BioSphere Medical, Inc.

Annual Report 2006

BioSphere™
Medical

converge on the common themes that minimally invasive UFE effectively relieves the symptoms of fibroids when compared to results from invasive procedures, such as hysterectomy and myomectomy, and that UFE is appealing to women because of the shorter length of hospital stay, lower complication rate, lower cost, and quicker return to daily activities. We believe these results have the potential to produce a positive impact on market acceptance and procedure adoption by altering the way physicians, hospitals, payers, and patients view UFE.

New Product Approvals and Expanding Applications

We made significant progress in broadening our proprietary product line during 2006 with FDA clearance of three new products: Sequitor™ Steerable Guidewire; EmboCath® Plus Infusion Microcatheter; and QuadraSphere™ Microspheres. The availability of Sequitor and EmboCath Plus is allowing us, for the first time, to provide a complete state-of-the-art product suite to our physician customers (wire, catheter, and embolic). Based on our pricing of Sequitor and EmboCath Plus, we believe that BioSphere's new combined product offering has the potential to increase revenue per UFE procedure by up to 40% in each account that adopts these new delivery products.

To expand our position in embolotherapy, we are attempting to mirror our success to date with UFE by seeking to also build a global position in interventional oncology—an emerging new field characterized by image-guided cancer therapy "linking traditional methods [of treatment] with innovative techniques to detect and treat many forms of cancer."[1] The ongoing worldwide use of our Embosphere Microspheres in treating patients with various forms of malignant hypervascularized tumors has encouraged us to take steps to further penetrate this market. In 2005, our first generation EmboCath® Infusion Catheter and Segway® Guidewire were cleared for sale in the People's Republic of China. Later that same year, our HepaSphere™ Microsphere embolic product commenced sales in the European Union. In November 2006, we achieved a very important milestone related to the development of our interventional oncology business with the 510K regulatory clearance and introduction of QuadraSphere Microspheres in the United States. We are hopeful that the launch of this product will allow us to accelerate domestic sales growth in interventional oncology, and generally raise market awareness of our products in this space.

Two last examples typify our endeavors to strengthen our position in interventional oncology: First, in June 2006, we commenced a Phase 2 single-arm clinical study that combines, for the first time, Avastin® with chemoembolization therapy utilizing BioSphere's patented Embosphere Microspheres to treat patients with primary liver cancer. This 30-patient, two-year study is being conducted under the direction of Dr. Jeff Geschwind, the Director of Vascular and Interventional Radiology at the Johns Hopkins University School of Medicine. Second, approximately one year after our launch of HepaSphere Microspheres, we sponsored a symposium highlighting the technical and clinical aspects of this new product in the treatment of primary and metastatic liver cancer at the Cardiovascular and Interventional Radiological Society of Europe, or CIRSE, Annual Meeting in Rome, Italy. This standing-room-only symposium was a great success, and we believe that as a result of this event, and others like it, physicians anticipate further communication from us about HepaSphere and our other new products.

Expanding Our Sales Footprint

In 2006, we increased our U.S. sales organization by 50 percent to 18 territory managers and three regional sales managers. This has allowed us to intensify our focus in each sales territory and strive to increase our productivity. In 2007, we expect to realize the impact of adding these new sales professionals as their individual efforts and our market development initiatives converge. Looking ahead, we will continue to assess our field needs and plan to add field personnel as appropriate to achieve our growth objectives.

Summary

In 2007, we are focused on concurrently growing our UFE and interventional oncology businesses. We expect that this will be possible because we have an expanded sales force, successful existing and promising new products, evidence of heightened physician and patient awareness, a growing presence in select geographies outside the United States, and a strong balance sheet. Our dedicated employees energize these resources. This Letter to Shareholders is only complete by acknowledging and sincerely thanking them for the work they do with our growing ensemble of physician customers to achieve our results.

Finally, as I trust you will see in the pages that follow, our commitment to success extends beyond just improved operating results and business achievements. While new product approvals raise industry standards for performance and reliability, these same products, like HepaSphere and QuadraSphere, may allow physicians around the world to advance promising new treatment protocols. While each new successful marketing initiative can translate into stronger customer relationships and increased utilization, it can also elevate the profile of minimally invasive treatment options among healthcare providers and their patients. We remain resolute in our belief that the delivery of products that improve patient outcomes and enhance quality of life will best position us to deliver long-term value to our shareholders.

On behalf of everyone at BioSphere, I thank you for your continued support and look forward to keeping you apprised of our progress.

Richard J. Faleschini
President and Chief Executive Officer

† Charboneau, J. W. (2007, January-March). Interventional Oncology—an emerging field. *Interventional News*, 1.

Dear BioSphere Shareholders:

In my closing remarks in last year's Letter to Shareholders, I stated that our goals for 2006 were to further strengthen BioSphere's dominant position in uterine fibroid embolization, or UFE, develop our emerging position in interventional oncology, launch our new products, and expand into select geographies. I am pleased to report that we made significant progress toward achieving these goals during 2006 and, in doing so, concluded the most successful year in the Company's history.

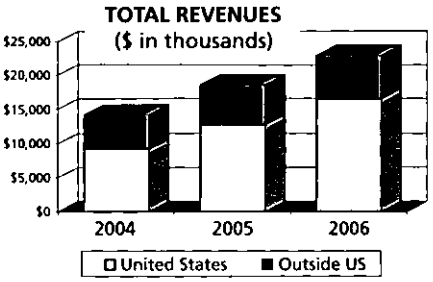
Continued Market Penetration Yields Record Results

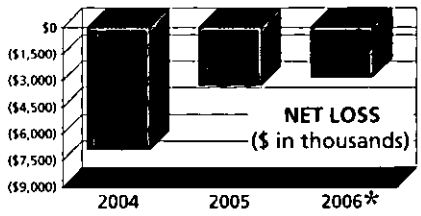
By the end of 2006, we believe we solidified our position in the UFE market in the United States, and thus continue to hold an approximate 75 percent share of this market. Our industry leading position was achieved by differentiating our Embosphere® Microsphere product, promoting the excellent UFE clinical data that has been published in the last year or so, increasing the size of our U.S. sales organization, and executing numerous local market development tactics. Revenues increased sequentially and over comparable prior periods in each of the four quarters of 2006, producing total annual revenues of $22.9 million, up 24% from 2005. This achievement was driven by a 30% increase in U.S. revenues and an 11% increase in sales outside the United States. Consolidated gross margin rose to 70% from 66%, and the net loss narrowed, despite increased investments in our sales, marketing, and operating infrastructure, and charges related to the adoption of SFAS 123(R) in 2006.

Our market development activities include utilizing, among other channels, targeted print, radio, television, and transit advertising to reach physicians, hospitals, payers, and female patients, in order to seek to advance UFE as a standard of care. To control our expenses, we largely focus these activities locally. So, we were very pleased when UFE once again achieved national attention as a result of a November 2006 *Wall Street Journal* article. This article featured the findings of a survey BioSphere developed in partnership with The National Women's Health Resource Center, a well-respected not-for-profit organization. Among the findings was that more than 40% of the women surveyed reported they discussed UFE as a treatment option for their symptomatic fibroid condition with their medical professional and, of those women, about 35% went on to have a UFE procedure. Although this is the first year we have conducted this specific survey, based on other market research we have done, we believe awareness of UFE is higher now than it was in the past. We also believe women and gynecologists are better informed today about UFE than they were two years ago, and that their decisions are influenced by more current information.

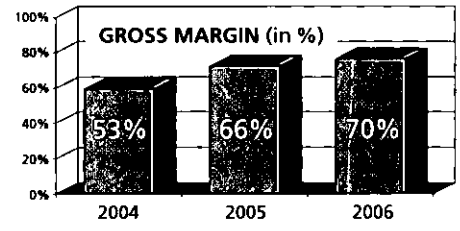
UFE also received support from referring physician specialists such as the American College of Obstetricians and Gynecologists, or ACOG, which sponsored a Congressional briefing entitled "Exploring Women's Health from Research to Outreach." Invited participants included leading UFE physician-investigators, and Congresswoman Stephanie Tubbs Jones, who has co-sponsored the bill "Uterine Fibroids Research and Education Act."

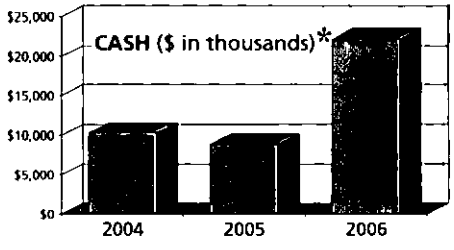
UFE was also the topic of additional important peer-reviewed clinical research in 2006, covering topics such as therapeutic efficacy, fertility and pregnancy after UFE, cost, and reimbursement. Specifically, the steering committee of the research foundation of the Society of Interventional Radiology closed the FIBROID Registry database and proceeded to draft the manuscript describing the long-term outcome of UFE at three years. We expect this manuscript will be submitted for publication in the first half of 2007, and published thereafter in a leading medical journal. This successful, multinational, 72-site, 3,100-plus patient study is the largest multicenter, prospective, voluntary registry on any procedure for benign uterine fibroids. The results of this registry, a European registry similar to it, and other top peer-reviewed journal articles all



