, generally, do not endorse palatal surgical procedures to their patients for the treatment of OSA or snoring, often citing uncertainty in clinical outcomes, among other factors. Our domestic sales organization has recently begun to call on a limited number of sleep medicine physicians in sleep centers to begin establishing a referral pathway for our Pillar Procedure. We cannot predict the extent to which sleep medicine physicians will, in the future, endorse or recommend the Pillar Procedure to their patients who suffer from chronic snoring or mild to moderate OSA even for those patients who are unwilling or unable to comply with CPAP therapy.

We face significant competition in the market for treating sleep breathing disorders.

The market for treating sleep disordered breathing is highly competitive and the Pillar Procedure must compete with more established products, treatments and surgical procedures, which may limit our growth and

negatively affect our business. Many of our competitors have an established presence in the field of treating sleep disordered breathing and have established relationships with sleep medicine physicians, sleep clinics and ENTs, which play a significant role in determining which product, treatment or procedure is recommended to the patient. We believe certain of our competitors are attempting to develop innovative approaches and new products for diagnosing and treating OSA and other sleep disordered breathing conditions. We cannot predict the extent to which ENTs, oral maxillofacial surgeons, primary care physicians or sleep medicine physicians would or will recommend our Pillar System over new or other established devices, treatments or procedures.

In addition, we have limited resources with which to market, develop and sell our Pillar System. Many of our competitors have substantially greater financial and other resources than we do, including larger research and development staffs who have more experience and capability in conducting research and development activities, testing products in clinical trials, obtaining regulatory approvals and manufacturing, marketing, selling and distributing products. Some of our competitors may achieve patent protection, regulatory approval or product commercialization more quickly than we do, which may decrease our ability to compete. If we are unable to be competitive in the market for sleep disordered breathing, our revenues will decline, negatively affecting our business.

Our Pillar System may become obsolete if we are unable to anticipate and adapt to rapidly changing technology.

The medical device industry is subject to rapid technological innovation and, consequently, the life cycle of any particular product can be short. Alternative products, procedures or other discoveries and developments to treat OSA and snoring may render our Pillar System obsolete. Furthermore, the greater financial and other resources of many of our competitors may permit them to respond more rapidly than we can to technological advances. If we fail to develop new technologies, products or procedures to upgrade or improve our existing Pillar System to respond to a changing market before our competitors are able to do so, our ability to market our products and generate substantial revenues may be limited.

Our international sales are subject to a number of risks that could seriously harm our ability to successfully commercialize our Pillar System in international markets.

Our international sales are subject to several risks, including:

- the ability of our independent distributors to market and sell our Pillar System and train physicians to perform the Pillar Procedure;
- the ability of our independent distributors to sell the quantity of Pillar Systems they have committed to purchase from us in their respective distribution agreements;
- our ability to identify new reputable and qualified independent third-party distributors in international markets where we do not currently have distributors;
- the impact of recessions in economies outside the United States;
- greater difficulty in collecting accounts receivable and longer collection periods;
- unexpected changes in regulatory requirements, tariffs or other trade barriers;
- weaker intellectual property rights protection in some countries;
- potentially adverse tax consequences; and
- political and economic instability.

The occurrence of any of these events could seriously harm our future international sales and our ability to successfully commercialize our products in international markets, thereby limiting our growth and revenues.

We depend on a few international third-party distributors that currently represent a significant portion of our Pillar System sales revenue, and the loss of one or more of such distributors could reduce our future sales revenue.

We currently market and sell the Pillar System internationally in 27 countries in Asia Pacific, Europe, the Middle East, South Africa and North and South America through third-party distributors. We began selling the Pillar System internationally during 2005. Our two largest distributors accounted for 39%, or $505,000, and 74%, or $1,074,000, of our international net sales in 2006 and 2005, respectively. A decision by these third-party distributors to discontinue selling our Pillar System or to reduce their future purchases of Pillar Systems could significantly reduce our future revenues.

The failure of large U.S. customers or international third-party distributors to pay for their purchases of Pillar Systems on a timely basis could reduce our future sales revenue and negatively impact our liquidity.

The timing and extent of our future growth in sales revenue depends, in part, on our ability to continue to increase the number of U.S. physicians performing the Pillar Procedure, as well as expanding the number of Pillar Procedures performed by these physicians. Similarly, our international distributors must continue to increase the number of physicians performing the Pillar Procedure in their respective territories, as well as expanding the number of Pillar Procedures performed by these physicians. To the extent one or more of our large U.S. physician customers or international distributors fails to pay us for Pillar Systems on a timely basis, we may be required to discontinue selling to these organizations and find new customers and/or replacement distributors, which could reduce our future revenues and negatively impact our liquidity.

We depend on our patents and proprietary technology, which we may not be able to protect.

Our success depends, in part, on our ability to obtain and maintain patent protection for the Pillar Procedure and our Pillar System and their components and processes. Our success further depends on our ability to obtain and maintain trademark protection for our name and mark, to preserve our trade secrets and know-how and to operate without infringing the intellectual property rights of others. We currently have issued or pending patents in several countries, including in the United States, Germany, Great Britain, Norway, Hong Kong, Singapore, Canada, China, the EU, Japan, South Korea, Australia, Indonesia, Malaysia and Taiwan, as well as pending Patent Cooperation Treaty applications. We cannot assure you that any of our pending or future patent applications will result in issued patents, that any current or future patents will not be challenged, invalidated or circumvented, that the scope of any of our patents will exclude competitors or that the patent rights granted to us will provide us any competitive advantage. We may discover that our technology infringes patents or other rights owned by others, and we cannot be certain that we were the first to make the inventions covered by each of our issued patents and our pending patent applications, or that we were the first to file patent applications for such inventions. In addition, we cannot assure you that our competitors will not seek to apply for and obtain patents that will prevent, limit or interfere with our ability to make, use or sell our products either in the United States or in international markets. Further, the laws of certain foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States.

In addition to patents, we rely on trademarks to protect the recognition of our company and product in the marketplace. We have trademark registrations for our name and mark principally in the United States, as well as registrations or pending applications in China, the EU, Indonesia and Singapore, and accordingly may not have protection for our name and mark in other jurisdictions. We also rely on trade secrets, know-how and proprietary knowledge that we seek to protect, in part, through confidentiality agreements with employees, consultants and others. We cannot assure you that our proprietary information will not be shared, that our confidentiality agreements will not be breached, that we will have adequate remedies for any breach or that our trade secrets will not otherwise become known to or independently developed by competitors.

We may face intellectual property infringement claims that would be costly to resolve.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry and our competitors and others may initiate intellectual property litigation as a means of competition. Intellectual property litigation is complex and expensive and outcomes are difficult to predict. We cannot assure you that we will not become subject to patent infringement claims, litigation or interference proceedings, to determine the priority of inventions. Litigation or regulatory proceedings also may be necessary to enforce our patent or other intellectual property rights. We may not always have the financial resources to assert patent infringement suits or to defend ourselves from claims. An adverse result in any litigation could subject us to liabilities or require us to seek licenses from or pay royalties to others that may be substantial. Furthermore, we cannot predict the extent to which the necessary licenses would be available to us on satisfactory terms, if at all.

We may face product liability claims that could result in costly litigation and significant liabilities.

The manufacture and sale of medical products entail significant risk of product liability claims. The medical device industry, in general, has been subject to significant medical malpractice litigation. Any product liability claims, with or without merit, could result in costly litigation, reduced sales, cause us to incur significant liabilities and divert our management's time, attention and resources. Because of our limited operating history and lack of experience with these claims, we cannot be sure that our product liability insurance coverage is adequate or that it will continue to be available to us on acceptable terms, if at all.

We depend on a few suppliers for key components, making us vulnerable to supply shortages and price fluctuation.

We purchase components for our Pillar System from a variety of vendors on a purchase order basis; we have no long-term supply contracts with any of our vendors. While it is our goal to have multiple sources to procure certain key components, in some cases it is not economically practical or feasible to do so. To mitigate this risk, we maintain an awareness of alternate supply sources that could provide our currently single-sourced components with minimal or no modification to the current version of our Pillar System, practice supply chain management, maintain safety stocks of critical components and have arrangements with our key vendors to manage the availability of critical components. Despite these efforts, if our vendors are unable to provide us with an adequate supply of components in a timely manner or if we are unable to locate qualified alternate vendors for components at a reasonable cost, the cost of our products would increase, the availability of our products to our customers would decrease and our ability to generate revenues could be materially limited.

Our sales and marketing efforts may not be successful.

We currently market and sell our Pillar System to ENTs and to a limited number of oral maxillofacial surgeons. The commercial success of our Pillar System ultimately depends upon a number of factors, including the number of physicians who perform the Pillar Procedure, the number of Pillar Procedures performed by these physicians, the number of patients who become aware of the Pillar Procedure by self-referral or referrals by their primary care physicians, sleep medicine physicians or sleep centers, the number of patients who elect to undergo the Pillar Procedure and the number of patients who, having successfully undergone the Pillar Procedure, endorse and refer the Pillar Procedure to other potential patients. The Pillar Procedure may not gain significant increased market acceptance among implanting physicians, patients, third-party healthcare insurers and managed care providers. Primary care physicians may elect to refer individuals suffering from sleep disordered breathing to sleep medicine physicians who treat sleep disordered breathing rather than to ENTs or oral maxillofacial surgeons and these physicians may not recommend the Pillar Procedure to patients for any number of reasons, including knowledge of the safety and clinical efficacy of the Pillar Procedure, the availability of alternative procedures and treatment options or inadequate levels of reimbursement. In addition, while positive patient experiences can be a significant driver of future sales, it is impossible to influence the manner in which this information is transmitted and received, the choices potential patients may make and the recommendations that treating physicians make to their patients.

We have limited experience in marketing and selling our Pillar System through a direct sales organization in the United States and through third-party distributors internationally. We may not be able to maintain a suitable sales force in the United States or suitable number of third-party distributors outside the United States, or enter into or maintain satisfactory marketing and distribution arrangements with others. Our marketing and sales efforts may not be successful in increasing awareness and sales of our Pillar System.

The failure to educate or train a sufficient number of physicians in the use of our Pillar System could reduce the market acceptance of our Pillar System and reduce our net sales.

It is critical to the success of our sales efforts that there is an increasing number of physicians familiar with, trained in and proficient in the use of our Pillar System. Currently, physicians learn to use our system through hands-on, on-site training by our representatives in conjunction with performing Pillar Procedures. However, to receive this training, physicians must be aware of the Pillar Procedure as a treatment option for mild to moderate OSA and snoring and be interested in using the Pillar Procedure in their practice. We cannot predict the extent to which physicians will dedicate the time and energy necessary for adequate training in the use of our Pillar System, have the knowledge of or experience in the clinical outcomes of the Pillar Procedure or feel comfortable enough performing the Pillar Procedure to recommend it to their patients. Even if a physician is well versed in the Pillar Procedure, he or she may be unwilling to require patients to pay for the Pillar Procedure out-of-pocket. If physicians do not continue to accept and recommend the Pillar Procedure, our revenues could be materially affected.

All of our operations are conducted at a single location; therefore, any disruption at our existing facility could substantially affect our business.

We manufacture our Pillar System at one facility using certain specialized equipment. Although we have contingency plans in effect for certain natural disasters, as well as other unforeseen events that could damage our facility or equipment, any such events could materially interrupt our manufacturing operations. In the event of such an occurrence, we have business interruption insurance to cover lost revenues and profits. However, such insurance would not compensate us for the loss of opportunity and potential adverse impact on relations with existing customers created by an inability to produce our products.

We depend on certain key personnel.

If we are unable to attract, train and retain highly-skilled technical, managerial, product development, sales and marketing personnel, we may be at a competitive disadvantage and unable to develop new products or increase revenue. The failure to attract, train, retain and effectively manage employees could negatively impact our research and development, sales and marketing and reimbursement efforts. In particular, the loss of sales personnel could lead to lost sales opportunities as it can take several months to hire and train replacement sales personnel. Uncertainty created by turnover of key employees could adversely affect our business.

We will need to carefully manage our expanding operations to achieve sustainable growth.

To achieve increased revenue levels, complete clinical studies and develop future products, we believe that we will be required to periodically expand our operations, particularly in the areas of sales and marketing, clinical research, reimbursement, research and development, regulatory, manufacturing and quality assurance. As we expand our operations in these areas, management will face new and increased responsibilities. To accommodate any growth and compete effectively, we must continue to upgrade and improve our information systems, as well as our procedures and controls across our business, and expand, train, motivate and manage our work force. Our future success will depend significantly on the ability of our current and future management to operate effectively. Our personnel, systems, procedures and controls may not be adequate to support our future operations. If we are unable to effectively manage our expected growth, this could have a material adverse effect on our business, financial condition and results of operations.

We incur significant increased costs as a result of operating as a public company, and our management devotes substantial time to new compliance requirements.

As a newly public company, we incur significant legal, accounting and other expenses that we did not incur as a private company prior to our IPO in May 2006. In addition, the Sarbanes-Oxley Act, together with new rules subsequently implemented by the Securities and Exchange Commission, or SEC, and the Nasdaq Stock Market, has imposed various new requirements on public companies, including requiring certain corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these new compliance requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

In addition, the Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, commencing in 2007, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. If we are not able to comply with the requirements of Section 404 in a timely manner, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

Our ability to raise capital in the future may be limited, and our failure to raise capital when needed could prevent us from executing our growth strategy.

The timing and amount of our working capital and capital expenditure requirements may vary significantly depending on numerous factors, including the other risk factors described in this report on Form 10-K. Additional financing may not be available on terms favorable to us, or at all. Any additional capital we raise through the sale of equity or convertible debt securities may dilute your percentage ownership of our common stock. Furthermore, any new equity securities we issue could have rights, preferences and privileges superior to our common stock. Capital raised through debt financings could require us to make periodic interest payments and could impose potentially restrictive covenants on the conduct of our business.

Risks Relating to Ownership of Our Common Stock

Our stock price may be volatile and a stockholder's investment may decline in value.