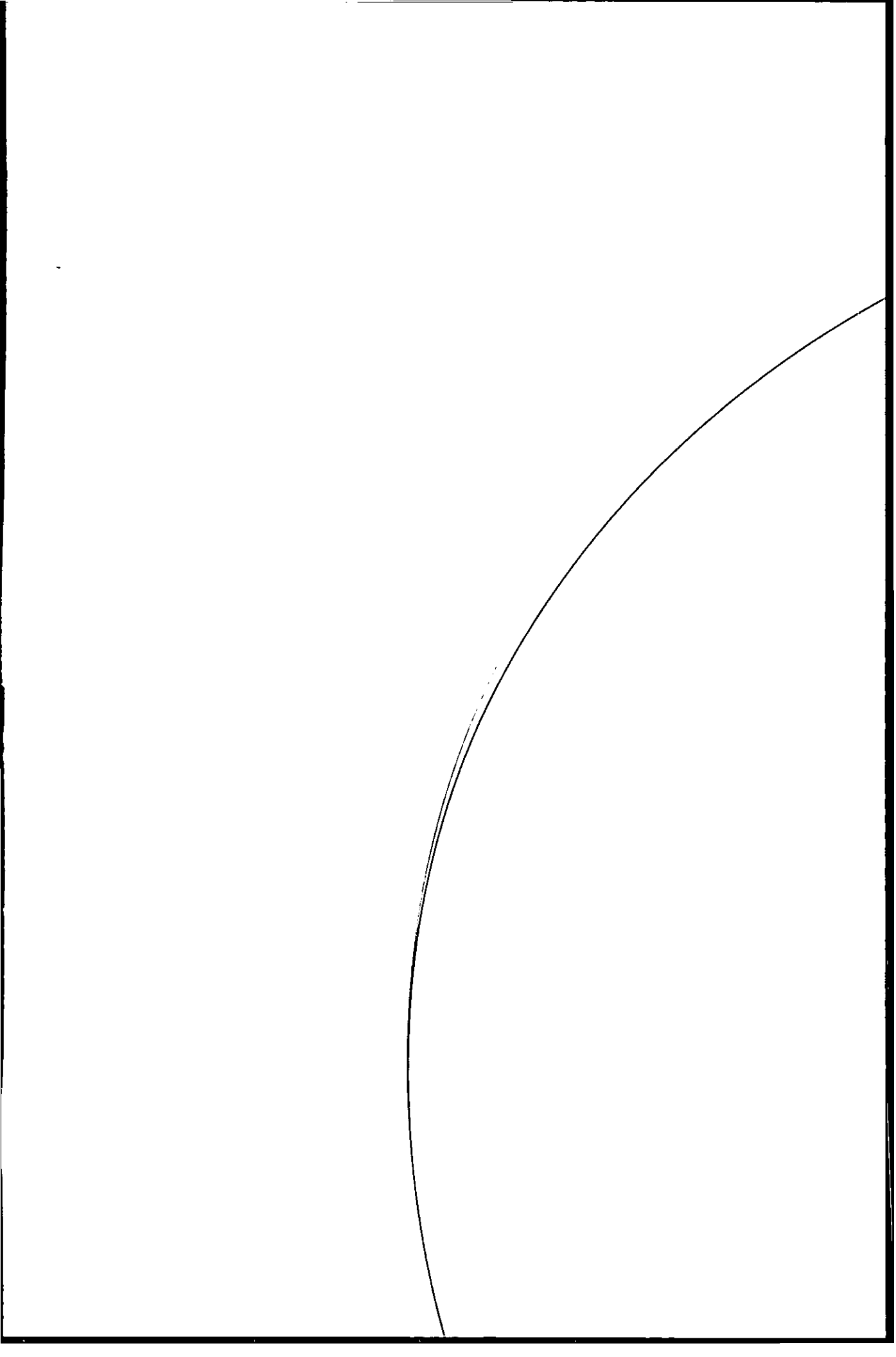


* 2006 net loss was impacted by stock option expense of $1.28 M as the Company began expensing stock options pursuant to the provisions of the Statement of Financial Accounting Standards No. 123 (R).

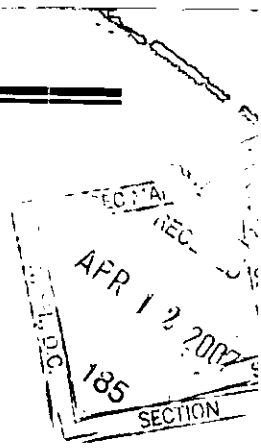




* Cash, Cash Equivalents and Marketable Securities as of December 31, 2004, 2005 and 2006.



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

or

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

For the transition period from to

Commission File Number: 0-23678

BioSphere Medical, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**04-3216867**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

1050 Hingham Street, Rockland, Massachusetts 02370
(Address of Principal Executive Offices) (Zip Code)

(781) 681-7900
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:
common stock, $.01 par value
(Title of class)

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 (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements 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 Act). Yes ☐ No ☒

The aggregate market value of voting common stock held by non-affiliates of the registrant on June 30, 2006, was $65,821,973 based on the closing price of the common stock as reported by the NASDAQ National Market as of such date.

The Registrant had 17,970,964 shares of common stock outstanding as of March 1, 2007.

Documents incorporated by reference:

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

BioSphere Medical, Inc.

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PART I

This annual report on Form 10-K contains forward-looking statements that involve risks, uncertainties and assumptions that, if they never materialize or prove incorrect, could cause the results of BioSphere Medical, Inc. to differ materially from those expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including any projections of revenues, expenses, earnings or losses from operations, or other financial items; any statements of the plans, strategies and objectives of management for future operations; any statements concerning product research, development, regulatory approval and commercialization timelines and expectations regarding market acceptance and market penetration for our products; any statements of expectation or belief; and any statements of assumptions underlying any of the foregoing. The risks, uncertainties and assumptions referred to above include risks that are described in "Risk Factors" and elsewhere in this annual report on Form 10-K and that are otherwise described from time to time in our Securities and Exchange Commission reports filed after this report on Form 10-K.

The forward-looking statements included in this annual report on Form 10-K represent our estimates as of the date of this annual report on Form 10-K. We specifically disclaim any obligation to update these forward-looking statements in the future. These forward-looking statements should not be relied upon as representing our estimates or views as of any date subsequent to the date of this annual report on Form 10-K.

Item 1. BUSINESS

OVERVIEW

We develop, manufacture and market products for medical procedures using embolotherapy techniques. Embolotherapy is the therapeutic introduction of various biocompatible substances into a patient's circulatory system to occlude a blood vessel, either to arrest or prevent hemorrhaging, or to devitalize the structure or organ by depleting its blood supply. Our core technologies consist of patented bioengineered polymers, which are chemical compounds that we create through the application to medical science of engineering principles and manufacturing methods. These core technologies are used to produce miniature spherical embolic particles with uniquely beneficial properties for a variety of medical applications. By selectively blocking the target tissue's blood supply, the deprived tissue will either become destroyed or devitalized, resulting in therapeutic benefit.

Our principal focus is the treatment of symptomatic uterine fibroids, which are noncancerous (benign) tumors growing within or on the wall of the uterus, using a procedure called uterine fibroid embolization, or UFE. UFE is a minimally invasive procedure in which microspheres are injected through a microcatheter into the blood vessels that supply the uterus. Blood flow guides these particles into the network of vessels that preferentially flow toward the fibroids, thereby blocking the blood supply to the fibroids, but not the surrounding healthy tissue. Most patients with uterine fibroids are not initially symptomatic and remain untreated until the patient experiences symptoms such as abnormal bleeding, increased urinary frequency, pain, pelvic discomfort or fertility difficulties. Our products are gaining acceptance in this procedure, as well as in a number of other new and established medical treatments, including the use of microspheres in the treatment of hypervascularized tumors like hepato-cellular carcinoma, or HCC, or primary cancer of the liver. Our strategy is to grow our embolotherapy business worldwide through increases in UFE and hypervascularized tumor embolization procedures, by increasing the awareness and availability of these procedures. Additionally, we expect to maintain our current technology leadership by introducing new products and product improvements through both internally developed and externally acquired technologies, that improve and broaden the use of embolotherapy techniques.

Our pioneering embolic products, Embosphere® Microspheres and EmboGold® Microspheres, have a number of beneficial properties that we believe make them well suited for embolotherapy procedures.

Because of their uniform, spherical shape and soft, slippery surface, our particles are easy to inject through small catheters, resulting in an even distribution within the vessel network. We provide these products in calibrated size ranges, so they can be selected to target occlusion of specific sized vessels designed to produce predictable results and optimize therapeutic benefit.

In November 2002, we received 510(k) clearance from the United States Food and Drug Administration, or FDA, to market our Embosphere Microspheres for UFE. Third-party clinical data and publications support the safety, efficacy, cost-effectiveness and long-term durability of the UFE procedure. We believe that the medical community accepts UFE as an effective option for most patients who are on drug therapy or are considering undergoing surgery, such as hysterectomy or myomectomy, for treatment of their uterine fibroids. For these reasons, we believe the number of UFE procedures will increase at an accelerating rate. We were the first company to gain regulatory clearance to market a product for UFE in the United States. Over the past two years, we focused on growing our Embosphere Microsphere business through the development of physician referral networks and patient awareness programs. We continue to expand our sales and marketing organization to maintain our leadership position in the field of UFE.

We also believe that there are growth opportunities for other embolotherapy procedures, notably in the treatment of hypervascularized tumors like primary liver cancer tumors. In May 2000, we obtained a worldwide exclusive royalty-bearing license to HepaSphere™ Microspheres from Dr. Shinichi Hori. HepaSphere Microspheres have different properties than Embosphere Microspheres and EmboGold Microspheres. Specifically, HepaSphere Microspheres have an ability to absorb fluids and expand to four times their dry state in the body while maintaining their spherical form. HepaSphere Microspheres occlude with a high degree of conformity to the vessel wall. Additionally, HepaSphere Microspheres can be used to deliver a chemotherapeutic agent to specified areas of the body when used in the treatment of liver tumors. We have CE mark approval to market our HepaSphere Microspheres in the European Union for the treatment of primary and metastatic liver cancer and are in early stage commercial introduction with limited sales of this product. CE mark approval denotes conformity with European standards for safety and allows certified devices to be placed in the market in European Union countries. Under Japanese private import regulations, Dr. Hori, as the inventor and licensor of our HepaSphere Microspheres, has purchased from us limited quantities of HepaSphere Microspheres for clinical evaluation and use in the treatment of liver cancer. In the future, we intend to seek regulatory approval of the HepaSphere Microspheres in Japan, but do not expect that such approval will be granted, if at all, in the near term. In March 2006, we instituted a voluntary recall of our HepaSphere Microspheres in Europe and Japan to correct a packaging defect that we identified while conducting aging studies routinely performed on all of our product packaging. HepaSphere Microspheres are contained in a prefilled vial that was in turn previously packaged inside a paper pouch. We determined that a defect in the paper pouch may compromise the sterility of the outside of the vial. If the sterility of the outside of the vial was not maintained, there was the risk that a physician's hands could become contaminated when handling the vial. We are not aware of any adverse events resulting from the defects in the paper packaging. Sales of HepaSphere Microspheres outside of the United States resumed in the paper pouch packaging with a shortened shelf life during the second quarter, and we launched a new packaging configuration for HepaSphere Microspheres in the third quarter of 2006.

In November 2006, the FDA granted market clearance for our proprietary QuadraSphere™ Microspheres, for treatment of hypervascularized tumors and peripheral defects in the body's circulatory system, known as arteriovenous malformations. Our QuadraSphere Microspheres are identical in all respects to our HepaSphere Microspheres, which are marketed outside of the United States for the treatment of primary and metastatic liver cancer. The FDA clearance for QuadraSphere Microsphere does not include specific indications for the treatment of primary and metastatic liver cancer. FDA regulations require that we conduct formal clinical trials prior to seeking to claim the use of QuadraSphere Microsphere for the treatment of a specific disease or condition, such as primary and metastatic liver

cancer, while European Union regulations do not require trials for this class of medical device. Accordingly, in order for us to seek FDA clearance to promote the use of QuadraSphere Microsphere for the embolization of primary and metastatic liver cancer, we must conduct clinical trials in the United States.

Also in 2006, we received the following regulatory approvals:

- in June 2006, the FDA granted market clearance for our Sequitor™ Steerable Guidewire, or Sequitor, in the United States,
- in August 2006, the FDA granted market clearance in the United States for our EmboCath® Plus Infusion Microcatheter, and
- in the third quarter of 2006, our Sequitor Guidewire and EmboCath Plus Infusion Microcatheter were CE marked for marketing in the European Union.

Additionally, we have filed for marketing approval of our Embosphere Microspheres in the People's Republic of China and in Korea, and we expect market release in 2007.

We believe that our microsphere technologies may have several non-embolotherapy uses, including tissue bulking, for the treatment of gastroesophageal reflux disease and for use in cosmetic dermatology and we have filed a number of patent applications, and have issued U.S. patents, related to the application of our technologies in these non-embolotherapy applications. Although our current focus is on embolotherapy markets, and significant additional preclinical and clinical research in non-embolotherapy areas will be required, we believe that these non-embolotherapy uses may provide us at some point in the future with development and commercialization opportunities through internal efforts or third-party licensing, collaboration or similar opportunities.

We were incorporated in Delaware in 1993. Our principal executive offices are located at 1050 Hingham Street, Rockland, MA 02370, and our telephone number is (781) 681-7900. Unless the context otherwise requires, references in this annual report on Form 10-K to "BioSphere," "we," and "our" refer to BioSphere Medical, Inc. and our subsidiaries.

We maintain a website with the address www.biospheremed.com. We are not including the information contained in our website as part of, or incorporating it by reference into, this annual report on Form 10-K. We make our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports available free of charge on our website as soon as reasonably practicable after we electronically file those materials with, or furnish those materials to, the United States Securities and Exchange Commission, or SEC.

BioSphere Medical™, Embosphere®, EmboGold®, EmboCath®, Segway®, EmboCath® Plus, Sequitor™, HepaSphere™, QuadraSphere™, ask4UFE.com®, and Passthru™ are trademarks of BioSphere Medical, Inc. Other trademarks appearing in this annual report are the property of their respective holders.

INDUSTRY OVERVIEW

Embolotherapy Markets

Embolotherapy has been in use for more than 20 years by interventional radiologists to mechanically block the flow of blood to treat certain peripheral tumors and arteriovenous malformations and to control blood loss. In the past decade, interventional radiologists around the world have adopted new embolotherapy procedures, including UFE and embolization for the treatment of certain cancers, in particular primary liver cancer tumors. Moreover, we believe that an increasing number of affected

patients are seeking alternative treatments with embolotherapy due to their desire for less invasive treatment options than those presented by non-embolotherapy procedures.

Uterine Fibroids

Until recently, women suffering from uterine fibroids have had few treatment options. These existing treatment options include the following:

- **Hysterectomy.** Hysterectomy is a surgical procedure to remove the uterus. While hysterectomy has a relatively low complication rate, it requires a hospital stay of several days, a recovery period of up to six to eight weeks, and results in loss of fertility. Furthermore, hysterectomies have been tied to adverse psychological effects, sexual and urinary dysfunction, as well as the onset of early menopause. In addition, for many women who have their ovaries removed during hysterectomy, this treatment means extended hormone replacement therapy.

- **Myomectomy.** Myomectomy is the surgical removal of the uterine fibroids without removal of the uterus. It is usually performed on women who wish to preserve their fertility. Only fibroids that can be easily accessed and excised are candidates for removal with this technique. Because some fibroids are difficult to identify while others are difficult to remove, there is a relatively high recurrence rate, between 10% and 60%, after myomectomy. Partly for this reason and because only a small percentage of gynecologists are trained to perform this procedure, relatively few myomectomies are performed compared to the number of eligible patients.

- **Drug Therapy and "Watchful Waiting."** Drug therapies include non-steroidal anti-inflammatory drugs, oral contraceptive pills, progestational agents and gonadotropin-releasing hormone agonists. Physicians may choose to monitor women with less severe symptoms who elect against drug therapy and those seeking to conceive and may determine to administer therapy only if the patient's condition worsens.

- **Other Treatments.** Other treatments for uterine fibroids include high intensity focused ultrasound and global endometrial ablation. High intensity focused ultrasound is a method of delivering ultrasonic energy to a discrete point with resultant heat and tissue destruction, but without causing a significant temperature increase or cellular injury to tissue in the path of the ultrasound beam. Global endometrial ablation describes the minimally invasive application of energy to destroy the endometrial lining in women who are experiencing severe menstrual bleeding and who do not desire future pregnancy.

Liver Cancer

Liver cancer is one of the most prevalent forms of cancer worldwide. There are several types of liver cancer.

Primary liver cancer is typically diagnosed at a stage that is too advanced to cure surgically. Primary liver cancer refers to cancer that begins within the liver itself. Chronic hepatitis B and chronic hepatitis C, inflammations of the liver associated with the hepatitis virus, are contributing factors to the development of primary liver cancer. In the United States approximately 80% of patients diagnosed with primary liver cancer are not surgical candidates. For these patients existing treatment options are primarily designed to improve quality of life rather than cure the underlying disease. Metastatic liver cancer occurs when cancer begins in another part of the body, such as the colon, and then migrates, or spreads, to the liver. In the United States, metastatic liver cancer is more prominent than primary liver cancer. However, the rate of primary liver cancer is expected to increase dramatically in the United States due to increased incidences of hepatitis C, a key risk factor for primary liver cancer. Outside the United States, there is a high

incidence of primary liver cancer in areas where there are high rates of the hepatitis B and C viruses, particularly Asia.

Numerous studies and medical publications indicate that embolotherapy has been used for at least 20 years to treat liver cancer. For example, particle embolization is commonly used in Japan to manage liver cancer patients. In the United States, embolic particles are commonly injected with chemotherapeutic agents to control and target distribution of the chemotherapy agents, thereby increasing the therapeutic exposure at a specific area. Recently, a new, targeted approach to treating liver cancer using radioactive particles has become available. These particles, which are similar to our Embosphere Microspheres, are delivered in a targeted fashion through catheters placed in the feeding vessels near the tumor site.

A number of other, less invasive technologies are either in use or in development to treat inoperable primary liver cancer. One example of these technologies is selective tumor ablation, which uses needle-like devices containing thermal energy or chemicals that are placed directly through the skin and into the tumor. However, application of this technique is practically limited to those with adequate liver function and relatively small tumors.

Non-Embolotherapy Applications

Although our current focus is to develop our embolotherapy business, we believe there may be alternative uses for our core technology in non-embolotherapy applications, particularly as bulking agents to replace or supplement tissue support. Bulking agents are materials, injected into body sites, used to provide extra physical support where normal anatomic support is not present. These applications include gastroesophageal reflux disease and cosmetic dermatology.

We have filed numerous patent applications for technologies related to non-embolotherapy applications. Although we are currently focusing our resources and efforts on the embolotherapy business and significant additional preclinical and clinical research in these areas would be required, we believe that these non-embolotherapy uses may provide us with development and commercialization opportunities in the future.

PRODUCTS

Our innovative microsphere technology evolved out of approximately 15 years of research and development of polymer formulations used in the field of biological separations and drug purification.

The following tables summarize information about our principal products and products in research and development.

Principal Products

PRODUCT	CLEARED FOR THE FOLLOWING INTENDED USES	GEOGRAPHIC APPROVALS
Microsphere Products:		
Embosphere Microspheres	Uterine fibroids, hypervascularized tumors and other arteriovenous malformations	United States, Canada, European Union, Argentina, Brazil, Colombia, Costa Rica, Ecuador, Panama, Peru, Uruguay, Hong Kong, Taiwan and Australia and clinical evaluation in China
EmboGold Microspheres	Hypervascularized tumors (other than uterine fibroids) and arteriovenous malformations	United States, Canada, European Union, Argentina, Brazil, Colombia, Costa Rica, Ecuador, Panama, Peru, Uruguay, Hong Kong, Taiwan and Australia
HepaSphere Microspheres	Primary and metastatic liver cancer	European Union
QuadraSphere Microspheres	Hypervascularized tumors and arteriovenous malformations	United States
Delivery System Products:		
EmboCath Infusion Catheter	Peripheral embolization procedures	United States, Canada, European Union, Argentina, Brazil, Costa Rica, Panama and China
Segway Guidewire	Peripheral embolization procedures	United States, Canada, European Union, Argentina, Brazil, Costa Rica, Panama and China
EmboCath Plus Infusion Microcatheter	Infusion of various diagnostic, embolic and therapeutic agents and super-selective angiography within peripheral vasculature	United States, Canada and European Union
Sequitor Steerable Guidewire	Various diagnostic and interventional procedures within peripheral vasculature	United States, Canada and European Union

Products in Research and Development

PRODUCT CANDIDATE	POTENTIAL MARKETS	DEVELOPMENT STATUS
MR Microspheres (magnetic resonance visible)	Uterine fibroids, hypervascularized tumors and other arteriovenous malformations	Preclinical research—animal studies
Resorbable Microspheres	Uterine fibroids, hypervascularized tumors and other arteriovenous malformations	Preclinical research—feasibility

Embosphere Microspheres

Our Embosphere Microspheres and EmboGold Microspheres products are intended for use in embolotherapy to block or control the blood supply to certain tumors and other vascular malformations. In November 2002, we received regulatory clearance in the United States from the FDA for use of our Embosphere Microspheres in treating uterine fibroids. In April 2000, we received 510(k) marketing clearance from the FDA for our Embosphere Microspheres for hypervascularized tumors and arteriovenous malformations.

We believe that UFE will become the principal application for our microsphere products. The majority of our revenues are currently derived from the sale of our Embosphere Microspheres for UFE. Uterine fibroid embolization is a minimally invasive procedure, performed principally by interventional radiologists, in which microspheres are injected through a small catheter into the blood vessels that supply the uterus. Blood flow guides these particles into the network of vessels that preferentially flow toward the fibroids, thereby blocking the blood supply to the fibroids, but not to the surrounding healthy tissue. The goal of the uterine fibroid embolization procedure is to eliminate the flow of blood to the uterine fibroids, thereby causing fibroid shrinkage and alleviating related symptoms, while preserving normal uterine and ovarian function.

We believe that embolotherapy is a significantly more attractive alternative for treatment of uterine fibroids, when compared to the invasiveness of such surgical procedures as hysterectomy or myomectomy, or to hormone therapy and "watchful waiting." Current therapies can have significant adverse side effects, including loss of fertility, lengthy recovery periods, high costs, discomfort and risk of recurrence of fibroids.

Although the effect of uterine fibroid embolization on continued fertility or fetal development has not been studied extensively, and our 510(k) clearance does not include women who intend future pregnancy, we believe that uterine fibroid embolization has the potential to preserve the fertility of at least some of the patients that would otherwise be lost through hysterectomy or may be compromised by the use of current therapies or technologies, and to reduce or eliminate the risk of recurrence of the uterine fibroid tumor and the complications associated with myomectomy. Most uterine fibroid embolization procedures can be performed in less than one hour, while the patient is sedated, but awake. The patient often stays overnight in the hospital to manage any discomfort and/or pain associated with the procedure and typically returns to everyday activities in several days. In contrast, hysterectomy patients undergo general anesthesia and typically stay in the hospital for two to three days and have a recovery period lasting up to six to eight weeks.

We believe Embosphere Microspheres are also being used in other disease areas and procedures, including embolization of primary liver cancer tumors and arteriovenous malformations, although we are currently devoting most of our internal efforts to marketing and selling this product for UFE.

Embosphere Microspheres have a variety of characteristics that may make them preferable to other currently marketed particles. These include:

- **Uniform Spherical Shape/Calibrated Particle Size.** We are able to synthesize beads with uniform sizing and a spherical shape. When embolic materials are non-spherical or irregularly sized, as is the case with the polyvinyl alcohol, or PVA particles that have been historically used in these applications, clinicians find vessel targeting more difficult and may also experience an increased incidence in unwanted embolization of blood vessels away from the site of the tumor.
- **Compliant and Resilient Properties.** We have developed a soft, elastic microsphere that has the capability to compress significantly, thus facilitating delivery through very small catheters known as microcatheters. Many clinicians prefer using microcatheters during embolization, since such catheters minimize the frequency of artery or vessel spasm during the procedure. Vessel spasm can be of particular concern during uterine fibroid embolization as it can disrupt the flow of blood,

which clinicians rely on during embolization to direct the microspheres to the vessel targeted for occlusion.

- **Hydrophilic Properties.** As a result of the materials used to manufacture microspheres, our products are hydrophilic, which means that they absorb moisture. This characteristic is important in that it prevents the microspheres from clumping in the catheter or in the artery during the procedure.
- **Nonbiodegradability.** Our microspheres are composed of a synthetic three-component polymer that is compatible with the human body. This polymer is insoluble and nonbiodegradable. We believe, therefore, that our Embosphere Microspheres are an appropriate agent for permanent vessel occlusion.
- **Cell Adhesion.** Our Embosphere Microspheres are cross-linked with a cell adhesion promoter composed of gelatin, which is designed to enhance a stable and complete occlusion of the vessel.
- **Charged Surface Property.** Our microspheres are positively charged, enhancing attraction to the negatively charged blood vessel wall. This attachment to the vessel wall minimizes the potential for the microspheres to migrate to nontargeted vessels.