We cannot predict the extent to which investors' interests will lead to an active trading market for our common stock or whether the market price of our common stock will be volatile from period to period. The market for medical device stocks has been extremely volatile. The following factors, most of which are outside of our control, could cause such volatility in the market price of our common stock:

- variations in our quarterly operating results;
- departure of key personnel;
- changes in governmental regulations and standards affecting the medical device industry and our products;
- decreases in financial estimates, or negative commentary about us or the medical device industry by equity research analysts;
- sales of common stock or other securities by us in the future;
- decreases in market valuations of medical device companies; and
- fluctuations in stock market prices and volumes.

In the past, securities class action litigation often has been initiated against a company following a period of volatility in the market price of the company's securities. If class action litigation is initiated against us, we will incur substantial costs and our management's attention will be diverted from our operations. All of these factors could cause the market price of our stock to decline, and you may lose some or all of your investment.

Future sales of our common stock by existing stockholders could cause our stock price to decline.

If our existing stockholders sell substantial amounts of our common stock, the market price of our common stock could decrease significantly. The perception in the public market that our stockholders might sell shares of common stock could also depress the market price of our common stock. A decline in the price of shares of our common stock might impede our ability to raise capital through the issuance of additional shares of our common stock or other equity securities, and may cause you to lose part or all of your investment.

Our organizational documents and Delaware law make a takeover of our company more difficult, which may prevent certain changes in control and limit the market price of our common stock.

Our charter and bylaws and Section 203 of the Delaware General Corporation Law contain provisions that might enable our management to resist a takeover of our company. These provisions might discourage, delay or prevent a change in the control of our company or a change in our management. These provisions also could discourage proxy contests and make it more difficult for you and other stockholders to elect directors and take other corporate actions. The existence of these provisions could limit the price that investors might be willing to pay in the future for shares of our common stock. Some provisions in our charter and bylaws may deter third parties from acquiring us, which may limit the market price of our common stock.

Item 1B. *UNRESOLVED STAFF COMMENTS*

None.

Item 2. *PROPERTIES*

Our headquarters and manufacturing facilities in St. Paul, Minnesota comprise approximately 24,000 square feet of leased space. We lease a total of approximately 38,000 square feet, and sublease 14,346 square feet to a third-party tenant. The lease space includes furnished office space, a 4,000 square foot Class 8 clean room housing manufacturing, an integrated client-server computer network, an ISO 13485 compliant intranet-based quality and product development system, a fully equipped 1,000 square foot research and development wet laboratory, a fully equipped prototype machine shop and warehouse space. The lease agreement for our St. Paul facility expires in October 2010.

Item 3. *LEGAL PROCEEDINGS*

We are not currently a party to any litigation and we are not aware of any pending or threatened litigation against us that could have a material adverse effect on our business, operating results or financial condition. The medical device industry in which we operate is characterized by frequent claims and litigation, including claims regarding patent and other intellectual property rights as well as improper hiring practices. As a result, we may be involved in various legal proceedings from time to time.

Item 4. *SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS*

No matters were submitted to a vote of security holders during the fourth quarter ended December 31, 2006.

PART II

Item 5. *MARKET FOR REGISTRANTS' COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY*

Stock Listing

Our common stock has been listed on the Nasdaq Global Market tier of the Nasdaq Stock Market™ under the symbol "REST" since May 17, 2006, following the pricing of our initial public offering. Prior to that time, there was no public market for our common stock. As of February 7, 2007, we had approximately 63 holders of record of our common stock. Such number of record holders does not reflect stockholders who beneficially own common stock in nominee or street name.

Stock Prices

High and low sale prices for each quarter during the year ended December 31, 2006, as reported on the Nasdaq Stock Market, were as follows:

Price Range of Common Stock

	High	Low
Year ended December 31, 2006:		
2nd Quarter (commencing May 17, 2006)	$8.40	$6.80
3rd Quarter	7.90	5.80
4th Quarter	7.05	3.09

Dividend Policy

We have never paid cash dividends on our common stock. The Board of Directors presently intends to retain all earnings for use in our business and does not anticipate paying cash dividends in the foreseeable future. We do not have a dividend reinvestment plan or a direct stock purchase plan.

Repurchases of Equity Securities

We did not repurchase any of our equity securities in the year ended December 31, 2006.

Pursuant to our employee stock plans relating to the grant of employee stock options and restricted stock awards, we have granted and may in the future grant employee stock options to purchase shares of our common stock for which the purchase price may be paid by means of delivery to us by the optionee of shares of our common stock that are already owned by the optionee (at a value equal to market value on the date of the option exercise). During the period covered by this report, no options to purchase shares of our common stock were exercised for which the purchase price was so paid.

Recent Sales of Unregistered Securities

In June 2006, we issued 47,547 shares of our common stock in connection with a cashless warrant exercise at an exercise price of $1.10 per share, with 7,853 warrants to purchase common stock being forfeited in the net exercise. In September 2006, we issued 3,850 and 276 shares of our common stock in connection with cashless warrant exercises at an exercise price of $1.08 per share and $5.32 per share, respectively, with 1,267 and 754 warrants to purchase common stock being forfeited in the net exercise, respectively. All shares were issued pursuant to Section 4(2) of the Securities Act of 1933, as amended. The ability to exercise the warrants for common stock on a net share basis was included in the original warrant agreements.

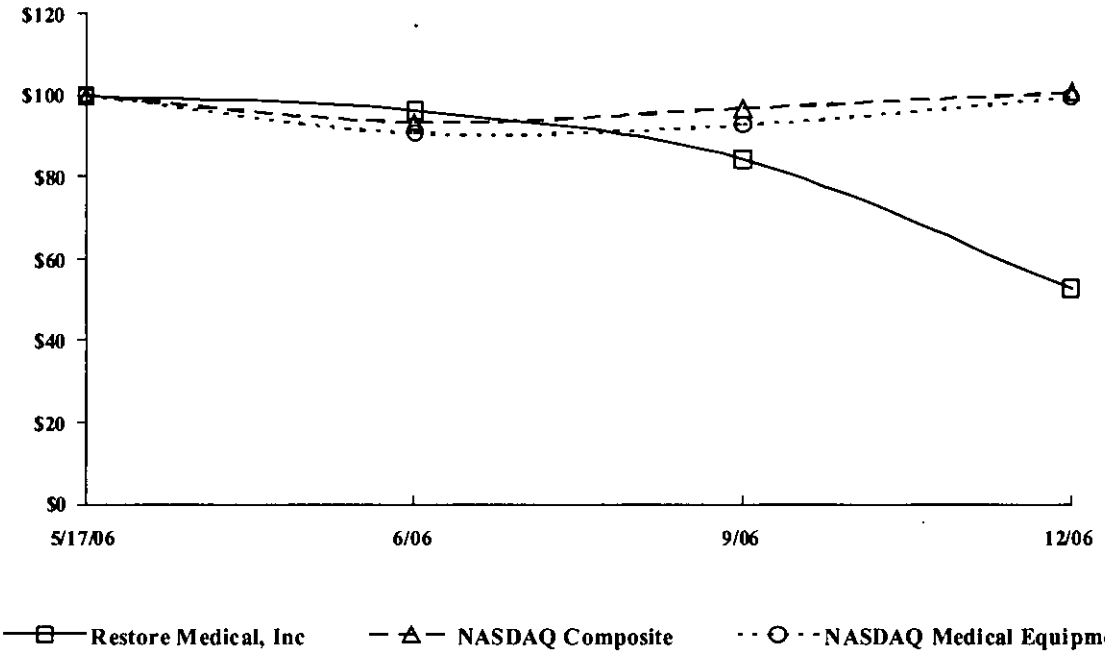
Use of Proceeds

On May 22, 2006, we completed our IPO of 4,000,000 shares of common stock (the "IPO Shares"). We sold the IPO Shares to the public at a price of $8.00 per share. Our sale of IPO Shares was registered under the Securities Act of 1933, as amended, pursuant to a registration statement on Form S-1 (Registration Stmt. No. 333-132368), which was declared effective by the Securities and Exchange Commission on May 16, 2006. We received net proceeds from the sale of the IPO Shares, after deducting the underwriters commissions and discounts, of approximately $27.7 million. The net proceeds have been invested in money market funds, investment grade commercial paper and debt instruments of the U.S. government and its agencies. During the year ended December 31, 2006, we used approximately $3.9 million of net proceeds from the IPO for general corporate purposes, including expanding domestic and international marketing and sales organizations and programs, increasing product development efforts and increasing our clinical study initiatives.

Stock Performance Graph

The graph depicted below shows a comparison of cumulative total stockholder returns for an investment in Restore Medical, Inc. common stock, the Nasdaq Stock Market (U.S.) Index and the Nasdaq Medical Equipment Index. The graph assumes an investment of $100 on May 17, 2006 (the first trading day of our common stock) and reinvestment of dividends. We did not pay any dividends during any period presented. Stockholder returns over the indicated period should not be considered indicative of future stockholder returns.

COMPARISON OF 7 MONTH CUMULATIVE TOTAL RETURN*
Among Restore Medical, Inc, The NASDAQ Composite Index
And The NASDAQ Medical Equipment Index



* $100 Invested on 5/17/06 in stock or on 4/30/06 in index-including reinvestment of dividends. Fiscal year ending December 31.

Item 6. *SELECTED FINANCIAL DATA*

The selected financial data set forth below should be read in conjunction with the financial statements and related notes, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other financial information appearing elsewhere in this Annual Report on Form 10-K. The statement of operations data for the years ended December 31, 2006, 2005 and 2004 and the balance sheet data as of December 31, 2006 and 2005 are derived from financial statements audited by KPMG LLP, and included elsewhere in this Annual Report on Form 10-K. The statement of operations data for the year ended December 31, 2003, and the balance sheet data as of December 31, 2004, are derived from our audited financial statements not included in this Annual Report on Form 10-K. The statement of operations data for the year ended December 31, 2002, and the balance sheet data as of December 31, 2003 and 2002 are derived from our unaudited financial statements not included in this Annual Report on Form 10-K. Our unaudited financial statements include, in the opinion of our management, all adjustments, consisting of only normal recurring adjustments, necessary for a fair presentation of those statements. The historical results are not necessarily indicative of the results to be expected for any future periods. (In thousands, except share and per share amounts)

	2006	2005	2004	2003	2002
Statement of operations data for the fiscal years ended December 31:					
Net sales	$ 5,886	$ 4,854	$ 945	$ 368	$ —
Cost of sales(1)	1,695	1,641	791	412	—
Gross margin (loss)	4,191	3,213	154	(44)	—
Operating expenses:					
Research and development(1)	3,007	1,869	2,282	3,301	3,346
General and administrative(1)	4,960	2,938	2,148	2,003	1,808
Sales and marketing(1)	10,022	4,981	4,039	2,333	229
Total operating expenses	17,989	9,788	8,469	7,637	5,383
Loss from operations	(13,798)	(6,575)	(8,315)	(7,681)	(5,383)
Other income (expense):					
Interest income	952	132	169	32	49
Interest expense	(734)	(25)	(426)	(2,660)	(32)
Put option gain	—	—	871	639	—
Preferred stock warrant gain (loss)	500	(572)	128	9	—
Other, net	50	18	19	(18)	4
Cumulative effect of change in accounting principle	—	—	—	267	—
Net loss	(13,030)	(7,022)	(7,554)	(9,412)	(5,362)
Deemed dividend from revision of preferred stock conversion price	(20,799)	—	—	—	—
Amortization of beneficial conversion feature of Series A and Series B preferred stock	—	—	(252)	(45)	(951)
Net loss attributable to common stockholders	$ (33,829)	$ (7,022)	$ (7,806)	$ (9,457)	$ (6,313)
Basic and diluted net loss per common share before deemed dividend from revision of preferred stock conversion price and amortization of beneficial coversion feature of Series A and Series B preferred stock	$ (1.26)	$ (5.77)	$ (6.31)	$ (11.37)	$ (7.12)
Effect of deemed dividend from revision of preferred stock conversion price	(2.00)	—	—	—	—
Effect of amortization of beneficial conversion feature of Series A and Series B preferred stock	—	—	(0.21)	(0.05)	(1.27)
Basic and diluted net loss per common share	$ (3.26)	$ (5.77)	$ (6.52)	$ (11.42)	$ (8.39)

	2006	2005	2004	2003	2002
Basic and diluted weighted average common shares outstanding	10,377,793	1,217,640	1,196,366	827,819	752,678
(1) Includes stock-based compensation of:					
Cost of sales	$ 79	$ 19	$ 2	$ —	$ —
Research and development	148	15	2	—	—
General and administrative	1,415	463	30	—	35
Sales and marketing	211	62	6	—	—
	$ 1,853	$ 559	$ 40	$ —	$ 35

	2006	2005	2004	2003	2002
Balance sheet data as of December 31:					
Cash and cash equivalents	$11,377	$ 3,397	$ 2,258	$ 853	$ 2,182
Working capital (deficit)	21,660	4,058	8,323	(9,486)	1,221
Total assets	26,765	6,395	9,659	2,260	3,131
Total current liabilities	4,320	1,769	974	10,891	1,284
Total liabilities	7,197	4,230	1,069	11,115	2,672
Convertible participating preferred stock	—	39,208	39,208	14,003	14,255
Convertible participating preferred stock warrants	—	—	—	—	344
Total common stockholders' equity (deficit)	$19,568	$(37,043)	$(30,618)	$(22,858)	$(14,140)

Item 7. *MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS*

The following discussion and analysis should be read in conjunction with the financial statements and related notes and the other financial information appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy, contains forward-looking statements that involve risk, uncertainties and assumptions. You should review the "Risk Factors" in Item 1A of Part I of this report for a discussion of important factors that could cause actual results to differ materially from those described in or implied by the forward-looking statements contained in the following discussion and analysis and elsewhere in this report.

Overview

We develop, manufacture and market our proprietary Pillar System, a simple, innovative, minimally invasive, implantable medical device to treat the soft palate component of sleep disordered breathing, which includes OSA and snoring. During the Pillar Procedure, a physician implants three small, braided, proprietary polyester inserts into the muscle of the soft palate. These Pillar inserts, together with the body's natural fibrotic response to the implanted Pillar inserts, add structural support and stiffen the soft palate, thereby minimizing or eliminating the palatal tissue vibration that can cause snoring and the retropalatal collapse that can obstruct the upper airway and cause OSA. We currently market and sell our Pillar System to otolaryngologists (ear, nose and throat physicians, or ENTs) and to a limited number of oral maxillofacial surgeons. We believe the Pillar Procedure is a safe, clinically effective, long-lasting, low-risk procedure with minimal pain or complications that offers significant benefits to both patients and physicians over other available treatment options for chronic snoring and mild to moderate OSA.