Embosphere Microspheres are currently available in six sizes, from 40 to 1,200 microns. They are designed to precisely fit the blood vessels, resulting in targeted and controlled occlusion. They can be used with our accessory catheter products or with other commercially available catheter and delivery systems.

EmboGold Microspheres

Our EmboGold Microspheres product was launched in the United States in September 2001 after receiving FDA clearance for treatment of hypervascularized tumors and arteriovenous malformations. In March 2002, we received CE mark approval in the European Union. This product enhancement adds color to the microspheres for improved visibility in the syringe during preparation and injection. We do not have FDA clearance to market our EmboGold Microspheres for use in the treatment of uterine fibroids, and have determined not to seek such approval at this time. We made this decision in 2003 because of reports that a small number of patients treated with UFE using EmboGold Microspheres, which we believe constitutes approximately 2% of the total number of patients receiving the UFE procedure using EmboGold Microspheres, reported a delayed onset of pain and/or rash.

HepaSphere Microspheres

HepaSphere Microspheres are marketed in the European Union for the treatment of primary and metastatic liver cancer. Under Japanese private import regulations, Dr. Hori, as the inventor and licensor of our HepaSphere Microspheres, has purchased from us limited quantities of HepaSphere Microspheres for clinical evaluation and use in the treatment of liver cancer and other malignant and benign tumors. In the future, we intend to seek regulatory approval of the HepaSphere Microspheres in Japan, but we do not expect regulatory approval to market HepaSphere Microspheres in Japan in the near term.

The product attributes of HepaSphere Microspheres are:

- an ability to expand and absorb fluids, such as saline, contrast agents and human serum, that create expansion to 4 times its dry state diameter in the body—64 times its initial volume—while maintaining its spherical form;
- a high degree of conformity to vessel anatomy;
- a capability for complete occlusion of a vessel with, on average, just a single particle; and
- the ability to carry a chemotherapeutic agent.

Like treatment of uterine fibroids, targeted liver embolotherapy is intended to starve the liver tumor without damaging the surrounding tissue or causing any adverse side effects on other parts of the body, such as those associated with chemotherapy and radiation. In May 2000, we obtained a worldwide exclusive royalty-bearing license to HepaSphere Microsphere from Dr. Shinichi Hori.

In March 2006, we instituted a voluntary recall of our HepaSphere Microspheres in Europe and Japan to correct a packaging defect that we identified while conducting aging studies routinely performed on all of our product packaging. HepaSphere Microspheres are contained in a prefilled vial that was in turn initially packaged inside a paper pouch. We determined that a defect in the paper pouch may compromise the sterility of the outside of the vial. If the sterility of the outside of the vial was not maintained, there was the risk that a physician's hands could become contaminated when handling the vial. We are not aware of any adverse events resulting from the defects in the paper packaging. We resumed sales of HepaSphere Microspheres outside the United States in the paper pouch with a shortened shelf life during the second quarter, and we launched a new plastic packaging configuration for HepaSpheres Microspheres in the third quarter of 2006.

QuadraSphere Microspheres

In November 2006, the FDA granted marketing clearance for our QuadraSphere Microspheres in the United States for the treatment of hypervascularized tumors and peripheral arteriovenous malformations. Our QuadraSphere Microsphere product is technically identical in all respects to our HepaSphere Microsphere product. However, the FDA clearance for QuadraSphere Microspheres does not include specific indications for the treatment of primary and metastatic liver cancer. FDA regulations require that we conduct formal clinical trials prior to seeking to claim the use of QuadraSphere Microspheres for the treatment of a specific disease or condition, such as primary and metastatic liver cancer, while European Union regulations do not require trials for this class of medical device. Accordingly, in order for us to seek FDA clearance to promote the use of QuadraSphere Microspheres for the embolization of primary and metastatic liver cancer, we must conduct clinical trials in the United States.

The product attributes of QuadraSphere Microspheres are:

- an ability to expand and absorb fluids, such as saline, contrast agents and human serum, that create expansion to 4 times its dry state diameter in the body—64 times its initial volume—while maintaining its spherical form;
- a high degree of conformity to vessel anatomy;
- a capability for complete occlusion of a vessel with, on average, just a single particle; and
- the ability to carry a chemotherapeutic agent.

Delivery Systems

In 2006, we introduced our EmboCath Plus Infusion Microcatheter and Sequitor Steerable Guidewire products, which are used to deliver embolization material into the target area. In developing these devices we sought to build on the advantages of our existing EmboCath Infusion Catheter and Segway Guidewire products by adding enhanced tracking, torque response, coating technology to the product lines and were specifically designed to be used together to optimize flexibility.

In August 2006, we received FDA clearance to market our EmboCath Plus Infusion Catheter. The EmboCath Plus Infusion Catheter is a microcatheter that is designed to be used to deliver embolic, diagnostic, and therapeutic agents into the peripheral vascular system for interventional procedures such as UFE and the embolization of hypervascular tumors.

The product attributes of the EmboCath Plus Infusion Catheter are:

- Controlled delivery, featuring the largest internal lumen diameter in its class—0.028"—which provides a 10% greater flow rate than competitive products;
- A flexible, kink-resistant, durable design that offers optimal balance for agile tracking;
- A clear, chemo-compatible hub designed for smooth, fluent injection of microspheres; and
- Enhanced fluoroscopic ability via an extra-bright tip.

In June 2006, we introduced our Sequitor Steerable Guidewire, designed specifically for use with our EmboCath Plus Infusion Catheter. Guidewires are used in most intravascular catheter procedures to establish a support structure for, and to aid placement of, the catheter. We designed our Sequitor Guidewire to address the needs of interventionalist with characteristics such as:

- A durable atraumatic polymer tip that reduces the risk of vascular spasm but retains its shape for selective vessel access;
- A highly visible distal segment, comprised of a radiopaque coil and polymer jacket, which provides visibility under live imaging;
- A specially tempered wire core designed to transmit one-to-one torque response without kinking; and
- Passthru™ lubricious, hydrophilic coating that facilities wire trackability.

Other Products

We also sell barium delivery kits and other ancillary products in the European Union. We purchase barium from a third party and resell it for use in gastrointestinal medical testing. We sell other ancillary devices as medical products for hospital and physician use. While we generated 11% and 13% of our revenues in 2006 and 2005, respectively, from these nonstrategic products, we expect these products to be a less significant component of our sales in 2007 and 2008.

Products Under Development

MR Microspheres (magnetic resonance visible sphere)

Our MR Microsphere product under development is intended to enhance our Embosphere Microspheres with features that make the microspheres visible under magnetic resonance imaging, or MRI. Non-invasive detection of microspheres may be useful to enable image-guided therapy as well as to optimize patient care. This product candidate is currently in the preclinical research stage.

Resorbable Microspheres

Our Resorbable Microsphere product under development is intended to enhance our Embosphere Microspheres with features that would allow the microspheres to dissolve and be absorbed into the body. This ability to dissolve once the desired therapeutic effect is achieved may be desirable for some patients. This product candidate is currently in the preclinical research stage.

MANUFACTURING

We currently produce and package all of our microsphere products at our facility located in Roissy, France. Manufacturing of microsphere products includes the synthesis and processing of raw materials and third-party manufactured compounds. In addition to the manufacturing of our microsphere products, we also manufacture and assemble our auxiliary products at our facility in France. The assembly and

packaging of delivery systems, which includes EmboCath, EmboCath Plus, Segway and Sequitor are all accomplished by medical device contract manufactures in both the United States and Europe.

MARKETING AND SALES

We currently market our embolotherapy and delivery systems products through a direct sales force of 34 persons in the United States and France and through distributors in Europe, Asia, Canada, the Middle East, Africa, South America and other parts of the world. Approximately 87% of our revenue was generated through our direct sales force in 2006.

As part of our sales and marketing efforts, we attend major medical conventions throughout the world pertaining to our targeted markets and invest in market development, including physician training, referral network education and patient outreach. We work closely with major interventional radiology centers in the areas of training, therapy awareness programs, clinical studies and ongoing research.

No single customer accounted for more than 10% of our revenue in 2006.

RESEARCH AND DEVELOPMENT

Our research and development group is focusing on developing our product technology in three areas:

- continuous improvement of our core technology;
- new embolotherapy materials and platforms; and
- complementary embolotherapy products.

Our core technologies include microsphere technologies, organic and inorganic polymer and surface chemistries for microsphere design and development, and expertise and know-how in microsphere manufacturing.

During the fiscal years ended December 31, 2006, 2005, and 2004, research and development expenses were $2.29 million, $2.36 million and $2.11 million, respectively.

COMPETITION

We encounter, and expect to continue to encounter, competition in the sale of our current and future embolotherapy and delivery system products. The primary competitive embolotherapy product has been polyvinyl alcohol, or PVA particles, a product introduced into the market more than 20 years ago. Our principal competitors in both the fields of embolotherapy and the delivery systems used in the UFE procedure are Angiodynamics Incorporated, Biocompatibles, Ltd., Boston Scientific Corporation, Cook Incorporated, Cordis Corporation, a Johnson and Johnson Company, Pfizer, Inc. and Terumo Corporation, as well as companies selling or developing non-embolotherapy solutions for the disease states targeted by us. Currently, the primary products with which our microspheres compete for some of our applications are spherical PVA, sold by Boston Scientific Corporation, Biocompatibles and Terumo, gel foam, sold by Pfizer, and non-spherical PVA, sold by Boston Scientific, Angiodynamics and Cook. Many of our current competitors have, and our future competitors are likely to have, greater financial, operational, sales and marketing resources and more experience in research and development than we have. We compete primarily on the basis of product performance, ease of use, degree of targeted embolization control, and quality of patient outcome. Within the field of uterine artery embolization, we believe we are the market share leader and one of only two companies in the United States to have embolic products specifically indicated for use in UFE. Boston Scientific, which markets both a non-spherical PVA product and a spherical PVA product, is our principal competitor in this area of the market. Based on both research and clinical studies conducted on our product for UFE, we believe we offer physicians a

high degree of ease of use, targeted delivery, durable vessel occlusion, and therefore satisfactory short and long-term clinical outcomes, when compared to our competitors.

GOVERNMENT REGULATION

FDA Regulation. The FDA, and other federal, state, local, and foreign authorities, regulate our products and manufacturing activities. Pursuant to the Federal Food, Drug, and Cosmetic Act and the regulations promulgated under that act, the FDA regulates the design, development, clinical trials, testing, manufacture, packaging, labeling, storage, distribution and promotion of medical devices. Before a new device that we develop can be introduced to the market, we must obtain market clearance through a 510(k) notification or approval through a premarket approval application. Additionally, the new cleared device may only be introduced to the market if manufacturer quality system complies with 21CFR Part 820 Quality System Regulations.

Changes in Approved Devices. We must obtain new FDA 510(k) clearance or premarket approval when there is a major change or modification in the intended use or indications for use of a legally marketed device or a change or modification of the device, including product enhancements and product line extensions, of a legally marketed device as required by FDA regulations.