Our Pillar System was cleared by the FDA for snoring in December 2002 and for mild to moderate OSA in July 2004. Our Pillar System received CE Mark certification for both snoring and mild to moderate OSA from the European Commission in May 2003 and December 2004, respectively.

Generally, patients pay the entire cost for the Pillar Procedure out-of-pocket, whether the patient is being treated for OSA or snoring. The cost of treatments for OSA, such as CPAP, and most surgical procedures generally are reimbursed by third-party healthcare insurers, including Medicare. We have begun the process of seeking third-party reimbursement approval for the use of the Pillar Procedure to treat mild to moderate OSA, and we intend to continue pursuing third-party reimbursement. Third-party healthcare insurers typically consider any snoring treatment to be an elective cosmetic procedure, and do not cover payment for such procedures. We believe that all treatments for snoring, including the Pillar Procedure, will continue to be considered elective procedures, and therefore, procedures for which patients will pay out-of-pocket.

We employ a direct sales force in the United States currently consisting of 20 sales representatives and 3 regional sales directors who are primarily focused on ENTs and oral maxillofacial surgeons who treat sleep disordered breathing. During 2006, we increased the number of domestic sales representatives to 20 from 12 at the end of 2005 and added 3 regional sales directors in 2006. We have worked closely with our physician customers to begin implementing practice support, education and development programs that are designed to help increase the number of sleep disordered breathing patients who are referred to, or self-refer to, their practices for diagnosis and/or treatment. These practice development programs include the creation and implementation of local physician and prospective patient sleep disordered breathing education programs, as well as customized local advertising, public relations and sleep disordered breathing information initiatives to promote physician practices to potential patients.

We currently market our products in 27 countries outside the United States through 20 independent distributors in North and South America, Asia Pacific, Europe, the Middle East and South Africa. We have entered into multi-year distribution agreements with each of these international distributors. Each of our independent distributors has the exclusive right to sell our Pillar System within a defined geographic territory. Many of these distributors also market and sell other medical products, although contractually they are not permitted to sell products directly competitive with our Pillar System. Our independent distributors purchase our Pillar System from us at a discount to our United States list price and resell our Pillar System to physicians, hospitals or clinics in their respective geographic territories. The end-user price of our Pillar System in each country is determined by the distributor and varies from country to country. Our two largest distributors accounted for 39% and 74% of our international net sales in 2006 and 2005, respectively. We expect our international net sales to decrease in 2007 as we focus our resources on growing U.S. revenue.

To date, our product development efforts have been primarily focused on developing and introducing clinically relevant improvements and enhancements to our current Pillar System. We have also begun development work to explore the possibility of leveraging our technology to treat base of tongue obstructions that cause OSA.

As a newly public company, we incur significant legal, accounting and other expenses that we did not incur as a private company prior to our IPO in May 2006. In particular, commencing in 2007, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our compliance with Section 404 will require that we incur substantial accounting expenses and expend significant management efforts.

Since we commenced operations in 1999, we have incurred net losses primarily from costs relating to the development and commercialization of our Pillar System. We incurred net losses attributable to common stockholders of $9.5 million in 2003, $7.8 million in 2004, $7.0 million in 2005 and $33.8 million, which includes the deemed dividend of $20.8 million from the revision of preferred stock conversion prices in conjunction with our initial public offering, or IPO, in 2006. At December 31, 2006, we had an accumulated deficit of $72.0 million, which includes the non-cash deemed dividend of $20.8 million from revision of preferred stock conversion price in conjunction with our IPO. We expect to continue and potentially increase our investment in marketing and sales and research and development activities, which will be primarily funded with our current available cash and the net proceeds from our IPO. With our plans to continue to expand our commercialization activities, we expect to continue to incur net losses through at least 2008.

Application of Critical Accounting Policies and Use of Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities, revenue and expenses, and disclosures of contingent assets and liabilities at the date of the financial statements. On a periodic basis, we evaluate our estimates, including those related to accounts receivable, inventories, warranty reserve, income taxes and deferred stock-based compensation. We use authoritative pronouncements, historical experience and other assumptions that we believe to be reasonable under the circumstances as the basis for making estimates. Actual results could differ from those estimates under different assumptions or conditions.

We believe the following critical accounting policies represent more significant judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

We generate revenue from sales of our Pillar System to physician customers in the U.S. and third-party distributors internationally. We generally have not sold our Pillar System to hospitals or healthcare institutions, although such sales may occur more frequently in the future.

Revenue is recognized when evidence of an arrangement exists, delivery to the customer has occurred, the selling price is fixed or determinable and collectability is reasonably assured. For physician customers in the U.S. the evidence of an arrangement generally consists of a signed order confirmation or verbal phone order as their normal business practices do not require a purchase order. Our international distributors place orders pursuant to a distribution agreement. The price for each sale is fixed and agreed with the customer prior to shipment and is based on established list prices. Sales to our international distributors are made according to the contractual terms of each individual distribution agreement. Revenue for all domestic and international sales is recognized upon shipment of product from our facility when title and risk of loss passes to the customer.

A provision for estimated sales returns on domestic product sales is recorded in the same period as the related revenue is recorded. The provision for estimated sales returns, if any, is based on an analysis of historical sales returns, as adjusted for specifically identified estimated changes in historical return activity. Sales terms to our international distributors do not contain a right to return product purchased from us.

In the U.S., as part of introducing our Pillar System to potential new physician customers, we offer physicians the opportunity to participate in a "practice introduction program," or PI program, in which they can treat up to three patients using Pillar Systems that we provide at no charge to the physician. The costs associated with providing these Pillar Systems to U.S. physicians under our PI program are accounted for as a sales and marketing expense at the time of each practice introduction. During 2005, our international distributors were offered the opportunity to participate in an international PI program whereby we would provide marketing support payments for practice introductions conducted by the distributor. The support payments made to each distributor who participated in our 2005 international PI program were accounted for as a reduction of revenue to that distributor. During the first quarter of 2006, we amended substantially all of our international distribution agreements to change the structure of our international PI program. Under the modified program, we provide our international distributors with free product to undertake a PI program with physician customers in their respective territories rather than provide our international distributors with a marketing support payment for practice introductions performed. The free product that we provide is recorded as a cost of sales.

Our standard payment terms for customers are net 30 to 60 days in the United States and net 60 to 90 days internationally. We have, on a customer-by-customer basis, granted payment terms in excess of those specified in our international distribution agreements. If we determine the facts and circumstances surrounding a customer's order justify alternative payment terms, we may grant extended payment terms on a customer-by-customer basis. Collectability is evaluated prior to shipment. Our customers typically are

physicians, clinics and distributors, and are generally deemed creditworthy; however, if we have collection concerns, we will require prepayment of the order.

Allowance for Doubtful Accounts

In estimating the collectability of our accounts receivable, we analyze historical bad debts, customer concentrations, customer credit-worthiness, current economic trends and changes in customer payment terms. In the normal course of our business, many of our international distributors pay us after their scheduled payment due date. In addition, on a case-by-case basis, we have allowed certain of our international distributors to extend the time of payment beyond their scheduled payment due date or to make periodic partial payments of past-due amounts owing to us. We make adjustments to our allowance for doubtful accounts in the period when the net revenues are recognized based on anticipated future events. If there are unanticipated future events, this allowance may need to be adjusted. On a monthly basis, we determine the amount of this reserve based on a review of slow-paying accounts, as well as accounts with changed circumstances indicating that the balances due and owing to us are unlikely to be collectible.

Warranties

We replace any defective Pillar System that is returned to us at no charge to the customer provided the returned unit is not past its product expiration date. We also will provide a replacement Pillar System at no charge to the physician customer in the event a patient treated by the physician with a Pillar Procedure experiences a partial extrusion of the Pillar insert, either at or subsequent to the time of implant. We adjust our estimated warranty expense accrual each month based on historical warranty claims experience, and record adjustments in an amount equal to the standard cost of the replacement Pillar Systems provided to physician customers.

Accounting for Income Taxes

Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have recorded a full valuation allowance on our net deferred tax assets as of December 31, 2006 and, 2005, respectively, due to uncertainties related to our ability to utilize our deferred tax assets in the foreseeable future. These deferred tax assets primarily consist of certain net operating loss carry forwards and research and development tax credits.

Stock-Based Compensation

Prior to the adoption of Statement of Financial Accounting Standard No. 123(R), *Share-Based Payment* (SFAS No. 123(R)) on January 1, 2006, we measured compensation costs for options issued or modified under our stock-based compensation plans using the intrinsic-value method of accounting. Under the intrinsic-value method, we recorded deferred compensation expense within stockholders' equity (deficit) for stock options awarded to employees and directors to the extent that the option exercise price was less than the fair market value of common stock on the date of grant. Recorded deferred compensation is amortized to compensation expense on a straight-line basis over the vesting period of the underlying stock option grants.

On January 1, 2006, we adopted the fair value recognition provisions of SFAS 123(R). We apply the provisions of SFAS 123(R) to new stock option grants and to stock option grants that are modified, repurchased or cancelled after December 31, 2005 using the prospective method of transition. Compensation expense calculated under SFAS 123(R) is amortized to compensation expense on a straight-line basis over the vesting period of the underlying stock option grants. We will continue to apply the intrinsic-value method to determine compensation expense for stock options granted prior to the adoption of SFAS 123(R).

Determining the appropriate fair value model and calculating the fair value of share-based payment awards requires the input of highly subjective assumptions, including the expected life of the share-based payment awards and stock price volatility. We use the Black-Scholes model to value our stock option awards. The assumptions used in calculating the fair value of share-based payment awards represent management's

best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and management uses different assumptions, share-based compensation expense could be materially different in the future. As we have been a public company since May 2006, we do not have sufficient historical volatility for the expected term of our options. Therefore, we use comparable companies as a basis for our expected volatility. As we become a more mature public company, we will rely more on our historical volatility to calculate the fair value of option grants. This may materially impact the fair value of employee stock option grants. In addition, we are required to estimate the expected term and forfeiture rate and only recognize expense for those shares expected to vest. If the actual forfeiture rate is materially different from the estimate, share-based compensation expense could be significantly different from what has been recorded in the current period.

As of December 31, 2006, we had outstanding stock options to acquire an aggregate of 2,399,306 shares of common stock. Of those outstanding common stock options, 709,038 shares had vested as of December 31, 2006, and 1,690,268 shares were unvested.

Results of Operations

Comparison of the years ended December 31, 2006 and 2005

Net Sales. Net sales increased by $1.0 million, or 21%, to $5.9 million in 2006 from $4.9 million in 2005. The increase in net sales during 2006 was attributable to the increased unit sales of our Pillar Systems in the U.S., partially offset by a decrease in sales in international markets.

Net sales in the United States increased by $1.2 million, or 34%, to $4.6 million in 2006 compared to $3.4 million in 2005. The growth in U.S. net sales was due primarily to a larger number of physicians performing the Pillar Procedure, which resulted in increased shipments of our Pillar System. The U.S. average selling price for the three Pillar inserts used in each Pillar Procedure increased from $645 in 2005 to $681 in 2006 due to a price increase initiated in October 2004 that provided for a gradual increase to the new price level for existing customers.

Net sales internationally decreased by $132,000 to $1.3 million in 2006 compared to $1.4 million in 2005. We commercially introduced our Pillar System into international markets beginning in January 2005 through independent third-party distributors. Our two largest distributors accounted for 39%, or $505,000, of our international net sales in 2006 and 74%, or $1.1 million, in 2005. Based on business plan reviews with these two distributors in July 2006, we concluded the Pillar System inventory levels at each of these distributors increased in the first half of 2006 as a result of delays in planned market launches, execution of certain market development activities and obtaining a required government pricing approval for the Pillar System in a key market. Due to their inventory levels, the expected timing of each distributor's planned market development activities and estimated sales, we did not receive orders from either of these two distributors in the second half of 2006. The timing of future orders from either distributor will depend upon the results of each distributor's market development and sales activities. Decreased sales to these two distributors in 2006 was partially offset by sales to new distributors and reorders from existing distributors. As a result, international sales decreased in 2006 as compared to 2005.

Due to the market development investment and distribution costs incurred by our international third-party distributors, our international average selling price is typically approximately 50% of domestic average selling price. As of December 31, 2006, our Pillar System was marketed and sold in 27 international markets in Asia Pacific, Europe, the Middle East, South Africa and North and South America.

Cost of sales and gross margin. Our cost of sales consists primarily of material, labor and manufacturing overhead expenses. Cost of sales also includes warranty expenses, as well as salaries and personnel-related expenses, including stock-based compensation, for our operations management team and quality control. Cost of sales increased by $54,000, or 3%, to $1.7 million in 2006 from $1.6 million in 2005. This increase was due to the increase in the number of our Pillar Systems sold in 2006. As a percentage of net sales, gross margin improved to 71% in 2006 from 66% in 2005. The improvement in the gross margin percent in 2006 was the result of reductions in the cost of our Pillar System following our launch of a redesigned second-

generation delivery system in May 2005, as well as volume-related production efficiencies. We expect that increased production volumes will result in improved gross margins because of the leverage gained from economies of scale.

Research and development expenses. Our research and development expenses consist of salaries and other personnel-related expenses, including stock-based compensation, for employees engaged in research, development and engineering activities and materials used and other overhead expenses incurred in connection with the design and development of our products. Research and development expenses increased by $1.1 million, or 61%, to $3.0 million in 2006 from $1.9 million in 2005. This increase was attributable to increased compensation expense of $352,000, stock-based compensation of $133,000 and development expenses of $289,000 over the prior year. We increased headcount in our research and development group during 2006 to accelerate several key clinical studies and the development of a technology to treat base of tongue obstruction. In future quarters, we expect research and development expenditures will increase as result of planned post-market clinical studies of the Pillar Procedure.