Current Good Manufacturing Practices / Quality System Regulations and Reporting. The Federal Food, Drug, and Cosmetic Act requires us to comply with Current Good Manufacturing Practices Quality System Regulations. We must comply with various quality system requirements pertaining to all aspects of our product design and manufacturing process, including requirements for packaging, labeling and record keeping, complaint handling, corrective and preventive actions and internal auditing. The FDA enforces these requirements through periodic inspections of medical device manufacturers. In addition, the medical device reporting regulation requires us to inform the FDA whenever information reasonably suggests that one of our devices may have caused or contributed to death or serious injury, or when one of our devices malfunctions, if the device would be likely to cause or contribute to a death or a serious injury in the event the malfunction recurred. We believe that we, and all who manufacture our delivery systems, are in compliance with applicable Current Good Manufacturing Practices / Quality Systems Regulations and with medical device reporting requirements.

Labeling and Advertising. Labeling and promotional activities are also subject to scrutiny by the FDA. Among other things, labeling violates the law if it is false or misleading in any respect or it fails to contain adequate directions for use. Moreover, product claims that are outside the labeling either approved or cleared by the FDA violate the Federal Food, Drug, and Cosmetic Act.

Our product promotion is also subject to regulation by the Federal Trade Commission under the Federal Trade Commission Act, which prohibits unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce, as well as unfair or deceptive practices such as the dissemination of any false advertisement pertaining to medical devices.

Import Requirements. To import a device, the importer must file an entry notice and bond with the United States Customs Service pending an FDA decision on the product's admissibility. All devices are subject to FDA examination before release from Customs. Any article that appears to be in violation of the Federal Food, Drug, and Cosmetic Act may be refused admission and a notice of detention and hearing may be issued.

Export Requirements. Products for export from Europe and from the United States are subject to foreign countries' import requirements and the FDA's or European regulating bodies' exporting requirements. In addition to the import requirements of foreign countries, we must also comply with the U.S. laws governing the export of products regulated by the FDA. However, foreign countries often require, among other things, an FDA certificate for products for export (Certificate for

Foreign Government). To obtain this certificate from the FDA, the device manufacturer must apply to the FDA. The FDA certifies that the product has been granted clearance or approval in the United States and that the manufacturing facilities are in compliance with Good Manufacturing Practices regulations at the time of the last FDA inspection.

Fines and Penalties for Noncompliance. Failure to comply with applicable FDA regulatory requirements could result in, among other things, market clearance or approval withdrawal, injunctions, market withdrawals, voluntary or mandatory patient/physician notifications, recalls, warning letters, product seizures, civil penalties, fines and criminal prosecutions. Federal Trade Commission enforcement can result in orders requiring, among other things, limits on advertising, corrective advertising, consumer redress, rescission of contracts and such other relief as may be deemed necessary.

Foreign Regulations. Medical device laws and regulations are also in effect in many countries outside of the United States. These range from comprehensive device approval requirements for some or all of our medical device products to simpler requests for product data or certification. The number and scope of these requirements are increasing. Sales of medical devices in the European Union are subject to compliance with the European Medical Device Directive. This directive contains requirements for quality system and Essential Requirements with which all manufacturers must comply. In February 2006, we obtained ISO 13485:2003 Quality Management Systems Requirements for Regulatory Purposes certification at our French facility and in April 2006 at our facility in Rockland, MA showing that our Quality System complies with standards for quality management.

Failure to Comply. Failure to materially comply with applicable federal, state and foreign medical device laws and regulations would likely have a material adverse effect on our business. In addition, federal, state and foreign regulations regarding the manufacture and sale of medical devices are subject to future changes.

Environmental Regulations. We are subject to various federal, state, local and foreign laws and regulations relating to the protection of the environment, as well as health and safety. In the course of our business, we are involved in the handling, storage and disposal of limited amounts of certain chemicals. The laws and regulations applicable to our operations include provisions that regulate the discharge of materials into the environment. Usually these environmental laws and regulations impose "strict liability," rendering a person liable without regard to negligence or fault on the part of such person. Such environmental laws and regulations may expose us to liability for the conduct of, or conditions caused by, others, or for acts that were in compliance with all applicable laws at the time the acts were performed. We have not been required to expend material amounts in connection with our efforts to comply with environmental requirements or that compliance with such requirements will have a material adverse effect upon our capital expenditures, results of operations or competitive position. Failure to comply with applicable environmental and related laws could have a material adverse effect on our business. In addition, because the requirements imposed by such laws and regulations are frequently changed, we are unable to predict the cost of compliance with such requirements in the future, or the effect of such laws on our capital expenditures, results of operations or competitive position.

Anti-Kickback Statutes. The federal healthcare program Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the furnishing, arranging for or recommending a good or service for which payment may be made in whole or part under a federal healthcare program such as Medicare or Medicaid. The definition of remuneration has been broadly interpreted to include anything of value, including, for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash and waivers of payments. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals or otherwise generate business involving goods or services reimbursed

in whole or in part under federal healthcare programs, the statute has been violated. The law contains a few statutory exceptions, including payments to bona fide employees, certain discounts and certain payments to group purchasing organizations. Violations can result in significant penalties, imprisonment and exclusion from Medicare, Medicaid and other federal healthcare programs. Exclusion of a manufacturer would preclude any federal healthcare program from paying for its products. In addition, some enforcement officials have argued that kickback arrangements can provide the basis for an action under the Federal False Claims Act, which is discussed in more detail below.

The Anti-Kickback Statute is broad and potentially prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, the Office of Inspector General of Health and Human Services, or OIG, has issued a series of regulations, known as the safe harbors, beginning in July 1991. These safe harbors set forth provisions that, if all the applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG. Arrangements that implicate the Anti-Kickback Statute, and that do not fall within a safe harbor, are analyzed by the OIG on a case-by-case basis.

Government officials have focused recent enforcement efforts on, among other things, the sales and marketing activities of healthcare companies, and recently have brought cases against individuals or entities with personnel who allegedly offered unlawful inducements to potential or existing customers in an attempt to procure their business. Settlements of these cases by healthcare companies have involved significant fines and/or penalties and in some instances criminal pleas.

In addition to the Federal Anti-Kickback Statute, many states have their own kickback laws. Often, these laws closely follow the language of the federal law, although they do not always have the same exceptions or safe harbors. In some states, these anti-kickback laws apply with respect to all payors, including commercial health insurance companies.

False Claims Laws. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. Manufacturers can be held liable under false claims laws, even if they do not submit claims to the government, if they are found to have caused submission of false claims. The Federal Civil False Claims Act also includes whistle blower provisions that allow private citizens to bring suit against an entity or individual on behalf of the United States and to recover a portion of any monetary recovery. Many of the recent highly publicized settlements in the healthcare industry related to sales and marketing practices have been cases brought under the False Claims Act. The majority of states also have statutes or regulations similar to the federal false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment.

Privacy and Security. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, and the rules promulgated thereunder require certain entities, referred to as covered entities, to comply with established standards, including standards regarding the privacy and security of protected health information, or PHI. HIPAA further requires that covered entities enter into agreements meeting certain regulatory requirements with their business associates, as such term is defined by HIPAA, which, among other things, obligate the business associates to safeguard the covered entity's PHI against improper use and disclosure. While not directly regulated by HIPAA, a business associate may face significant contractual liability pursuant to such an agreement if the business associates breaches the agreement or causes the covered entity to fail to comply with HIPAA. In the course of our business operations, we have entered into several business associate agreements with certain of our customers that are also covered entities. Pursuant to the terms of these business associate agreements, we have agreed, among other things, not to use or further disclose the covered entity's PHI except as permitted or required by the agreements or as required by law, to use reasonable safeguards to prevent prohibited disclosure of such PHI and to report to the covered entity any unauthorized uses or disclosures of such PHI. Accordingly, we incur compliance related costs in meeting HIPAA-related obligations under business associates agreements to which we are a party. Moreover, if we fail to meet our contractual obligations under such agreements, we may incur significant liability.

In addition, HIPAA's criminal provisions could potentially be applied to a non-covered entity that aided and abetted the violation of, or conspired to violate HIPAA, although we are unable at this time to determine conclusively whether our actions could be subject to prosecution in the event of an impermissible disclosure of health information to us. Also, many state laws regulate the use and disclosure of health information, and are not necessarily preempted by HIPAA, in particular those laws that afford greater protection to the individual than does HIPAA. Finally, in the event we change our business model and become a HIPAA covered entity, we would be directly subject to HIPAA, its rules and its civil and criminal penalties.

PROPRIETARY TECHNOLOGY AND PATENT RIGHTS

We seek to establish and protect our proprietary technologies and products by developing and using a strategy involving a combination of patents, copyrights, trademarks and trade secrets, as well as by entering into licensing agreements and utilizing confidentiality provisions where appropriate. We have implemented a patent strategy designed to maximize our intellectual property rights. We are pursuing patent coverage in the United States and foreign countries to protect the technology, inventions and improvements that we consider critical to the development of our products and business.

In January 1998, we entered into an agreement with L'Assistance Publique-Hopitaux De Paris, referred to as AP-HP, pursuant to which AP-HP has granted us the exclusive right to use two United States patents and their foreign counterparts that we jointly own with AP-HP relating to Embosphere Microspheres. We are required to pay to AP-HP a royalty on the commercial sale of any products that incorporate technology covered by the patents. We may only sublicense these exclusive rights under the agreement with the prior written consent of AP-HP, which consent cannot be unreasonably withheld. The rights granted under the contract are for an initial period, which ends on September 16, 2009, and are renewable by mutual agreement between the parties. The agreement can be terminated on three months' notice by either party if the other party does not perform one or more of its obligations under the agreement and fails to cure its nonperformance during the notice period. These jointly-owned U.S. and foreign counterpart patents will expire in 2014 and 2012, respectively.

In 2000, we entered into an agreement with Dr. Shinichi Hori, pursuant to which we have an exclusive royalty-bearing license to Japanese patent rights for our HepaSphere Microsphere product. These patent rights expire in 2012. We continue to develop this technology and we are prosecuting U.S. and foreign patent applications related to this technology. However, present applications may not issue as patents, and

these patents, if issued, may not provide us with sufficient protection against competitors. Further, we may be required to obtain additional licenses concerning the Japanese patent application and any licenses, if obtained, may not be on terms that are acceptable to us.

In addition to those listed above, we have a number of United States and foreign patents and pending applications related to our microsphere technology and uses thereof. For example, we have at least five U.S. and three foreign patents, and four U.S. and ten foreign counterpart pending applications related to microspheres and uses thereof for tissue bulking, tissue construction, dermal augmentation, and the treatment of gastroesophageal reflux disease, or GERD, and urinary incontinence. The issued U.S. and foreign counterpart patents expire at various dates between 2019 and 2020. We also have at least four U.S. and five foreign counterpart pending applications related to microspheres and uses thereof for drug delivery and gene therapy. Additionally, we have at least one patent in each of the U.S. and Europe, as well as at least one pending application in each of the U.S. and Japan, related to PVA microspheres useful for embolization and methods thereof. The U.S. and European PVA patents expire in 2019. Other U.S. and foreign counterpart patent applications have also issued or are currently pending. The subjects of these patents and applications include new materials for embolization, new methods of using our materials for embolization and other applications, as well as new uses of our materials outside of embolization.