General and administrative expenses. Our general and administrative expenses consist primarily of salaries and other personnel-related expenses, including stock-based compensation, for executive, accounting and administrative personnel, professional fees, and other general corporate expenses. General and administrative expenses increased by $2.1 million, or 69%, to $5.0 million in 2006 from $2.9 million in 2005. The increase is due to an increase of $601,000 in audit and consulting fees incurred during the first five months of 2006 in preparation for our IPO. In addition, stock-based compensation expense increased by $952,000 for the year ended December 31, 2006 to $1.4 million from $463,000 in 2005. The increase in stock-based compensation included $191,000 of expense related to the severance agreement with our former Vice President of Finance.

Sales and marketing expenses. Our sales and marketing expenses consist primarily of salaries, commissions and other personnel-related expenses, including stock-based compensation, for employees engaged in sales, marketing and support of our products, trade show, marketing, promotional and public relations expenses and management and administration expenses in support of sales and marketing. Sales and marketing expenses increased by $5.0 million, or 101%, to $10.0 million for 2006 from $5.0 million in 2005. This increase was attributable to an increase in compensation expense of $2.0 million related to the hiring of additional sales and marketing personnel, including an increase in stock-based compensation of $149,000 for the year ended December 31, 2006. In addition, advertising and promotional expenses increased by $2.0 million as we increased our focus on developing our consumer marketing programs.

Interest income. Interest income increased to $952,000 in 2006 from $132,000 in 2005. The increase is attributable to an increase in amounts invested in cash equivalents and short-term investments from the proceeds of our IPO.

Interest expense. Interest expense increased to $734,000 in 2006 from $25,000 in 2005. This increase was due to interest expense resulting from draws on our loan facility with Lighthouse Capital Partners and an additional capital lease.

Preferred stock warrant gain/loss. In 2006, we recognized a gain of $500,000 related to the change in fair value of our preferred stock warrants subject to redemption compared to a loss of $572,000 in 2005 for the change in fair value during the same period in 2005.

Deemed dividend from revision of preferred stock conversion price. In 2006, we recognized a non-cash dividend of $20.8 million due to a change in the conversion price of our Series C and C-1 preferred stock prior to our IPO. All outstanding Series A, B, C and C-1 preferred stock automatically converted into shares of common stock at the then current conversion prices.

Comparison of Years Ended December 31, 2005 and 2004

Net Sales. Net sales increased by $3.9 million, or 414%, from $945,000 in 2004 to $4.9 million in 2005. The net sales increase in 2005 was attributable to the increased sale of our Pillar Systems, both in the United States and international markets.

U.S. net sales increased by $2.5 million, or 265%, from $937,000 in 2004 to $3.4 million in 2005. The growth in U.S. net sales was primarily driven by an increase in the number of new physician customers performing Pillar Procedures. We first began selling our Pillar System for the treatment of snoring in April 2003 and continued under that indication until October 2004 when we began selling our Pillar System under both the snoring and mild to moderate OSA indications. The U.S. average selling price for the three Pillar inserts used in each Pillar Procedure increased from $540 in 2004 to $645 in 2005 as a result of a price increase in October 2004.

International net sales increased from $7,900 in 2004 to $1.4 million in 2005. We commercially introduced our Pillar System into international markets beginning in January 2005 through independent third-party distributors. At the end of 2005, our Pillar System was marketed and sold in 12 international markets in Asia Pacific, Europe, the Middle East and South Africa. Due to the market development investment and distribution costs incurred by our international third-party distributors, our international average selling price is typically approximately 50% of domestic average selling price.

Cost of sales and gross margin. Cost of sales increased by $850,000, or 108%, from $791,000 in 2004 to $1.6 million in 2005. This increase was due to the increase in our Pillar Systems sold in 2005. As a percentage of net sales, gross margin improved from 16% in 2004 to 66% in 2005. The improvement in the gross margin percent in 2005 was the result of significant reductions in the cost of our Pillar System following our launch of a redesigned second generation delivery system in May 2005, as well as increased volume-related production efficiencies.

Research and development expenses. Research and development expenses decreased by $413,000, or 18%, from $2.3 million in 2004 to $1.9 million in 2005. This decrease was attributable to a reduction in research and development personnel and the transfer of resources from research and development to manufacturing during 2004 and 2005 in connection with the commercialization of a redesigned Pillar delivery system. Additionally, we completed our initial series of post-market clinical studies and the publication of the results of these studies in peer-reviewed medical journals.

General and administrative expenses. General and administrative expenses increased by $790,000, or 37%, from $2.1 million in 2004 to $2.9 million in 2005. This increase was primarily attributable to increases in payroll and other benefit expenses of $739,000 due to increased headcount, including the hiring of our President and CEO in 2005, as well as the resignation of his predecessor, including stock-based compensation expenses of $434,000.

Sales and marketing expenses. Sales and marketing expenses increased by $942,000, or 23%, from $4.0 million in 2004 to $5.0 million in 2005. This increase was primarily attributable to increased payroll and other benefit expenses for additional sales and marketing personnel. We also incurred $228,000 of increased expenses associated with initiating our efforts to obtain a reimbursement code and coverage policies for the Pillar Procedure from the United States government and private third-party health insurers in 2005. However, this increased spending on reimbursement was offset by a reduction in other marketing expenses of $230,000, primarily related to expenses incurred in 2004 for the initial design, development and production of marketing programs to commercially launch the FDA clearance of the mild to moderate OSA indication for the Pillar Procedure.

Interest income. Interest income declined by $37,000, or 22%, from $169,000 in 2004 to $132,000 in 2005. This decrease was attributable to a decline in the amounts invested in short term investments purchased with the funds received from the sale of Series C and Series C-1 preferred stock during 2004.

Interest expense. Interest expense decreased by $401,000, or 94%, from $426,000 in 2004 to $25,000 in 2005. This decrease was due to all of our debt either being converted into Series C-1 preferred stock or repaid in 2004 and no further debt being assumed until December 2005.

Preferred stock warrant gain/loss. In 2005, we recognized a loss of $572,000 related to the change in fair value of our preferred stock warrants subject to redemption compared to a gain of $128,000 in 2004 for the change in fair value during the same period in 2005.

Amortization of beneficial conversion feature of Series A and Series B preferred stock. In 2004, we recognized amortization of $252,000 related to the accretion of the Series A and Series B preferred stock liquidation preferences.

Liquidity and Capital Resources

Since our inception and prior to May 2006, we funded our operations primarily through issuances of convertible preferred stock and related warrants, which provided us with aggregate gross proceeds of $39.9 million. On May 22, 2006, we sold 4,000,000 shares of common stock in an IPO for aggregate gross proceeds of $32.0 million to finance current operations and provide for general corporate purposes, including expanding domestic and international marketing and sales organizations and programs, increasing product development efforts and increasing our clinical study initiatives. After deducting the underwriters' commissions and discounts, we received net proceeds of approximately $27.7 million. As of December 31, 2006, we had total cash, cash equivalents and marketable securities of $23.8 million. We believe that our current cash and cash equivalents and cash generated from operations will be sufficient to fund our working capital and capital resource needs for at least the next 24 months.

Net cash used in operating activities was $10.6 million, $6.6 million and $8.3 million during 2006, 2005 and 2004, respectively. Cash used in operating activities has historically resulted from operating losses and net increases in accounts receivable and inventories resulting from the growth of our business, with the exception of a net decrease in inventories in 2006.

Net cash used in investing activities was $12.4 million during 2006, primarily related to the purchase of marketable securities. During 2005, cash provided by investing activities was $5.7 million, primarily related to the proceeds from sales of marketable securities. During 2004, cash used in investing activities was $6.3 million and primarily related to the purchase of marketable securities with a portion of the proceeds from the sale of preferred stock. Additionally, we purchased capital equipment of $190,000 in the year ended December 31, 2006 and $208,000 and $160,000 during 2005 and 2004, respectively.

Net cash provided by financing activities was $31.0 million during 2006, primarily related to the issuance of common stock in our IPO. Net cash provided by financing activities during 2005 was $2.0 million, primarily consisting of proceeds from the issuance of long-term debt. Net cash provided by financing activities during 2004 was $16.1 million, primarily consisting of net proceeds from the issuance of Series C preferred stock of $18.6 million and proceeds of $6,000 from the exercise of stock options.

In March 2005, we entered into a term debt agreement with Lighthouse Capital Partners with a maximum principal draw-down of $5.0 million, which was amended on March 3, 2006 to provide for a maximum principal draw-down of $8.0 million. We received $2.0 million in December 2005, $1.0 million in February 2006 and an additional $3.0 million in March 2006 under the term debt agreement. We elected not to draw the remaining $2.0 million on or before June 30, 2006 when the option to draw additional funds expired. Interest on the loan accrues at a variable rate of prime plus 3% and is payable monthly, with principal due at the maturity date of December 31, 2008 and an additional final payment in an amount equal to 5% of the original loan principal. The term debt loan is collateralized by substantially all of our assets excluding our intellectual property. As of December 31, 2006, we were in compliance with all of the financial and other covenants contained in the term debt loan agreement.

Our future capital requirements will depend upon a number of factors, including, but not limited to, the amount of cash generated by operations, competitive and technological developments and the rate of growth of the business. Although we have been successful in raising funds in the past, there is no assurance that any such financings or borrowings can be obtained in the future on terms acceptable to us. We believe cash, cash equivalents, investments and cash provided from daily activities, together with the term debt facility, described below, will be sufficient to fund working capital and capital resource needs through 2008.

Disclosures about Contractual Obligations and Commercial Commitments

The following table aggregates all contractual commitments and commercial obligations that affect our financial condition and liquidity position at December 31, 2006.

	Payments Due by Period				
Contractual Obligations	Total	Less Than 1 Year	2-3 Years	4-5 Years	After 5 Years
			(In thousands)		
Term debt facility	$5,004	$2,202	$2,802	$ —	$—
Capital lease obligations	125	27	62	36	—
Operating leases	1,432	376	768	288	—
Deposit payable	5	—	5	—	—
Total contractual cash obligations	$6,566	$2,605	$3,637	$324	$—

During 2006, we borrowed an additional $4.0 million under the term debt facility. We made repayments of $643,000 in 2006 on the total borrowings and will pay, in accordance with the agreement, $5.0 million in 2007 through 2008, which includes the required 5% repayment premium.

Off-Balance-Sheet Arrangements

As of December 31, 2006 or 2005, we did not have any significant off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 123(R), *Share Based Payment* (SFAS 123(R)). Generally, the approach in SFAS 123(R) is similar to the approach described in SFAS No. 123, *Accounting for Stock Based Compensation.* However, SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair value. Pro forma disclosure is no longer an alternative. We adopted SFAS 123(R) on January 1, 2006, using the prospective method. We will recognize compensation cost based on the requirements of SFAS 123(R) for all share-based payments granted or modified after January 1, 2006. We continue to apply the intrinsic value method for awards granted before January 1, 2006.

The adoption of SFAS 123(R) had a significant impact on our results of operations, although it has no impact on our overall financial position. In addition, the impact of adopting SFAS 123(R) is expected to have a material negative impact on future earnings.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections — A Replacement of APB Opinion No. 20 and FASB Statement No. 3* (SFAS 154). SFAS 154 replaces Accounting Principles Board (APB) Opinion 20, *Accounting Changes* (APB 20) and FASB Statement No. 3, *Reporting Accounting Changes in Interim Financial Statements*, and changes the requirements for the accounting for and reporting of a change in accounting principle. APB 20 previously required that most voluntary changes in accounting principle be recognized by including in net income of the period of the change the cumulative effect of changing to the new accounting principle. SFAS 154 requires retrospective application to prior periods' financial statements for voluntary changes in accounting principle. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The impact of SFAS 154 will depend on the accounting change, if any, in a future period.

In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109* (FIN 48). FIN 48 clarifies the accounting for uncertainties in income taxes recognized in a company's financial statements in accordance with Statement No. 109 and prescribes a recognition threshold and measurement attributable for financial disclosure of tax positions taken or expected to be taken on a tax return. Additionally, FIN 48 provides guidance on derecognition,

classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. Because we have not reported any income tax expense, we do not expect adoption will materially impact our financial position, results of operations or cash flows.

In September 2006, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin 108, *Considering the Effects on Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* (SAB 108). SAB 108 requires registrants to quantify errors using both the income statement method (i.e. iron curtain method) and the rollover method and requires adjustment if either method indicates a material error. If a correction in the current year relating to prior year errors is material to the current year, then the prior year financial information needs to be corrected. A correction to the prior year results that are not material to those years would not require a "restatement process" where prior financials would be amended. SAB 108 is effective for the Company for the year ended December 31, 2006. The adoption of this bulletin did not have a material effect on our financial position, results of operations or cash flows.

Item 7A. *QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK*

Foreign Currency Exchange Risk

In future periods, we believe a greater portion of our revenues could be denominated in currencies other than the United States dollar, thereby increasing our exposure to exchange rate gains and losses on non-United States currency transactions. Historically, our only foreign denominated payments were for clinical expenditures. Foreign currency gains and losses associated with these expenditures have not been significant. We do not currently enter into forward exchange contracts to hedge exposure denominated in foreign currencies or any other derivative financial instruments for trading or speculative purposes. In the future, if we believe an increase in our currency exposure merits further review, we may consider entering into transactions to help mitigate that risk.

Interest Rate Risk

Our cash is invested in bank deposits and money market funds denominated in United States dollars. The carrying value of these cash equivalents approximates fair market value. Our investments in marketable securities are subject to interest rate risk and our financial condition and results of operations could be adversely affected due to movements in interest rates.

Item 8. *FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA*

Report of Independent Registered Public Accounting Firm

The Board of Directors
Restore Medical, Inc.:

We have audited the accompanying balance sheets of Restore Medical, Inc. as of December 31, 2006 and 2005 and the related statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2006. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Restore Medical, Inc. as of December 31, 2006 and 2005, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2006 in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the financial statements, the Company adopted Statement of Financial Accounting Standards No. 123R, *Share-Based Payment, on* January 1, 2006.

/s/ KPMG LLP

Minneapolis, Minnesota
February 26, 2007

RESTORE MEDICAL, INC.