We currently own the following U.S. trademarks:

- ask4UFE.com®
- BioSphere Medical™
- Embosphere®
- EmboCath®
- EmboCath® Plus
- EmboGold®
- Passthru™
- QuadraSphere™
- Segway®
- Sequitor™

Our success depends to a significant degree upon our ability to develop proprietary products and technologies and to obtain patent coverage for these products and technologies. We intend to continue to file patent applications covering any newly developed products and technologies. However, as discussed above, there can be no guarantee that any of our pending or future filed applications will be issued as patents. There can be no guarantee that the United States Patent and Trademark Office or some third party will not initiate an interference proceeding involving any of our pending applications or issued patents. Finally, there can be no guarantee that our issued patents or future issued patents, if any, will provide adequate protection from competition, as further discussed below.

Patents provide some degree of protection for our proprietary technology. However, the pursuit and assertion of patent rights, particularly in areas like medical device development, involve complex legal and factual determinations and, therefore, are characterized by significant uncertainty. Specifically, enforcement or defense of our patents against potential or actual third party infringers may impose a significant burden on our financial and human resources, and we may be limited in our ability to protect all of our rights. If we enforce our patents against third parties, they may challenge the validity or

enforceability of our patents. We cannot predict whether we will be successful in enforcing our patents or defending their validity or enforceability.

In addition, the laws governing patent issuance and the scope of patent coverage continue to evolve, particularly in life sciences, and the patent rights we possess, or are pursuing, generally cover our technologies to varying degrees. As a result, we cannot ensure that patents will issue from any of our patent applications or from applications licensed to us, or that any of our issued patents will offer meaningful protection. In addition, our issued patents or patents licensed to us may be successfully challenged, invalidated, circumvented or rendered unenforceable so that our patent rights may not create an effective competitive barrier. Moreover, the laws of some foreign countries may not protect our proprietary rights to the same extent, as do the laws of the United States. There can be no assurance that any patents issued to us will provide a legal basis for establishing an exclusive market for our products or provide us with any competitive advantages, or that the patents of others will not have an adverse effect on our ability to do business or to continue to use our technologies freely. In view of these factors, the value of our intellectual property position is uncertain.

We have one granted European Patent, EP 1128816, related to PVA microspheres useful for embolization and methods thereof. We have validated this European patent in Germany, Spain, France, United Kingdom and Italy. On January 13, 2005, we were notified of a Notice of Oppositions filed by Biocompatibles UK Limited on December 23, 2004 against this European patent. We have filed a response to the Notice of Opposition and we filed Auxiliary Claims in August 2005. Biocompatible UK Limited subsequently filed a response in 2006. We will continue defending our European PVA patent in this proceeding. While we are not able to predict the outcome of this proceeding, it will not impact our ability to sell our Embosphere Microsphere, HepaSphere Microsphere or QuadraSphere Microsphere products, which are not comprised of PVA.

We may be subject to third parties filing claims asserting that our technologies or products infringe on their intellectual property. We cannot predict whether third parties will assert such claims against us or our licensees or against the licensors of technology licensed to us, or whether those claims will harm our business. If we are forced to defend against such claims, regardless of their merit or whether they are resolved in favor of or against us, our licensees or our licensors, we may face costly litigation and diversion of management's attention and resources. As a result of such disputes, we may have to develop, at a substantial cost, non-infringing technology, or enter into licensing agreements. These agreements, if necessary, may be unavailable on terms acceptable to us, or at all, which could seriously harm our business or financial condition.

We also rely in part on trade secret protection of our intellectual property. We attempt to protect our trade secrets by entering into confidentiality agreements with third parties, employees and consultants. Our employees also sign agreements assigning to us their interests in inventions and original expressions and any corresponding patents and copyrights arising from their work for us. However, it is possible that these agreements may be breached, invalidated or rendered unenforceable, and, if so, our trade secrets could be disclosed to others, including our competitors, and there may not be an adequate corrective remedy available. Despite the measures we have taken to protect our intellectual property, parties to our agreements may breach the confidentiality provisions in our contracts or infringe or misappropriate our patents, copyrights, trademarks, trade secrets and other proprietary rights. In addition, third parties may independently discover or invent competitive technologies, or reverse engineer our trade secrets or other technology. Therefore, the measures we are taking to protect our proprietary technology may not be adequate.

EMPLOYEES

As of December 31, 2006, we employed 83 persons. Of these employees, nine are primarily engaged in research, development and clinical activities, 26 are engaged in manufacturing, 38 are engaged in sales and marketing, and the remainder are engaged in finance and administration. Of these 83 persons, 45 are located in the United States and 38 are located in France.

Our employees in the United States are not covered by a collective bargaining agreement. In Europe, our employees are covered by the provisions of an agreement setting forth national guidelines and standards for labor relations within our industry. We consider our relations with our employees to be good.

Item 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. The risks described below are not the only ones facing our company. Additional risks not presently known to us or that we deem immaterial may also impair our business operations. Any of the following risks could materially adversely affect our business, operating results and financial condition and could result in a complete loss of your investment.

Risks Relating to Our Future Profitability, Our Financial Results and Need For Financing

Because we have a history of losses and our future profitability is uncertain, our common stock is a speculative investment.

We have incurred operating losses since our inception and, as of December 31, 2006, had an accumulated deficit of approximately $81.65 million. We expect to spend substantial funds to continue research and product testing, to maintain sales, marketing, quality control, regulatory, manufacturing and administrative capabilities and for other general corporate purposes. We expect to continue to incur operating losses in 2007, as we seek to execute on our business plan, including continuing to establish sales and marketing capabilities and conducting research and development activities.

We may never become profitable. If we do become profitable, we may not remain profitable on a continuing basis. Our failure to become and remain profitable would depress the market price of our common stock and impair our ability to raise capital and expand, diversify or continue our operations.

We will continue to need additional funds, and if additional capital is not available, we may have to limit or scale back our operations.

We believe that our existing cash and other working capital, together with anticipated proceeds from sales of our products, will be sufficient to fund our operating and capital requirements, as currently planned through at least 2007.

Our currently planned operating and capital requirements primarily include the need for working capital to:

- produce and manufacture our products;
- support our sales and marketing efforts for our Embosphere Microsphere products for UFE and other indications, as well as our other products for sale;
- support our research and development activities; and
- fund our general and administrative costs and expenses.

However, our cash requirements may vary materially from those now planned due to a number of factors, including, without limitation, the amount of revenues we generate from sales of our products, in particular from the use of our Embosphere Microspheres for UFE; changes in our UFE regulatory and

marketing programs; anticipated research and development efforts; cost and time involved in preclinical and clinical testing; costs resulting from changes in the focus and direction of our research and development programs; competitive advances that make it harder for us to market and sell our products; the timing and cost of FDA regulatory review and, the market's acceptance of any approved products.

We also expect to incur additional costs related to ongoing research and development activities, preclinical studies, clinical trials, and the expansion of our manufacturing, laboratory and administrative capabilities, as well as costs relating to further market development and commercialization efforts. We may also need additional funds for possible strategic acquisitions of synergistic businesses, products and/or technologies. If adequate funds are not available, we may be required to delay, scale back or eliminate some of our research, development, sales and marketing initiatives, which would have a material adverse effect on our business, results of operations and ability to achieve profitability.

We may need to raise additional funds to develop and commercialize our new products successfully. If we cannot fund these new products through cash generated from existing operations and cannot raise more funds, we could be required to reduce our capital expenditures, scale back our product development, reduce our workforce and license to others products or technologies that we otherwise would seek to commercialize ourselves. Although we may seek additional funding through collaborative arrangements, borrowing money or the sale of additional equity securities, we may not receive additional funding on reasonable terms, or at all. Any sales of additional shares of our capital stock are likely to dilute our existing stockholders.

Further, if we issue additional equity securities, the new equity securities may have rights, preferences or privileges senior to those of existing holders of our common stock. Alternatively, we may borrow money from commercial lenders, possibly at high interest rates, which will increase the risk of your investment in us.

If operating results fluctuate significantly from quarter to quarter, then our stock price may decline.

Our operating results could fluctuate significantly from quarter to quarter. These fluctuations may be due to a number of factors, including:

- the timing and volume of customer orders for our products;
- procedure cancellations;
- introduction or announcement of competitive products;
- regulatory approvals;
- product recalls;
- turnover in our direct sales force;
- timing and amount of expenses;
- reductions in orders by our distributors;
- effectiveness of new marketing and sales programs;
- changes in management;
- negative publicity; and
- general economic conditions.

Due to these fluctuations, our operating results in some quarters may not meet the expectations of our investors. In that case, our stock price may decline.

In addition, a large portion of our expenses, including expenses for facilities, equipment and personnel, are relatively fixed. Accordingly, if our revenues decline or do not grow as much as we anticipate, we might not be able to improve our operating margins.

Failure to achieve anticipated levels of revenues could therefore significantly harm our operating results for a particular fiscal period.

Risks Relating to Our Industry, Business and Strategy

If we do not achieve widespread market acceptance of our microsphere products, our business prospects will be seriously harmed.

Our microspheres are based on new technologies and therapeutic approaches. In the United States, we began selling our first microsphere product in the first half of 2000. In November 2002, we received FDA clearance to market our Embosphere Microspheres in the United States for specific use in the embolization of uterine fibroids. We have only begun to market and sell our HepaSphere Microspheres in the European Union in the fourth quarter of 2005 and received marketing clearance for our QuadraSphere Microspheres in November 2006. For the fiscal years ended December 31, 2006 and 2005, we generated revenues primarily from the sales of our Embosphere Microspheres in North America and the European Union. Our success will depend upon increasing acceptance by the medical community, patients and third-party payers that our Embosphere Microspheres and other products are medically therapeutic and cost effective. Our embolotherapy techniques are administered by interventional radiologists. To date we have not achieved widespread market acceptance of our Embosphere Microspheres or other products. In the treatment of uterine fibroids using UFE, we believe that we have not yet achieved widespread acceptance primarily because obstetrics and gynecology physicians may elect to offer and provide other forms of treatment to their patients with uterine fibroids that do not require a referral to another specialist, such as an interventional radiologist. The majority of our revenues are from the sale of our Embosphere Microspheres for UFE. Accordingly, our future success will depend upon obstetrics and gynecology physicians referring patients to interventional radiologists to receive treatment using our Embosphere Microspheres in lieu of, or in addition to, receiving other forms of treatment that the obstetrics and gynecology physicians can otherwise provide directly.

Negative publicity associated with any adverse medical effects attributed to embolization treatments generally, or our products specifically, may create the market perception that our products are unsafe. For example, in UFE procedures patients commonly experience a day or two of post-procedure abdominal pain or cramping. Other infrequently occurring complications may include allergic reactions, rashes, early onset of menopause, infertility and infection that may, in some cases, require a hysterectomy. We are also aware that a small number of the patient population, which we believe constitutes approximately 2% of those receiving the UFE procedure using EmboGold Microspheres, reported a delayed onset of rash and/or pain.

If our microsphere products are not properly used or if the market concludes that our products are not safe or effective, our business could be adversely affected.

Our microspheres are designed to permanently occlude targeted blood vessels. There is some risk that some or all of the microspheres used in a medical procedure may travel in the blood system to sites other than the intended surgical site and occlude, or block, other blood vessels, resulting in the potential for significant adverse health effects on the patient or, in a worst case, even death. Moreover, to use our microspheres correctly for a particular medical procedure, trained physicians must select and use the proper size and quantity. A physician's selection and use of the wrong size or quantity of our microspheres could potentially have significant adverse health effects on the patient, including death. It is necessary for us to educate physicians about the selection and use of the proper size and quantity of microspheres in patient therapy. In addition, there is only limited data concerning the long-term health effects on persons receiving embolotherapy using our microspheres. For example, the effect of UFE on continued fertility has not yet been specifically studied, and our FDA clearance for Embosphere Microspheres currently does not include women who desire future pregnancy.