Balance Sheets

(In thousands, except per share amounts)

	December 31, 2006	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,377	$ 3,397
Short-term investments	12,463	248
Accounts receivable, net of allowance for doubtful accounts of $86 and $60, respectively	1,262	1,240
Related-party receivables	33	28
Inventories	598	744
Prepaid expenses	237	116
Other current assets	10	54
Total current assets	25,980	5,827
Machinery and equipment, net	539	426
Deferred debt issuance costs, net of accumulated amortization of $108 and $21, respectively	246	81
Deferred offering costs	—	61
Total assets	$ 26,765	$ 6,395
LIABILITIES, CONVERTIBLE PARTICIPATING PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 670	$ 113
Accrued expenses	939	645
Accrued payroll and related expense	519	673
Current portion of long-term debt, net of debt discount of $37 and $22, respectively	2,192	338
Total current liabilities	4,320	1,769
Long-term debt, net of debt discount of $37 and $44, respectively	2,863	1,619
Other long-term liabilities	14	7
Preferred stock warrants subject to redemption	—	835
Total liabilities	7,197	4,230
Series A through C-1 convertible participating preferred stock, $0.01 par value; none and 17,715,000 authorized, none and 15,049,919 issued and outstanding, respectively	—	39,208
	—	39,208
Commitments and contingencies (note 11)		
Stockholders' equity (deficit):		
Common stock $0.01 par value: 50,000,000 shares authorized; issued and outstanding 15,534,244 and 855,676 shares, respectively	155	9
Additional paid-in capital	92,772	3,188
Deferred stock-based compensation	(1,395)	(2,105)
Accumulated deficit	(71,964)	(38,135)
Total common stockholders' equity (deficit)	19,568	(37,043)
Total liabilities, convertible participating preferred stock and stockholders' equity (deficit)	$ 26,765	$ 6,395

See accompanying notes to financial statements.

RESTORE MEDICAL, INC.

Statements of Operations

(In thousands, except per share amounts)

	Year Ended December 31,		
	2006	2005	2004
Net sales	$ 5,886	$ 4,854	$ 945
Cost of sales(1)	1,695	1,641	791
Gross margin	4,191	3,213	154
Operating expenses:			
Research and development(1)	3,007	1,869	2,282
General and administrative(1)	4,960	2,938	2,148
Sales and marketing(1)	10,022	4,981	4,039
Total operating expenses	17,989	9,788	8,469
Loss from operations	(13,798)	(6,575)	(8,315)
Other income (expense):			
Interest income	952	132	169
Interest expense	(734)	(25)	(426)
Put option gain	—	—	871
Preferred stock warrant gain (loss)	500	(572)	128
Other, net	50	18	19
Total other income (expense)	768	(447)	761
Net loss	(13,030)	(7,022)	(7,554)
Deemed dividend from revision of preferred stock conversion price (note 7)	(20,799)	—	—
Amortization of beneficial conversion feature of Series A and Series B preferred stock	—	—	(252)
Net loss attributable to common stockholders	$ (33,829)	$ (7,022)	$ (7,806)
Basic and diluted net loss per common share before deemed dividend from revision of preferred stock conversion price and amortization of beneficial coversion feature of Series A and Series B preferred stock	$ (1.26)	$ (5.77)	$ (6.31)
Effect of deemed dividend from revision of preferred stock conversion price	(2.00)	—	—
Effect of amortization of beneficial conversion feature of Series A and Series B preferred stock	—	—	(0.21)
Basic and diluted net loss per common share	$ (3.26)	$ (5.77)	$ (6.52)
Basic and diluted weighted average common shares outstanding	10,377,793	1,217,640	1,196,366
(1) Includes stock-based compensation of:			
Cost of sales	$ 79	$ 19	$ 2
Research and development	148	15	2
General and administrative	1,415	463	30
Sales and marketing	211	62	6
	$ 1,853	$ 559	$ 40

See accompanying notes to financial statements.

RESTORE MEDICAL, INC.

Statements of Stockholders' Equity (Deficit)

(In thousands, except per share amounts)

	Common Stock		Additional Paid-In Capital	Deferred Stock-Based Compensation	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance, December 31, 2003	817,261	$ 8	$ 693	$ —	$(23,559)	$(22,858)
Amortization of beneficial conversion feature of Series A and B preferred stock	—	—	(252)	—	—	(252)
Stock options exercised	4,451	—	6	—	—	6
Changes to deferred compensation	—	—	206	(166)	—	40
Net loss	—	—	—	—	(7,554)	(7,554)
Balance, December 31, 2004	821,712	8	653	(166)	(31,113)	(30,618)
Stock options exercised	33,964	1	37	—	—	38
Changes to deferred compensation	—	—	2,498	(1,939)	—	559
Net loss	—	—	—	—	(7,022)	(7,022)
Balance, December 31, 2005	855,676	9	3,188	(2,105)	(38,135)	(37,043)
Issuance of shares in initial public offering, net of offering costs	4,000,000	40	27,641	—	—	27,681
Conversion of participating convertible preferred stock to common stock	10,395,288	104	39,104	—	—	39,208
Conversion of preferred warrants to common stock warrants	—	—	648	—	—	648
Stock options exercised	231,607	2	249	—	—	251
Stock warrants exercised	51,673	—	—	—	—	—
Changes to deferred compensation	—	—	(98)	710	—	612
Stock-based compensation under 123(R)	—	—	1,241	—	—	1,241
Deemed dividend from revision of preferred stock conversion price	—	—	20,799	—	(20,799)	—
Net loss	—	—	—	—	(13,030)	(13,030)
Balance, December 31, 2006	15,534,244	$155	$92,772	$(1,395)	$(71,964)	$ 19,568

See accompanying notes to financial statements.

RESTORE MEDICAL, INC.

Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2006	2005	2004
Cash flows from operating activities:			
Net loss	$(13,030)	$(7,022)	$(7,554)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	193	169	111
Stock-based compensation	1,853	559	40
Put option gain	—	—	(871)
Preferred stock warrant (gain) loss	(500)	572	(128)
Bad debt expense	97	62	14
Non-cash interest expense	141	22	337
Change in operating assets and liabilities:			
Trade receivables	(119)	(1,028)	(161)
Related-party receivables	(5)	46	57
Inventories	146	(328)	(128)
Prepaid expenses	(121)	(20)	(3)
Other current assets	44	(50)	(5)
Accounts payable	557	5	(111)
Accrued expenses	294	175	(194)
Accrued payroll and related expenses	(154)	276	267
Other long-term liabilities	7	7	—
Net cash used in operating activities	(10,597)	(6,555)	(8,329)
Cash flows from investing activities:			
Maturities of short-term investments	36,979	13,212	—
Purchase of short-term investments	(49,194)	(7,286)	(6,174)
Purchases of machinery and equipment	(190)	(208)	(160)
Net cash provided by (used in) investing activities	(12,405)	5,718	(6,334)
Cash flows from financing activities:			
Proceeds from issuance of long-term debt	4,000	2,000	—
Increase in deferred offering costs	—	(61)	—
Repayments on long-term debt	(997)	—	(2,515)
Capital lease payments	(14)	(1)	—
Proceeds from stock options exercised	251	38	6
Proceeds from sale of Series C and C-1 preferred stocks, net of financing costs and note conversion	—	—	18,577
Net proceeds from initial public offering	27,681	—	—
Other	61	—	—
Net cash provided by financing activities	30,982	1,976	16,068
Net increase in cash and cash equivalents	7,980	1,139	1,405
Cash and cash equivalents:			
Beginning of year	3,397	2,258	853
End of year	$ 11,377	$ 3,397	$ 2,258
Supplemental disclosure:			
Interest paid	$ 593	$ 4	$ 88
Non-cash investing and financing activities:			
Value of preferred stock warrants issued with long-term debt	$ 273	$ 169	$ —
Capital lease financing	116	25	—
Deemed dividend on revision of preferred stock conversion price	20,799	—	—
Conversion of Series A through C-1 preferred stock to common stock	39,208	—	—
Conversion of preferred stock warrants to common stock warrants	648	—	—
Conversion of notes payable to Series C-1 preferred stock	—	—	5,880
Conversion of interest payable to Series C-1 preferred stock	—	—	497

See accompanying notes to financial statements.

(1) Organization and Summary of Significant Accounting Policies

Nature of Business — Restore Medical, Inc. (hereinafter "we," "us" or the "Company") develops and markets medical devices designed to treat sleep disordered breathing. In December 2002, we received Food and Drug Administration (FDA) 510(k) clearance to market and sell the Pillar® palatal implant system (Pillar System) in the United States for the treatment of snoring. We received 510(k) clearance from the FDA in July 2004 to market and sell our Pillar System in the United States for mild to moderate obstructive sleep apnea (OSA). We received CE Mark certification to market and sell our Pillar System in Europe for snoring in May 2003 and for OSA in December 2004. International sales of our products are subject to regulatory requirements that vary widely from country to country. The Company markets and sells its products domestically through a direct sales force and internationally through independent distributors.

Use of Estimates — The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Ultimate results could differ from those estimates.

Cash and Cash Equivalents — We consider highly liquid investments with original maturities of 90 days or less to be cash equivalents. Cash equivalents are stated at cost, which approximates market value. The Company's cash equivalents are primarily invested in commercial paper, money market funds and U.S. government-backed securities. The Company performs periodic evaluations of the relative credit standing of the financial institutions and issuers of its cash equivalents and limits the amount of credit exposure with any one issuer.

Short-term investments — Investments with original maturities in excess of three months are classified as short-term investments. Marketable securities consist of high-grade commercial paper and corporate bonds. All marketable securities as of December 31, 2006 and 2005 are classified as held-to-maturity due to the Company's intent and ability to hold such securities to maturity. The carrying value of these instruments approximates fair market value. Declines in value of marketable securities classified as held-to-maturity are considered to be temporary.

Fair Value of Financial Instruments — The following methods and assumptions were used to estimate the fair value of each class of financial instruments:

Short-term investments — The carrying amount approximates fair value due to the short maturity of the instruments.

Long-Term Debt — Due to the recent nature of the debt agreement, the borrowing rates, loan terms and maturity date reflect the current market value of debt issued to the Company. Accordingly, the carrying amount approximates fair value of this instrument as of December 31, 2006.

Warrants Subject to Redemption — As further described in Note 9, the Company adjusted the carrying amount of warrants subject to redemption to fair value based upon an independent valuation of the warrants as of December 31, 2005. These warrants were converted to common stock warrants in 2006 upon the completion of the Company's initial public offering (IPO).

Inventories — We state our inventories at the lower of cost or market, using the first-in, first-out method. Market is determined as the lower of replacement cost or net realizable value. Inventory write-downs are established when conditions indicate that the selling price could be less than cost due to physical deterioration, usage, obsolescence, reductions in estimated future demand and reductions in selling prices. Costs associated with excess capacity are charged to earnings as incurred. Inventory write-downs are measured as the difference

(In thousands, except share and per share amounts)

between the cost of inventory and estimated realizable value. Inventories at December 31, 2006 and 2005 were as follows:

	December 31, 2006	December 31, 2005
Raw materials	$ 57	$113
Work in process	320	372
Finished goods	221	259
	$598	$744

Machinery and Equipment — Machinery and equipment is recorded at cost and depreciated utilizing the straight-line method over the estimated useful lives of the respective assets. Leasehold improvements are amortized over the shorter of the useful life of the assets or term of the lease. Repairs and maintenance are expensed as incurred.

Impairment of Long-Lived Assets — Long-lived assets, such as machinery and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated undiscounted future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset.

Deferred Debt Issuance Costs — The Company issued preferred stock warrants in relation to the issuance of the long-term debt with Lighthouse Capital Partners. Debt issuance costs are recognized as interest expense using the effective-interest method over the period from issuance until the debt is extinguished in December 2008. All warrants for preferred stock were converted into warrants for common stock upon the completion of our IPO.

Revenue Recognition — Revenue is recognized when evidence of an arrangement exists, delivery to the customer has occurred, the selling price is fixed or determinable and collectability is reasonably assured. For physician customers in the U.S., the evidence of an arrangement generally consists of a signed order confirmation or verbal phone order as their normal business practices do not require a purchase order. The Company's international distributors place orders pursuant to a distribution agreement. The price for each sale is fixed and agreed with the customer prior to shipment and is based on established list prices. Sales to the Company's international distributors are made according to the contractual terms of each individual distribution agreement. Revenue for all domestic and international sales is recognized upon shipment of product from our facility when title and risk of loss passes to the customer.

A provision for estimated sales returns on domestic product sales is recorded in the same period as the related revenue is recorded. The provision for estimated sales returns, if any, is based on an analysis of historical sales returns, as adjusted for specifically identified estimated changes in historical return activity. Sales terms to the Company's international distributors do not contain a right to return product purchased from us.

(In thousands, except share and per share amounts)

The following table summarizes the number of customers who individually comprise greater than 10% of total net sales and their aggregate percentage of the Company's total net sales:

	Number of Customers	Percent of Total Net Sales
December 31, 2004	—	0%
December 31, 2005	1	11%
December 31, 2006	—	0%

The following table summarizes the number of customers who individually comprise greater than 10% of total net accounts receivables and their aggregate percentage of the Company's total net accounts receivables:

	Number of Customers	Percent of Total Net Receivables
December 31, 2005	2	31%
December 31, 2006	2	26%

The following table summarizes the geographic dispersion of the Company's net sales:

	Year Ended December 31,		
	2006	2005	2004
United States	$4,580	$3,416	$937
Asia Pacific	570	1,111	3
Europe	487	153	5
All other markets	249	174	—
	$5,886	$4,854	$945

Allowance for Doubtful Accounts — The Company maintains allowances for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. This allowance is an estimate and is regularly evaluated by the Company for adequacy by taking into consideration factors such as past experience, credit quality of the customer base, age of the receivable balances, both individually and in the aggregate, and current economic conditions that may affect a customer's ability to pay. Provisions for the allowance for doubtful accounts are recorded in general and administrative expenses. If the financial condition of the Company's customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required. A roll forward of the allowance for doubtful accounts is as follows:

	2006	2005	2004
Beginning balance	$ 60	$ 12	$ 6
Provision	97	62	14
Write-offs	(71)	(14)	(8)
Ending balance	$ 86	$ 60	$12

Warranty Costs — The Company provides its customers with the right to receive a replacement Pillar System in the event a device malfunctions or the physician needs to remove and replace a Pillar implant in a patient for any reason. The Company has based its warranty provision on an analysis of historical warranty

(In thousands, except share and per share amounts)

claims. Actual results could differ from those estimates. Warranty reserve provisions and claims for the years ended December 31, 2006, 2005 and 2004 were as follows:

	2006	2005	2004
Beginning balance	$ 5	$ —	$—
Warranty provision	15	17	1
Warranty claims	(17)	(12)	(1)
Ending balance	$ 3	$ 5	$—

The Company is exposed to potential product liability claims that are inherent in the testing, production, marketing and sale of medical devices. Management believes any losses that may occur from these matters are adequately covered by insurance. As of December 31, 2006, the Company has experienced no product liability claims.