If we are not able to successfully educate physicians to properly use our product, or if the market determines or concludes that any of our products are not safe or effective for any reason, we may be exposed to product liability claims, product recalls, fines or other penalties or enforcement actions by regulatory agencies and associated adverse publicity. For example, in August 2005 we were named as a defendant in a product liability lawsuit in which the defendant, a minor child, claims that he was rendered blind in both eyes as a result of the use of our Embosphere Microsphere product during a nasal angiofibroma embolization. See "We may be exposed to product liability claims, and if we are unable to obtain or maintain adequate product liability insurance, then we may have to pay significant monetary damages in a successful product liability claim against us." While we have product liability insurance, we may not be able to maintain such insurance at favorable rates, or at all, and any successful judgments against us could exceed our coverage. In addition, we have provided to our customers a satisfaction guarantee that requires us to accept the return of any inventory and credit the entire amount of the original order if a properly trained customer is not satisfied with the performance of our microspheres or our delivery system products.

If we experience adverse publicity or are subject to product liability claims, excessive guarantee claims, recalls, fines and the like, we will be unable to achieve widespread market acceptance of our microsphere products and achieve profitability. For example, in March 2006 we instituted a voluntary recall of our HepaSphere Microspheres in Europe and Japan to correct a packaging defect that we identified while conducting aging studies routinely performed on all of our product packaging. HepaSphere Microspheres are contained in a prefilled vial that was in turn initially packaged inside a paper pouch. We determined that a defect in the paper pouch may compromise the sterility of the outside of the vial. If the sterility of the outside of the vial is not maintained, there is the risk that a physician's hands can become contaminated when handling the vial. Although we are not aware of any adverse events resulting from the defects in the paper packaging, our voluntary recall of this product could result in reputational harm or a perception that the product is not safe, either of which could adversely affect market acceptance of our microsphere products.

If we do not successfully market and promote our Embosphere Microspheres for use in uterine fibroid embolization, our product revenues will not increase.

In the first quarter of 2003, we launched our ask4UFE campaign to increase awareness among patients, referring physicians, interventional radiologists and third-party payers of UFE as an alternative treatment for fibroids. We believe the majority of our revenues in the United States for the two years ended December 31, 2006 were derived from the sale of Embosphere Microspheres for use in UFE. Although we believe that EmboGold Microspheres accounted for a significant portion of revenue, we

currently do not intend to seek 510(k) clearance for use of EmboGold Microspheres in UFE. Because we do not intend to seek 510(k) clearance of EmboGold Microspheres, we believe that our future product revenues are substantially dependent on our ability to achieve widespread acceptance of the use of Embosphere Microspheres for the treatment of UFE, and if we do not achieve increased market acceptance, our product revenues, profitability and success will be adversely affected. We are continuing to market EmboGold Microspheres for use in hypervascularized tumors (other than uterine fibroids) and arteriovenous malformations. If we cease to market EmboGold Microspheres for any reason, we could incur substantial costs to write off and replace existing inventories. As of December 31, 2006, we had EmboGold inventory with a carrying value of $185,000, including in-process inventory of $91,000 and finished goods syringes of $94,000. We currently believe no provision for the write-off or replacement of EmboGold Microspheres inventory is required in the accompanying financial statements.

If we do not maintain our relationships with the healthcare community, our growth will be limited and our business could be harmed. If gynecologists, obstetricians, interventional radiologists and other healthcare providers do not recommend and endorse our products, our sales may decline or we may be unable to increase our sales and profits.

Our relationships with gynecologists, obstetricians, interventional radiologists and other healthcare providers are critical to our continued growth. We believe that these relationships are based on the quality of our products, our long-standing commitment to embolotherapy treatments, our marketing efforts and our presence at medical society and trade association meetings. Any actual or perceived diminution in our reputation or the quality of our products, or our failure or inability to maintain these other efforts could damage our current relationships, or prevent us from forming new relationships, with healthcare professionals and cause our growth to be limited and our business to be harmed.

In order for us to sell our products, healthcare professionals must recommend and endorse them. We may not obtain the necessary recommendations or endorsements from this community. Acceptance of our products depends on educating the medical community as to the distinctive characteristics, perceived benefits, safety, clinical efficacy and cost-effectiveness of our products compared to traditional methods of treatment and the products of our competitors, and on training healthcare professionals in the proper application of our products. If we are not successful in obtaining the recommendations or endorsements of gynecologists, obstetricians, interventional radiologists and other healthcare professionals for our products, our sales may decline or we may be unable to increase our sales and profits.

If we experience delays, difficulties or unanticipated costs in establishing the sales, distribution and marketing capabilities necessary to successfully commercialize our products, we will have difficulty maintaining and increasing our sales.

We are continuing to develop sales, distribution and marketing capabilities in the United States, the European Union, Asia and in South America. In 2003 we began a marketing strategy to promote UFE awareness and the benefits of our product for the treatment of uterine fibroids. It will be expensive and time-consuming for us to develop a global marketing and sales force. Moreover, we may choose, or find it necessary, to enter into strategic collaborations to sell, market and distribute our products. At December 31, 2006 we had a sales force of 25 persons located principally in the United States. Competition for skilled salespersons in the medical device industry is intense, and we may not be able to provide adequate incentive to maintain our sales force or to attract new sales personnel or to establish and maintain favorable distribution and marketing collaborations with other companies to promote our products. We have only limited sales and marketing experience both in the United States and internationally and may not be successful in developing and implementing our strategy. Among other things, we need to:

- provide or assure that distributors provide the technical and educational support customers need to use our products successfully;

- establish and implement successful sales and marketing and education programs that encourage our customers to purchase our products;
- manage geographically dispersed operations; and
- modify our products and marketing and sales programs for foreign markets.

We currently have distribution agreements with approximately 40 third-party distributors. Any third party with whom we have established a marketing and distribution relationship may not devote sufficient time to the marketing and sales of our products, thereby exposing us to potential expenses in terminating such distribution agreements. For example, in 2002, our subsidiary, BSMA, ended a distribution agreement with a third party in part because of such party's failure to achieve sales forecasts agreed upon by the parties. As a result of subsequent litigation BSMA was required to pay approximately $800,000 in damages arising from such termination and incurred additional legal and administrative expenses incident to the legal proceeding. We and any of our third-party collaborators must also market our products in compliance with federal, state and local laws relating to the providing of incentives and inducements. Violation of these laws can result in substantial penalties. If we are unable to successfully motivate and expand our marketing and sales force and further develop our sales and marketing capabilities, or if our distributors fail to promote our products, we will have difficulty maintaining and increasing our sales.

We will be required to expend significant resources for research, development, testing and regulatory approval of our products under development, and these products may not be developed successfully.

We are developing and commercializing products for medical applications using embolotherapy techniques. Most of our next-generation embolotherapy product candidates, including MR Microspheres and Resorbable Microspheres, are still in the early stages of research and development. Our products may not provide greater benefits than current treatments or products, or alternative treatments or products under development. All of our products under development will require significant additional research, development, engineering, preclinical and/or clinical testing, regulatory approval and a commitment of significant additional resources prior to their commercialization. Our potential products may not:

- be developed successfully;
- be proven safe and effective in clinical trials;
- offer therapeutic or other improvements over current treatments and products;
- meet applicable regulatory standards or receive regulatory approvals;
- be capable of production in commercial quantities at acceptable costs; or
- be successfully marketed.

We may be unable to grow revenues for certain of our products, and if we do not develop and introduce new products, we may not achieve additional revenue opportunities.

We derived approximately 11% of our revenues for the period ended December 31, 2006, from the sale of nonstrategic medical products that we expect will constitute a less significant portion of our revenues on an ongoing basis. These nonstrategic medical products include barium delivery kits sold by us in the European Union, as well as other ancillary devices for hospital and physician use. In addition, we estimate that a significant portion of our revenues for the year ended December 31, 2006, were derived from the sale of EmboGold Microspheres for UFE, an indication for which we do not have, and do not presently intend to seek, clearance from the FDA to market. We made the decision not to seek FDA clearance for our EmboGold Microsphere product because of reports that a small number of patients treated with UFE using EmboGold Microspheres, which we believe constitute approximately 2% of the

total number of patients receiving the procedure, reported a delayed onset of rash and/or pain. Accordingly, we need to develop and introduce new applications for our embolotherapy technology and pursue opportunities for microsphere technology in other medical applications. Any such new application for our embolotherapy technology or microsphere technology will be subject to a number of risks inherent in the development and commercialization of a medical device product, including uncertainties with respect to the successful completion of clinical trials, our ability to achieve and maintain, and our willingness to seek, required regulatory approvals and our ability to successfully commercialize, market and sell these new applications assuming FDA approval is achieved. If, as a result of these or other risks, we are not successful in developing new applications and products, we will not achieve new revenue opportunities.

We may be exposed to product liability claims, and if we are unable to obtain or maintain adequate product liability insurance, then we may have to pay significant monetary damages in a successful product liability claim against us.

The development and sale of medical devices entails an inherent risk of product liability. For example, if we are not able to successfully educate physicians to properly use our products, if patients experience adverse side effects in procedures in which our products are used, or if the market determines or concludes that any of our products are not safe or effective for any reason, we may be exposed to product liability claims. Although we maintain insurance, including product liability insurance, we cannot provide assurance that any claim that may be brought against us will not result in court judgments or settlements in amounts that are in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance.

In August 2005 we were named as a defendant in a lawsuit commenced in the Circuit Court, Twenty-Second Judicial Circuit, St. Louis, Missouri, which we refer to as the Pingel Claim. The lawsuit alleges, among other things, that a juvenile patient suffered permanent bilateral blindness in a nasal angiofibroma embolization as a result of the use of our Embosphere Microspheres or the negligence of the healthcare providers or both factors combined. Plaintiffs seek compensatory and punitive damages. Although we currently maintain product liability insurance coverage for our products, including the Embosphere Microsphere product that is the subject of the Pingel claim, our existing insurance and any additional insurance we may subsequently obtain may not provide us with adequate coverage against all potential claims. For example, although our product liability insurer has agreed to vigorously defend us with regards to all of the counts set forth against us in the Pingel Claim, the insurer has advised us in writing that any verdict against us for punitive damages is specifically excluded from coverage. The insurer has also advised us that it does not waive any other defenses to coverage that may apply.

Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure additional insurance coverage in the future. A product liability claim, whether meritorious or not, could be time consuming, distracting and expensive to defend, could be harmful to our reputation, could result in a diversion of management and financial resources away from our primary business and could result in product recalls. In any such case, our business may suffer.

We instituted a voluntary recall of our HepaSphere Microspheres product in the European Union and Japan, which may result in decreased market acceptance of this product and reputational harm, as well as hindering our ability to generate revenue from sales of the product.

In March 2006, we instituted a voluntary recall of our HepaSphere Microspheres in Europe and Japan to correct a packaging defect that we identified while conducting aging studies routinely performed on all of our product packaging. We received CE mark approval to sell HepaSphere Microspheres in the

European Union in 2004 and commercial launch began in late 2005. We also have had limited sales of HepaSphere Microspheres to Dr. Shinichi Hori, the inventor and licensor of HepaSphere Microspheres, in Japan under private import restrictions. HepaSphere Microspheres are contained in a prefilled vial that was in turn initially packaged inside a paper pouch. We determined that a defect in the paper pouch may compromise the sterility of the outside of the vial. If the sterility of the outside of the vial is not maintained, there is the risk that a physician's hands can become contaminated when handling the vial. Although we are not aware of any adverse events resulting from the defects in the paper packaging, our voluntary recall of this product could result in reputational harm or a perception that the product is not safe, either of which could adversely affect market acceptance of our microsphere products and result in decreased sales. In the third quarter of 2006 we launched a new plastic packaging configuration for our HepaShere Microsphere product designed to correct this defect.