Stock-Based Compensation — On January 1, 2006, the Company adopted the provisions of Financial Accounting Standards Board Statement No. 123R, *Share-Based Payment* (SFAS 123(R)). SFAS 123(R) requires companies to measure and recognize compensation expense for all employee stock-based payments at fair value over the service period underlying the arrangement. As a result, the Company records the grant-date fair value of its employee stock-based payments (i.e., stock options and other equity-based compensation) in the statement of operations. The Company adopted SFAS 123R prospectively to new awards and to awards modified, repurchased or cancelled after December 31, 2005.

Prior to the adoption of SFAS No. 123(R) on January 1, 2006, the Company measured compensation costs for options issued or modified under our stock-based compensation plans using the intrinsic-value method of accounting. Under the intrinsic-value method, the Company recorded deferred compensation expense within stockholders' equity (deficit) for stock options awarded to employees and directors to the extent that the option exercise price was less than the fair market value of common stock on the date of grant. Recorded deferred compensation is amortized to compensation expense on a straight-line basis over the vesting period of the underlying stock option grants. The Company will continue to apply the intrinsic-value method to determine compensation expense for stock options granted prior to the adoption of SFAS 123(R). Net amortization of deferred stock-based compensation for awards granted prior to January 1, 2006 totaled $612, $559 and $40 for the years ended December 31, 2006, 2005 and 2004, respectively.

Severance — The Company does not have an established severance payment policy for terminated employees. The Company recognizes severance costs when costs are probable and estimable. The severance accrual at December 31, 2006 is expected to be paid during 2007. Severance activity is illustrated in the following table for the years ending December 31:

	2006	2005	2004
Beginning balance	$ 173	$ 191	$ —
Expense	481	192	262
Payments	(486)	(210)	(71)
Ending balance	$ 168	$ 173	$191

Research and Development Costs — Research and development costs are charged to expense as incurred.

Advertising Expense — Advertising costs are expensed as incurred and totaled $1,984, $100 and $10 for the years ended December 31, 2006, 2005 and 2004, respectively.

(In thousands, except share and per share amounts)

Foreign Currency Transactions — The Company incurs some of its clinical study expenditures in foreign currencies. Foreign currency transaction gains and losses, which are not significant, are included in other, net in the accompanying statements of operations.

Income Taxes — Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance for deferred income tax assets is recorded when it is more likely than not that some portion or all of the deferred income tax assets will not be realized.

Net Loss per Share — Basic net loss per common share (Basic EPS) is computed by dividing net loss by the weighted average number of common shares outstanding. Diluted net loss per common share (Diluted EPS) is computed by dividing net loss by the weighted average number of common shares and dilutive potential common shares outstanding. Potential common shares consist of shares issuable upon the exercise of stock options and warrants. Diluted EPS is identical to Basic EPS since potential common shares are excluded from the calculation, as their effect is anti-dilutive. The weighted average shares outstanding for basic and diluted loss per share includes 378,122 shares of common stock underlying warrants to purchase common stock as such warrants are immediately exercisable and have an exercise price of $0.02 per share. The common stock underlying the warrants is considered outstanding in substance for EPS purposes. Historical outstanding potential common shares not included in diluted net loss per share at year end attributable to common stockholders' calculations were 2,762,799, 9,487,031 and 8,922,304 for the years ended December 31, 2006, 2005 and 2004, respectively.

	Year Ended December 31,		
	2006	2005	2004
Net loss attributable to common stockholders	$ (33,829)	$ (7,022)	$ (7,806)
Weighted average common shares and equivalents outstanding:			
Common shares outstanding	9,999,671	839,518	818,244
Warrants issued at a nominal exercise price	378,122	378,122	378,122
Weighted average shares outstanding — basic and diluted	10,377,793	1,217,640	1,196,366
Net loss per share — basic and diluted	$ (3.26)	$ (5.77)	$ (6.52)

Recently Issued Accounting Statements — In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 123(R), *Share Based Payment* (SFAS 123(R)). Generally, the approach in SFAS 123(R) is similar to the approach described in SFAS No. 123, *Accounting for Stock Based Compensation.* However, SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair value. Pro forma disclosure is no longer an alternative. We adopted SFAS 123(R) on January 1, 2006, using the prospective method. We will recognize compensation cost based on the requirements of SFAS 123(R) for all share-based payments granted or modified after January 1, 2006. We continue to apply the intrinsic value method for awards granted before January 1, 2006.

The adoption of SFAS 123(R) had a significant impact on our results of operations, although it has no impact on our overall financial position. The impact of adopting SFAS 123(R) on future period earnings

(In thousands, except share and per share amounts)

cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, it is expected to have a material negative impact on future earnings.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections — A Replacement of APB Opinion No. 20 and FASB Statement No. 3* (SFAS 154). SFAS 154 replaces Accounting Principles Board (APB) Opinion 20, *Accounting Changes* (APB 20) and FASB Statement No. 3, *Reporting Accounting Changes in Interim Financial Statements*, and changes the requirements for the accounting for and reporting of a change in accounting principle. APB 20 previously required that most voluntary changes in accounting principle be recognized by including in net income of the period of the change the cumulative effect of changing to the new accounting principle. SFAS 154 requires retrospective application to prior periods' financial statements for voluntary changes in accounting principle. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. The impact of SFAS 154 will depend on the accounting change, if any, in a future period.

In June 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109* (FIN 48). FIN 48 clarifies the accounting for uncertainties in income taxes recognized in a company's financial statements in accordance with Statement No. 109 and prescribes a recognition threshold and measurement attributable for financial disclosure of tax positions taken or expected to be taken on a tax return. Additionally, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. Because we have not reported any income tax expense, we do not expect adoption will materially impact our financial position, results of operations or cash flows.

In September 2006, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin 108, *Considering the Effects on Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* (SAB 108). SAB 108 requires registrants to quantify errors using both the income statement method (i.e. iron curtain method) and the rollover method and requires adjustment if either method indicates a material error. If a correction in the current year relating to prior year errors is material to the current year, then the prior year financial information needs to be corrected. A correction to the prior year results that are not material to those years would not require a "restatement process" where prior financials would be amended. SAB 108 is effective for the Company for the year ended December 31, 2006. The adoption of this bulletin did not have a material effect on our financial position, results of operations or cash flows.

(2) Machinery and Equipment, net

Machinery and equipment consists of the following as of December 31, 2006 and 2005:

	2006	2005	Estimated Useful Lives
Furniture and office equipment	$ 95	$ 79	5 years
Computer hardware and software	390	303	3 years
Production and production support equipment	534	415	5 years
Leasehold improvements	88	21	4 years
	1,107	818	
Less accumulated depreciation and amortization	(568)	(392)	
	$ 539	$ 426	

(In thousands, except share and per share amounts)

Depreciation and amortization expense was $193, $169 and $111 for the years ended December 31, 2006, 2005 and 2004, respectively. At December 31, 2006, the cost and accumulated amortization of assets under capital leases was $140 and $16, respectively, and was $25 and $1, respectively, at December 31, 2005.

(3) Accrued Expenses

Accrued expenses consist of the following as of December 31, 2006 and 2005:

	2006	2005
Clinical trials	$168	$186
Legal and accounting	188	12
Other	583	447
	$939	$645

(4) Long-Term Debt

Long-term debt consists of the following as of December 31, 2006 and 2005:

	December 31, 2006	December 31, 2005
Term loan (interest at prime plus 3% maturing December 2008), net of $74 debt discount at December 31, 2006 and $66 at December 31, 2005	$ 4,930	$1,933
Capital lease for equipment (interest at 9.14%, monthly payments maturing September 2009)	18	24
Capital lease for leasehold improvements (interest at 14.33%, monthly payments maturing March 2010)	27	—
Capital lease for equipment (interest at 12.14%, monthly payments maturing July 2011)	80	—
	5,055	1,957
Less current portion, net of debt discount of $37 at December 31, 2006 and $22 at December 31, 2005	(2,192)	(338)
Total long-term debt	$ 2,863	$1,619

Future long-term debt payments as of December 31, 2006 are:

2007	$2,229
2008	2,832
2009	32
2010	22
2011	14
	$5,129

In March 2005, the Company entered into a term debt facility with Lighthouse Capital Partners (Lighthouse) with maximum principal drawdown of $5,000. The Company drew down $2,000 and $1,000 on December 30, 2005 and February 28, 2006, respectively. On March 3, 2006, the agreement was amended to increase the term debt facility from $5,000 to $8,000. The Company drew $3,000 against the amended

(In thousands, except share and per share amounts)

Lighthouse loan facility on March 30, 2006. The Company elected not to draw the additional $2,000 on the loan facility and the ability to make additional draws expired on June 30, 2006.

Borrowings under the agreement bear interest at the lender's prime rate plus 3.0%, with monthly interest-only payments from the time of funding until June 30, 2006. Beginning on July 1, 2006, each draw began to be amortized over 30 consecutive monthly payments of principal and interest, with an additional final payment in an amount equal to 5% of the original loan principal due by December 31, 2008. The 5% final payment will be recognized ratably as interest expense from the date of the draw down over the remaining term of the loan. Lighthouse has a perfected first position lien on all of the Company's assets with the exception of intellectual property. As of December 31, 2006, the Company was in compliance with all of the covenants in the credit agreement, which include maintaining all collateral in good condition, filing quarterly and annual financial information with the SEC and keeping Lighthouse informed of Company events.

An initial warrant to purchase 95,420 shares of Series C-1 preferred stock was issued on March 23, 2005, which represented 5.0% of the $5,000 facility divided by the exercise price of $2.62 per share. As additional consideration for the expanded loan commitment in March 2006, Lighthouse received 103,053 Series C-1 preferred stock warrants. These warrants were physically delivered on June 30, 2006.

As further discussed in Note 9, the Series C-1 preferred stock warrants were classified as liabilities under preferred stock warrants subject to redemption prior to our IPO. The Series C-1 warrants issued in March 2005 upon entering into the term debt facility and in March 2006 when the facility agreement was amended resulted in non-cash debt issuance costs of $102 and $273, respectively, which are being amortized over the term of the debt on a straight-line basis. As a result of the $2,000 funding on December 30, 2005 and $1,000 funding on February 28, 2006, we issued 30,534 and 15,267 Series C-1 preferred stock warrants, respectively, which resulted in a debt discount of $67 and $40, respectively, which is recognized using the effective-interest method.

As further described in Note 7, the Series C-1 preferred stock warrants were converted to common stock warrants upon completion of the Company's IPO in 2006.

(5) Income Taxes

The Company has incurred net operating losses since inception. The Company has not reflected any benefit of such net operating loss carry forwards in the accompanying financial statements. The income tax expense (benefit) differed from the amount computed by applying the U.S. federal income tax rate of 34% net loss as a result of the following:

	Year Ended December 31,		
	2006	2005	2004
Computed "expected" tax benefit	(34.0)%	(34.0)%	(34.0)%
State income tax	(3.1)	(1.7)	(1.8)
Change in state tax rate	(2.0)	—	—
Nondeductible expenses	—	3.1	1.6
Research and development tax credit	(0.9)	(0.8)	(1.2)
Other	—	0.1	—
Change in valuation allowance	40.0	33.3	35.4
	—%	—%	—%

(In thousands, except share and per share amounts)

The tax effect of temporary differences that give rise to significant portions of the deferred tax assets is presented below:

	December 31, 2006	December 31, 2005
Deferred tax assets (liabilities):		
Reserves and accruals	$ 188	$ 95
Machinery and equipment	(12)	(6)
Net operating loss carryforwards	17,479	12,131
Start-up costs	384	896
Stock-based compensation	326	—
Deferred stock compensation	—	215
Research tax credit carryforwards	488	223
Net gross deferred tax assets	18,853	13,554
Valuation allowance	(18,853)	(13,554)
Net deferred tax assets	$ —	$ —

The valuation allowance for deferred tax assets as of December 31, 2006 and 2005 was $18,853 and $13,554, respectively. The net change in the total valuation allowance for the years ended December 31, 2006, 2005 and 2004 was an increase of $5,299, $2,387 and $2,674, respectively.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during periods in which those temporary differences become deductible.

Based on the level of historical taxable income and projections of future taxable income over the periods in which the deferred tax assets are deductible, management believes that it is more likely than not that the Company will not realize the benefits of these deductible differences. Accordingly, the Company has provided a valuation allowance against the net deferred tax assets as of December 31, 2006 and 2005.

As of December 31, 2006, the Company has federal and state net operating loss and research and development credit carry forwards of approximately $45,500 and $488, respectively. The net operating loss and tax credit carry forwards, if unutilized, will expire in the years 2019 through 2023. The Company has established a valuation allowance from net operating loss carryforwards of $818, which when utilized, the benefit of $303 will be recorded to additional paid-in capital as it relates to stock-based compensation.

Federal tax laws impose significant restrictions on the utilization of net operating loss carry forwards in the event of a change in ownership of the Company, as defined by the Internal Revenue Code Section 382. The Company's net operating loss carry forwards may be subject to the above limitations.

(6) Stockholder's Equity (Deficit)

On May 12, 2006, the Company's Board of Directors and stockholders approved a 1-for-2 reverse stock split of its preferred and common shares. Such reverse stock split was effected on May 17, 2006. All preferred and common stock data presented herein have been restated to retroactively reflect the stock split.

On May 22, 2006, we sold 4,000,000 shares of common stock in an IPO for aggregate gross proceeds of $32,000. After deducting the underwriters' commissions and discounts and offering costs, we received net proceeds of $27,681.

(In thousands, except share and per share amounts)

(7) Participating Convertible Preferred Stock

Prior to the completion of the IPO, we amended our Certificate of Incorporation to change the conversion price to common stock of the Series C and Series C-1 preferred stock from $5.24 per share to $3.48 per share. This change in conversion price to common stock was effective immediately prior to the conversion of all outstanding shares of our preferred stock upon the completion of our IPO, and was in consideration for a modification of the definition of a "qualified" offering such that our IPO trigged the mandatory conversion of our preferred stock into common stock. As a result of this change in the conversion price of Series C and Series C-1 preferred stock, the common stock outstanding upon completion of our IPO increased by 2,679,783 shares, including 122,091 common shares issuable pursuant to the Series C-1 preferred stock warrants. For purposes of calculating net loss per share in the period in which the IPO was completed, net loss attributable to common stockholders has been increased by $20,799 for the fair value of the additional common shares issued upon conversion as a result of the change in the Series C and Series C-1 preferred stock conversion price. Upon completion of the IPO, all outstanding Series A, B, C and C-1 preferred stock automatically converted into 10,395,288 shares of common stock at the then current conversion prices.

Preferred stock consisted of the following prior to the conversion of preferred stock to common stock:

	Amount
Series A, $0.01 par value: 775,000 shares authorized and 750,000 shares issued and outstanding	$ 747
Series B, $0.01 par value: 4,500,000 shares authorized and 4,185,411 shares issued and outstanding	13,507
Series C, $0.01 par value: 9,500,000 shares authorized and 7,615,675 shares issued and outstanding	18,723
Series C-1, $0.01 par value: 2,940,000 shares authorized and 2,498,833 shares issued and outstanding	6,231
Total convertible participating preferred stock	$39,208

(In thousands, except share and per share amounts)

Preferred stock activity was as follows:

	Series A		Series B		Series C		Series C-1		Total	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Balance, December 31, 2003	750,000	$ 709	4,185,411	$ 13,293	—	$ —	—	$ —	4,935,411	$ 14,002
Issued, net of issuance costs	—	—	—	—	7,615,675	18,723	2,498,833	6,231	10,114,508	24,954
Amortization of benefical conversion feature	—	38	—	214	—	—	—	—	—	252
Balance, December 31, 2004	750,000	747	4,185,411	13,507	7,615,675	18,723	2,498,833	6,231	15,049,919	39,208
Balance, December 31, 2005	750,000	747	4,185,411	13,507	7,615,675	18,723	2,498,833	6,231	15,049,919	39,208
Conversion to common stock upon initial public offering	(750,000)	(747)	(4,185,411)	(13,507)	(7,615,675)	(18,723)	(2,498,833)	(6,231)	(15,049,919)	(39,208)
Balance, December 31, 2006	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —

(8) Debt Financing Arrangement and Warrant Issuances

The Company issued common and preferred stock warrants in connection with various debt financings prior to our IPO in May 2006. In connection with the 2006 and 2005 Lighthouse debt financings, as amended on March 3, 2006, the Company issued warrants to acquire a total of 244,274 shares of Series C-1 preferred stock. See Note 4 for further details.

Stock warrant activity is as follows:

	Common Shares	Weighted Average Price	Preferred Series A Shares	Weighted Average Price	Preferred Series B Shares	Weighted Average Price	Preferred Series C-1 Shares	Weighted Average Price
Balance as of:								
December 31, 2003	433,522	$0.16	9,191	$1.00	210,161	$3.00	—	$ —
Exchanged	—		—		(208,334)	3.00	238,545	2.62
December 31, 2004	433,522	0.16	9,191	1.00	1,827	3.00	238,545	
Granted	—		—		—		95,420	2.62
December 31, 2005	433,522	0.16	9,191	1.00	1,827	3.00	333,965	2.62
Granted	—		—		—		148,854	2.62
Converted to common	369,640	3.44	(9,191)	1.00	(1,827)	3.00	(482,819)	2.62
Exercised	(61,547)	0.99	—	—	—	—	—	—
December 31, 2006	741,615	$1.72	—	$ —	—	$ —	—	$ —

All warrants issued by the Company are fully vested. Pursuant to the original terms, all classes of preferred stock warrants were converted into 369,640 common warrants upon the completion of our IPO in May 2006.

(9) Preferred Stock Warrants Subject to Redemption

The Company classified preferred stock warrants as liabilities prior to the completion of our IPO as the preferred stock had liquidation rights upon the sale or merger of the Company. The warrants were required to be marked to market with adjustments recorded in the statements of operations. These adjustments were a gain (loss) of $500, ($572) and $128 for the years ended December 31, 2006, 2005 and 2004, respectively. Preferred stock warrants were converted to common stock warrants upon the completion of our IPO in May 2006.

(10) Stock Options

The Company has adopted the Restore Medical, Inc. 1999 Omnibus Stock Plan (the "Plan") that includes both incentive stock options and nonqualified stock options to be granted to employees, officers, consultants, independent contractors, directors and affiliates of the Company. At December 31, 2006, 3,325,000 shares have been authorized for issuance under this plan.

Incentive stock options must be granted at an exercise price not less than the fair market value of the common stock on the grant date. The options granted to participants owning more than 10% of the Company's outstanding voting stock must be granted at an exercise price not less than 110% of fair market value of the common stock on the grant date. The options expire on the date determined by the Company's board of directors, but may not extend more than 10 years from the grant date, while incentive stock options granted to participants owning more than 10% of the Company's outstanding voting stock expire five years from the grant date. Options typically vest 25% after the first year of service with the remaining vesting 1/36th each month thereafter.

(In thousands, except share and per share amounts)

Stock option activity was as follows:

	Shares Available for Grant	Shares Under Options	Weighted Average Exercise Price per Share	Weighted Average Fair Value	Options Exercisable at Period End
Balance, December 31, 2003	367,550	502,687	$1.06		
Granted	(525,875)	525,875	1.10	$1.36	
Exercised	—	(4,450)	1.10		
Cancelled	137,748	(137,748)	1.10		
Balance, December 31, 2004	(20,577)	886,364	1.08		300,878
Authorized	1,000,000	—			
Granted	(584,700)	584,700	1.10	$5.18	
Exercised	—	(33,967)	1.10		
Cancelled	31,483	(31,483)	1.10		
Balance, December 31, 2005	426,206	1,405,614	1.09		615,918
Authorized	1,387,500	—			
Granted	(1,380,200)	1,380,200	6.89	$3.95	
Exercised	—	(231,607)	1.08		
Cancelled	154,901	(154,901)	5.11		
Balance, December 31, 2006	588,407	2,399,306	$4.17		709,038

The following table summarizes information concerning options outstanding and exercisable at December 31, 2006:

	Outstanding			Vested and Exercisable			Weighted Average Remaining Contractual Life in Years
Exercise Price	Shares	Aggregate[1] Intrinsic Value	Weighted Average Exercise Price	Shares	Aggregate[1] Intrinsic Value	Weighted Average Exercise Price	
$0.40	19,000			19,000			3.2
1.10	1,090,556			690,038			7.3
3.37	324,500			—			9.9
7.28	36,000			—			9.6
8.00	929,250			—			9.3
	2,399,306	$3,737	$4.17	709,038	$2,218	$1.08	8.4

(1) The aggregate intrinsic value represents the total pre-tax intrinsic value, based on the Company's closing stock price of $4.21 as of December 29, 2006, which would have been received by the option holders had all option holders exercised their options as of that date.

(In thousands, except share and per share amounts)

The following table summarizes information concerning unvested options for the period ended December 31, 2006:

	Shares	Weighted Average Grant Date Fair Value
Non-vested at January 1, 2006	779,718	$3.39
Granted	1,380,200	3.95
Vested	(338,094)	2.89
Forfeited	(131,556)	4.24
Non-vested at December 31, 2006	1,690,268	$3.85

On February 1, 2007, the Board of Directors of the Company approved an amendment to 247,750 stock options that were granted to eleven Company employees between May 15, 2006 and July 20, 2006 whereby the exercise price of such stock options was reduced to $3.89, which was the closing price of the Company's common stock on February 1, 2007. All other terms of the stock options, including vesting and termination dates, remained the same.

On January 1, 2006, we adopted the fair value recognition provisions of SFAS 123(R) prospectively to new awards and to awards modified, repurchased, or cancelled after December 31, 2005. Prior to the adoption of SFAS 123(R) we used the minimum value method of measuring equity share options for the pro forma disclosure under SFAS 123. We will continue to apply the intrinsic-value method for awards granted prior to the adoption of SFAS 123(R). The Company's financial statements as of and for the year ended December 31, 2006 reflect the impact of SFAS 123(R).

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model. Since we are a newly public entity with no historical data on volatility of our stock, the expected volatility is based on the volatility of similar entities (referred to as guideline companies). In evaluating similarity, we considered factors such as industry, stage of life cycle, size and financial leverage. The expected term of options granted is determined using the "shortcut" method allowed by SAB 107. Under this approach, the expected term is presumed to be the mid-point between the vesting date and the end of the contractual term. The shortcut approach is not permitted for options granted, modified or settled after December 31, 2007. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the estimated life of the option. We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. We use historical termination behavior to support an estimated annual forfeiture rate of 8% for employees and 2% for directors. In addition, SFAS 123(R) requires us to reflect the benefits of tax deductions in excess of recognized compensation cost to be reported as both a financing cash inflow and an operating cash outflow upon adoption. We have recognized no such tax benefits to date.

The weighted average grant date fair value of share options granted during the year ended December 31, 2006 and 2005 was approximately $3.95 and $5.18, respectively. The Company recorded cash received from the exercise of stock options of $251 and did not recognize any related tax benefits during 2006. Upon exercise, the Company issues new shares of stock. The aggregate intrinsic value of share options exercised during the year ended December 31, 2006 and 2005 was approximately $1,224 and $171, respectively. As of December 31, 2006, there was $3,869 of total unrecognized compensation costs related to outstanding options granted after the adoption of SFAS 123(R), which is expected to be recognized over a weighted average period of 3.1 years.

Prior to our IPO, certain stock options were granted with exercise prices that were below the estimated fair value of the common stock at the date of grant. We recorded deferred stock compensation of $2,500 for

(In thousands, except share and per share amounts)

the period through December 31, 2005 (until the adoption of SFAS 123(R)), in accordance with APB 25. As of December 31, 2006, there was $1,395 of deferred stock-based compensation related to options granted prior to the adoption of SFAS 123(R) that will be amortized on a straight-line basis over a weighted average period of 2.6 years.

In-the-money options granted during the year ended December 31, 2005 were as follows:

Grant date	Options granted	Exercise price	Fair Value of Common Stock on Grant Date
January 1, 2005	49,250	$1.10	$ 1.88
January 18, 2005	5,000	1.10	2.36
January 25, 2005	5,450	1.10	2.56
February 14, 2005	500	1.10	3.10
March 21, 2005	2,500	1.10	4.06
March 29, 2005	5,000	1.10	4.28
April 1, 2005	1,000	1.10	4.38
April 11, 2005	408,500	1.10	4.72
April 18, 2005	250	1.10	4.98
May 2, 2005	500	1.10	5.48
May 23, 2005	15,000	1.10	6.22
June 6, 2005	500	1.10	6.70
June 30, 2005	2,500	1.10	7.56
July 11, 2005	5,250	1.10	7.74
July 18, 2005	500	1.10	7.86
July 21, 2005	10,000	1.10	7.92
August 1, 2005	10,500	1.10	8.10
September 1, 2005	15,000	1.10	8.64
September 6, 2005	10,000	1.10	8.74
November 15, 2005	37,500	1.10	10.44
	584,700	$1.10	$ 5.18

In March 2006, the Company modified certain stock options held by one individual to accelerate the vesting period. The modified stock options resulted in $191 of additional compensation expense for the year ended December 31, 2006. The following assumptions were used to estimate the fair value of the 27,180 common stock options modified during the year ended December 31, 2006 using the Black-Scholes option-pricing model:

	2006
Volatility	67.5%
Risk-free interest rates	4.6%
Expected option life	90 Days
Stock dividend yield	0%

(In thousands, except share and per share amounts)

For the year ended December 31, 2006, results of operations reflect compensation expense for new stock options granted or modified under our stock incentive plans during the year ended December 31, 2006, and the continued amortization of the deferred compensation for options granted prior to January 1, 2006.

(11) Commitments and Contingencies

Leases

Assets held under capital leases are included in property and equipment and are charged to depreciation and interest over the life of the lease. Operating leases are not capitalized and lease rentals are expensed on a straight-line basis over the life of the lease.

On October 1, 2005, the Company entered into a non-cancelable operating lease agreement for office/warehouse space. The lease expires on September 30, 2010, and the Company has an option to renew for an additional five years. The Company has sublet part of the office/warehouse space for a three-year period beginning on October 1, 2005 to a related party, EnteroMedics, Inc., whose president and CEO, Mark B. Knudson, Ph.D, is the chairman of the Company's board of directors. Previously, the Company had entered into a non-cancelable sublease agreement for office/warehouse space that expired on September 30, 2005. Rent expense totaled $367, $264 and $233 and for the years ended December 31, 2006, 2005 and 2004, respectively.

The following is a schedule of total future minimum lease payments due as of December 31, 2006:

	Operating Leases	Capital Leases
2007	$ 376	$ 40
2008	385	40
2009	383	38
2010	288	25
2011	—	15
Total future minimum lease payments	1,432	158
Less amounts representing interest		(33)
Total capital lease obligations		$125
Less noncancelable sublease payments:		
2007	(168)	
2008	(104)	
	(272)	
Minimum lease payments	$1,160	

(12) Retirement Plan

The Company has a 401(k) profit sharing plan that provides retirement benefits to all full-time employees. Eligible employees may contribute a percentage of their annual compensation, subject to Internal Revenue Service limitations. The Company's matching is at the discretion of the Company's Board of Directors. For the years ended December 31, 2006, 2005 and 2004, the Company did not provide for matching of employees' contributions.

(In thousands, except share and per share amounts)

(13) Quarterly Financial Data (Unaudited)

	Year Ended December 31, 2006				
	Q1	Q2	Q3	Q4	Total
Net sales	$ 1,752	$ 1,810	$ 1,218	$ 1,106	$ 5,886
Gross margin	1,162	1,345	987	697	4,191
Loss from operations	(2,844)	(2,822)	(3,879)	(4,253)	(13,798)
Net loss attributable to common stockholders	(3,054)	(22,956)	(3,728)	(4,091)	(33,829)
Net loss per share	$ (2.48)	$ (2.74)	$ (0.24)	$ (0.26)	$ (3.26)

	Year Ended December 31, 2005				
	Q1	Q2	Q3	Q4	Total
Net sales	$ 903	$ 1,162	$ 1,227	$ 1,562	$ 4,854
Gross margin	463	808	858	1,084	3,213
Loss from operations	(1,912)	(1,702)	(1,304)	(1,657)	(6,575)
Net loss	(2,048)	(1,918)	(1,349)	(1,707)	(7,022)
Net loss per share	$ (1.70)	$ (1.57)	$ (1.11)	$ (1.39)	$ (5.77)

The summation of quarterly loss per share computations may not equate to the year-end computation as the quarterly computations are performed on a discrete basis.

Item 9. *CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE*

None.

Item 9A. *CONTROLS AND PROCEDURES*

As of the end of the period covered by this report (the "Evaluation Date"), we carried out an evaluation, under the supervision and with the participation of management, including the Chief Executive Officer and the Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")). Based upon that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that, as of the Evaluation Date, our disclosure controls and procedures were effective to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in applicable rules and forms, and (ii) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

During the fourth quarter ended December 31, 2006, there was no change made in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

Item 9B. *OTHER INFORMATION*

None.

PART III

Certain information required by Part III is omitted from this report, and is incorporated by reference to our definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A (the "Proxy Statement") in connection with our 2007 Annual Meeting of Stockholders.

Item 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE*

The information relating to our directors is incorporated by reference to the Proxy Statement as set forth under the caption "Election of Directors." Information relating to our executive officers is set forth in Part I of this report under the caption "Executive Officers of Restore."

Information with respect to delinquent filings pursuant to Item 405 Regulation S-K is incorporated by reference to the Proxy Statement as set forth under the caption "Section 16(a) Beneficial Ownership Reporting Compliance."

Information regarding our corporate governance practices, including information regarding which members of the audit committee are audit committee financial experts and the code of conduct applicable to principal executive officers, principal financial officers and principal accounting officers (a copy of which is included as an exhibit to this report on Form 10-K), is incorporated by reference to the Proxy Statement as set forth under the caption "Corporate Governance."

Item 11. *EXECUTIVE COMPENSATION*

The information relating to executive compensation is incorporated by reference to the Proxy Statement under the captions "Executive Compensation" (except for the information set forth under the subcaption "Compensation Committee Report") and "Certain Relationships and Related Transactions — Compensation Committee Interlocks and Insider Participation." The information relating to director compensation is incorporated by reference to the Proxy Statement under the caption "Director Compensation."

Item 12. *SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.*

(a) Equity Compensation Plans

The following table sets forth information as of December 31, 2006, with respect to our equity compensation plans:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Second Column)
Equity compensation plans approved by security holders	3,140,921(1)	$3.59	588,407(2)
Equity compensation plans not approved by security holders	—	—	—
Total	3,140,921	$3.59	588,407

(1) Consists of options awarded under the 1999 Omnibus Stock Plan and outstanding warrants to purchase common stock.

(2) Represents the maximum number of shares of common stock available to be awarded as of December 31, 2006.

(b) Security Ownership

The information relating to ownership of our equity securities by certain beneficial owners and management is incorporated by reference to the Proxy Statement as set forth under the caption "Stock Ownership of Certain Beneficial Owners and Management."

Item 13. *CERTAIN RELATIONSHIPS, RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE*

The information relating to certain relationships, related transactions and director independence is incorporated by reference to the Proxy Statement under the captions "Certain Relationships and Related Transactions" and "Corporate Governance — Director Independence."

Item 14. *PRINCIPAL ACCOUNTANT FEES AND SERVICES*

The information relating to principal accountant fees and services is incorporated by reference to the Proxy Statement under the caption "Payment of Fees to Auditor."

PART IV

Item 15. *EXHIBITS AND FINANCIAL STATEMENT SCHEDULE*

(a) The following documents are filed as part of this Annual Report on Form 10-K:

1. Financial Statements (see Part II, Item 8).

2. All schedules have been omitted since the information required by the schedule is not applicable, or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the financial statements and notes thereto.

(b) Exhibits:

See Exhibit Index.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in St. Paul, Minnesota on February 28, 2007.

RESTORE MEDICAL, INC.

By: /s/ J. Robert Paulson, Jr.
J. Robert Paulson, Jr.
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints J. Robert Paulson, Jr. and Christopher R. Geyen, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to the Annual Report on Form 10-K of Restore Medical, Inc., and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below on February 28, 2007 by the following persons in the capacities indicated.

Signature	Title
/s/ J. Robert Paulson, Jr. J. Robert Paulson, Jr.	President, Chief Executive Officer and Director (principal executive officer)
/s/ Christopher R. Geyen Christopher R. Geyen	Chief Financial Officer (principal financial and accounting officer)
/s/ Mark B. Knudson, Ph.D. Mark B. Knudson	Chairman and Director
/s/ Richard Nigon Richard Nigon	Director
/s/ Howard Liszt Howard Liszt	Director
/s/ Luke Evnin, Ph.D. Luke Evnin, Ph.D.	Director
/s/ Stephen Kraus Stephen Kraus	Director
/s/ John Schulte John Schulte	Director

EXHIBIT INDEX

Exhibit Number	Description
3.1	Second Amended and Restated Certificate of Incorporation of Restore Medical, Inc. (Incorporated herein by reference to Exhibit 3.2 to Amendment No. 4 to the registrant's Registration Statement on Form S-1 filed on May 12, 2006 (File No. 333-132368)).
3.2	Amended and Restated Bylaws of Restore Medical, Inc. (Incorporated herein by reference to Exhibit 3.4 to Amendment No. 4 to the registrant's Registration Statement on Form S-1 filed on May 12, 2006 (File No. 333-132368)).
4.1	Investors' Rights Agreement, dated as of January 28, 2004, by and between Restore Medical, Inc. and the parties named therein (Incorporated herein by reference to Exhibit 4.2 to the registrant's Registration Statement on Form S-1 filed on March 13, 2006 (File No. 333-132368)).
4.2	First Amendment to Investors' Rights Agreement, dated as of March 17, 2005, by and between Restore Medical, Inc. and the parties named therein (Incorporated herein by reference to Exhibit 4.3 to the registrant's Registration Statement on Form S-1 filed on March 13, 2006 (File No. 333-132368)).
4.3	Waiver to Investors' Rights Agreement, dated as of March 30, 2005, by and between Restore Medical, Inc. and the parties named therein (Incorporated herein by reference to Exhibit 4.4 to the registrant's Registration Statement on Form S-1 filed on March 13, 2006 (File No. 333-132368)).
10.1	Commercial Lease, dated as of August 5, 2005, by and between Roseville Properties Management Company, as agent for Commers-Klodt III, and Restore Medical, Inc. (Incorporated herein by reference to Exhibit 10.1 to the registrant's Registration Statement on Form S-1 filed on March 13, 2006 (File No. 333-132368)).
10.2	Loan and Security Agreement No. 4541, dated as of March 23, 2005, by and between Lighthouse Capital Partners V, L.P. and Restore Medical, Inc. (Incorporated herein by reference to Exhibit 10.2 to the registrant's Registration Statement on Form S-1 filed on March 13, 2006 (File No. 333-132368)).
10.3	Amendment No. 1 to the Loan and Security Agreement No. 4541, dated as of March 23, 2005, by and between Lighthouse Capital Partners V, L.P. and Restore Medical, Inc., dated March 3, 2006 (Incorporated herein by reference to Exhibit 10.2A to the registrant's Registration Statement on Form S-1 filed on March 13, 2006 (File No. 333-132368)).
10.4*	Employment and Change in Control Agreement, dated as of April 11, 2005, by and between Restore Medical, Inc. and J. Robert Paulson, Jr. (Incorporated herein by reference to Exhibit 10.3 to the registrant's Registration Statement on Form S-1 filed on March 13, 2006 (File No. 333-132368)).
10.5*	Employment and Change in Control Supplemental Agreement, dated as of March 15, 2006, by and between Restore Medical, Inc. and J. Robert Paulson, Jr. (Incorporated herein by reference to Exhibit 10.3A to Amendment No. 1 to the registrant's Registration Statement on Form S-1 filed on April 14, 2006 (File No. 333-132368)).
10.6*	Employment and Change in Control Agreement, dated as of March 13, 2006, by and between Restore Medical, Inc. and Christopher R. Geyen (Incorporated herein by reference to Exhibit 10.16 to Amendment No. 1 to the registrant's Registration Statement on Form S-1 filed on April 14, 2006 (File No. 333-132368)).
10.7*	1999 Omnibus Stock Plan, as amended March 2, 2006 (Incorporated herein by reference to Exhibit 10.7 to Amendment No. 4 to the registrant's Registration Statement on Form S-1 filed on May 12, 2006 (File No. 333-132368)).
10.8*	Standard form of Incentive Stock Option Agreement pursuant to the 1999 Omnibus Stock Plan (Incorporated herein by reference to Exhibit 10.8 to the registrant's Registration Statement on Form S-1 filed on March 13, 2006 (File No. 333-132368)).
10.9*	Standard form of Non-Qualified Stock Option Agreement pursuant to the 1999 Omnibus Stock Plan (Incorporated herein by reference to Exhibit 10.9 to the registrant's Registration Statement on Form S-1 filed on March 13, 2006 (File No. 333-132368)).
10.10*	Management Incentive Plan (Incorporated herein by reference to Exhibit 10.10 to the registrant's Registration Statement on Form S-1 filed on March 13, 2006 (File No. 333-132368)).

Exhibit Number	Description
10.11*	Executive Compensation Plan (Incorporated herein by reference to Exhibit 10.11 to Amendment No. 4 to the registrant's Registration Statement on Form S-1 filed on May 12, 2006 (File No. 333-132368)).
10.12	EU Authorized Representative Contract for Services, dated as of June 16, 2003, by and between Quality First International and Restore Medical, Inc. (Incorporated herein by reference to Exhibit 10.12 to the registrant's Registration Statement on Form S-1 filed on March 13, 2006 (File No. 333-132368)).
10.13	Research and Development Agreement, dated as of August 11, 2000, by and between Restore Medical, Inc. and Advanced Composite Industries, Inc. (Incorporated herein by reference to Exhibit 10.14 to the registrant's Registration Statement on Form S-1 filed on March 13, 2006 (File No. 333-132368)).
10.14	Assignment and Grant Back of License Agreement, dated as of November 28, 2001, by and between Restore Medical, Inc. and Venturi Development Inc. (Incorporated herein by reference to Exhibit 10.15 to the registrant's Registration Statement on Form S-1 filed on March 13, 2006 (File No. 333-132368)).
10.15*	Form of Indemnification Agreement entered into by and between Restore Medical, Inc. and each of its executive officers and directors (Incorporated herein by reference to Exhibit 10.23 to Amendment No. 4 to the registrant's Registration Statement on Form S-1 filed on May 12, 2006 (File No. 333-132368)).
14.1	Code of Conduct and Ethics (Incorporated herein by reference to Exhibit 14.1 to the registrant's Registration Statement on Form S-1 filed on March 13, 2006 (File No. 333-132368)).
23.1	Consent of KPMG LLP, Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on signature page to this Form 10-K)
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certificate of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Management contract or compensatory plan or arrangement.

(This page intentionally left blank)

Board of Directors

Mark B. Knudson, PhD
President and Chief Executive Officer
EnteroMedics Inc.

Luke B. Evnin, PhD
General Partner
MPM Capital

Stephen H. Kraus
Consultant
Bessemer Venture Partners

Howard P. Liszt
Senior Fellow
University of Minnesota

Richard J. Nigon
Managing Director, Private Placements
Stifel Nicolaus

J. Robert Paulson, Jr.
President and Chief Executive Officer
Restore Medical, Inc.

John G. Schulte
President and Chief Executive Officer
The Spectranetics Corporation

Senior Management

J. Robert Paulson, Jr.
President and Chief Executive Officer

Christopher R. Geyen
Senior Vice President and Chief
Financial Officer

Craig G. Palmer
Senior Vice President, U.S. Sales

David L. Bremseth
Vice President, Clinical, Regulatory
and Quality Affairs

Paul J. Buscemi
Vice President, Research and
Development

Michael R. Kujak
Vice President, Marketing

Philip E. Radichel
Vice President, Information Systems

John P. Sopp
Vice President, Operations

Corporate Headquarters

2800 Patton Road
St. Paul, Minnesota 55113
(651) 634-3111
Fax: (651) 634-3025
www.restoremedical.com

Independent Registered Public Accountants

KPMG LLP
Minneapolis, MN

Legal Counsel

Dorsey & Whitney LLP
Minneapolis, MN

Investor Relations Contact

Lippert/Heilshorn & Associates
800 Third Avenue, 17th Floor
New York, New York 10022
(212) 838-3777

Stock Transfer Agent and Registrar

Wells Fargo Shareholder Services
161 N. Concord Exchange
South St. Paul, MN 55075
(651) 306-4498

Listing

The common stock of Restore Medical trades on the Nasdaq Global Market under the symbol REST.

Annual Meeting

May 15, 2007 – 2:00 p.m. Central Time
Dorsey & Whitney LLP
Suite 1500, 50 South Sixth Street
Minneapolis, MN 55402

Restore Medical, Inc.
2800 Patton Road, St. Paul, MN 55113
www.restoremedical.com
www.pillarprocedure.com

P: (651) 634-3111 F: (651) 634-3025
E: info@restoremedical.com
Customer Service P: (866) 869-7237
E: customerservice@restoremedical.com

Restore MEDICAL

LRF-548 4/07

END