If we are not able to compete effectively, we may experience decreased demand for our products, which may result in price reductions.

We have many competitors in the United States and abroad, including medical device, biotechnology and other alternative therapeutic companies, universities and other private and public research institutions. We have experienced increased competition since receiving FDA approval for use of our Embosphere Microspheres for UFE. Our success depends upon our ability to develop and maintain a competitive position in both the embolotherapy and related delivery systems markets. Our key competitors in both the fields of embolotherapy and the delivery systems used in the UFE procedure are Angiodynamics Incorporated, Biocompatibles, Ltd., Boston Scientific Corporation, Cook Incorporated, Cordis Corporation, a Johnson and Johnson Company, Pfizer, Inc. and Terumo Corporation. These and many of our other competitors have greater capabilities, experience and financial resources than we do. As a result, they may develop products more quickly or at less cost, that compete with our microsphere products and related delivery systems. In addition, we may experience decreased demand for our products if these or other competitors announce that they have begun to develop products that compete with our products. For example, in 2004, some of our competitors provided free or reduced-price samples of competing forms of microspheres for the treatment of medical procedures for which our Embosphere Microspheres are indicated. The availability of these free or reduced-price samples has had, and may continue to have, a material adverse effect on our product revenues, primarily due to a loss of market share for the sale of our products. Currently, the primary products with which our microspheres compete for some of our applications are spherical PVA sold by Boston Scientific, Terumo and Biocompatibles, and gel foam sold by Pfizer and non-spherical PVA sold by Angiodynamics, Boston Scientific and Cook. In addition, our competitors may develop technologies that render our products obsolete or otherwise noncompetitive.

We may not be able to improve our products or develop new products or technologies quickly enough to maintain a competitive position in our market and continue to commercially develop our business. Moreover, we may not be able to compete effectively, and competitive pressures may result in less demand for our products and impair our ability to become profitable.

In the treatment of symptomatic uterine fibroids, we also compete with obstetrics and gynecology physicians who elect to offer and provide other forms of treatment to their patients with uterine fibroids that do not require referral to another specialist.

If we fail to maintain, or in some instances obtain, an adequate level of reimbursement for our products by third-party payers, there may be no commercially viable markets for our products.

The availability and levels of reimbursement by governmental and other third-party payers affects the market for any medical device. We may not be able to sell our products profitably if reimbursement is unavailable or limited in scope or amount. Some insurance companies do not fully reimburse for

embolization procedures. These third-party payers may attempt to contain or reduce the costs of healthcare by lowering the rate at which providers are reimbursed for embolization procedures or challenging the prices that companies such as ours charge for medical products. For example, on November 1, 2006, the Centers for Medicare and Medicaid Services, or CMS, issued a preliminary rule, which became final on January 1, 2007, providing for a single all-inclusive reimbursement code for UFE. This new code is inclusive of all services occurring on the day of the procedure. This new physician reimbursement rate is lower than the rate generally historically received by physicians. In some foreign countries, particularly the countries of the European Union where our microsphere products are currently marketed and sold, the pricing of medical devices is subject to governmental control, and the prices charged for our products have in some instances been reduced as a result of these controls.

Initiatives to limit the growth of healthcare costs, including price regulation, are underway in the United States and other major healthcare markets. For example, these proposals include prescription drug benefit legislation recently enacted in the United States, and healthcare reform initiatives proposed in certain state and local jurisdictions and other countries. While these initiatives have in many cases related to pharmaceutical pricing, implementation of more sweeping healthcare reforms in significant markets may limit the price of, or the level at which reimbursement is provided for, our products and may influence a physician's selection of products used to treat patients.

If we do not recruit and retain senior management and other key employees we may not be able to successfully implement our business strategy.

Our success is substantially dependent on our ability to recruit and retain members of our senior management and other key employees. All of the agreements with our officers provide that their employment may be terminated either by the employee or by us at any time and without notice. Although we do not have any reason to believe that we may lose the services of any of these persons in the foreseeable future, the loss of the services of any of these persons might impede the achievement of our research, development, and commercialization objectives. We do not carry key man life insurance on any of our executive officers or other personnel.

If we make any acquisitions, we will incur a variety of costs and may never successfully integrate the acquired business into ours.

We may attempt to acquire businesses, technologies, services or products that we believe are a strategic complement to our business model. We may encounter operating difficulties and expenditures relating to integrating an acquired business, technology, service or product. These acquisitions may also absorb significant management attention that would otherwise be available for ongoing development of our business. Moreover, we may never realize the anticipated benefits of any acquisition. We may also make dilutive issuances of equity securities, incur debt or experience a decrease in the cash available for our operations, or incur contingent liabilities in connection with any future acquisitions.

Because key stockholders beneficially own a significant amount of our common stock, they may be able to exert control over us.

As of March 1, 2007, we believe that Sepracor Inc., or Sepracor, and funds affiliated with Cerberus Capital Management, L.P., or Cerberus, beneficially owned approximately 22% and 14% of our outstanding common stock, respectively, including shares of common stock issuable upon the exercise of warrants and series A preferred stock held by these stockholders. Moreover, two of our directors are executive officers of Sepracor, and we have granted board observation rights to Cerberus. Accordingly, Sepracor and Cerberus may have significant influence over corporate actions requiring stockholder approval, such as the election of directors, amendment of our charter documents and the approval of merger or significant asset sale transactions. In addition, the shares of our series A preferred stock held by

Sepracor and Cerberus entitled them to certain voting rights in accordance with the terms and conditions of the series A preferred stock. Specifically, we will need the consent of holders of at least 50% of the series A preferred stock initially purchased by Sepracor and Cerberus to undertake certain key corporate actions, including the following:

- amending our charter or bylaws in a manner that adversely affects the holders of series A preferred stock;
- authorizing or issuing any equity security that is senior to or pari passu with the series A preferred stock; and
- declaring or paying any dividends on, or redeeming or repurchasing any shares of, our capital stock, subject to customary exceptions.

The ownership concentration of Sepracor and Cerberus could cause the market price of our common stock to decline. In addition, conflicts of interest between these key stockholders and us may arise, including with respect to competitive business activities and control of our management and our affairs.

The holders of shares of our series A preferred stock have rights that could adversely affect an investment in our common stock.

The holders of our series A preferred stock have the right to an adjustment in the conversion rate of the series A preferred stock if we issue securities at a price below the purchase price paid by these holders. These provisions could substantially dilute stockholders' interest in BioSphere in the event of future financing transactions. The holders of series A preferred stock also have the right to receive a 6% dividend per annum which, at our election, may be paid in cash or additional shares of series A preferred stock. To date all such dividend payments have been made in additional shares of series A preferred stock. If such dividends continue to be paid in stock, this dividend could also further dilute stockholders' ownership interest. In addition, the holders of our series A preferred stock have the right to participate in future capital raising transactions by BioSphere. The existence of this right may reduce our ability to establish terms with respect to, or enter into, any financing with parties other than the investors.

In the event that we enter into an acquisition or business combination in which we sell all or substantially all of our assets or if there occurs a change of control of a majority of our common stock outstanding prior to such transaction, the holders of our series A preferred stock will have the right to receive, before any distributions or payments to the holders of our common stock, an amount in cash equal to their initial purchase price, $8,000,000, plus an amount equal to any accrued but unpaid dividends, and will then participate with the holders of the common stock on a pro rata basis with respect to the distribution of any remaining assets. The existence of this right may make it difficult for us to raise capital in financing transactions with third parties and will also result in holders of our common stock receiving less distributions or payments upon a change of control or asset sale than they would be entitled to receive if no preferential payments were required to be made to holders of our series A preferred stock.

Risks Relating to Regulatory Matters

If we do not obtain and maintain the regulatory approvals or clearances required to market and sell our products, then our business may be unsuccessful and the market price of our stock may decline.

We are subject to regulation by government agencies in the United States and abroad with respect to the design, manufacture, packaging, labeling, advertising, promotion, distribution and sale of our products. For example, our products are subject to approval or clearance by the FDA prior to commercial marketing in the United States. Similar regulations exist in most major foreign markets, including the European Union, Latin America and Asia. The process of obtaining necessary regulatory approvals and clearances will be time-consuming and expensive for us. If we do not receive required regulatory approval or clearance to market our products, or if any approvals or clearances we have received are revoked or terminated, we may not be able to commercialize our products and become profitable, and the value of our common stock may decline.

We are also subject to numerous U.S. and foreign regulatory requirements governing the conduct of clinical trials, marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process includes all of the risks associated with FDA approval described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Approval by the FDA does not assure approval by regulatory authorities of some countries outside the United States. Many foreign regulatory authorities, including those in major markets such as Japan and China, have different approval procedures than those required by the FDA and may impose additional testing requirements for our medical device candidates.

If the FDA or other regulatory agencies place restrictions on, or impose additional approval requirements with respect to, products we are then marketing, we may incur substantial additional costs and experience delays or difficulties in continuing to market and sell these products.

Even if the FDA grants us clearance with respect to marketing any product, such products will be subject to ongoing regulatory review and restrictions, including the review of clinical results which are reported after such products are made commercially available, and restrictions on the indications for which we can market the product. The FDA can propose to withdraw approval if new clinical data or experience shows that a product is not safe for use under the approved conditions of use. The marketing claims we are permitted to make in labeling or advertising regarding our microspheres are limited to those consistent with any FDA clearance or approval. For example, because our EmboGold Microspheres are not cleared for specific use in UFE, we may not promote them for this specific use. Although our QuadraSphere Microspheres are technically identical in all respects to our HepaSphere Microspheres, which are currently marketed in the European Union for use in the embolization of hepato-cellular carcinoma and hepatic metastasis, our QuadraSphere Microspheres are not specifically indicated for use in hepato-cellular carcinoma and hepatic metastasis. FDA regulations require that we conduct formal clinical trials prior to seeking to claim the use of the QuadraSphere Microspheres for the treatment of a specific disease or condition, such as hepato-cellular cancer or hepatic metastasis, while European Union regulations do not mandatorily require it for this class of medical devices. Accordingly, in order for us to seek FDA clearance to promote the use of QuadraSphere Microspheres for the embolization of hepato-cellular carcinoma and hepatic metastasis, we will be required to undertake clinical trials in the United States.

For our 510(k) cleared products, the FDA requires us to submit to the FDA copies of our advertisements and labeling. If the FDA believes these materials, or statements made by our sales representatives or other company officials, promote our products for unapproved indications, the FDA could allege that our promotional activities misbrand our products. Specifically, the FDA could issue an untitled letter or warning letter, which requests, among other things, that we cease such promotional activities, including disseminating the advertisements and promotional labeling, and that we issue

corrective advertisements and labeling, including sending letters to healthcare providers. The FDA also could take enforcement action including seizure of allegedly misbranded product, injunction or criminal prosecution against us and our officers or employees. If we repeatedly or deliberately fail to submit such advertisements and labeling to the agency, the FDA could withdraw our approvals. The FDA also monitors manufacturers' support of continuing medical education, or CME, programs where the programs involve the manufacturers' or a competitor's products to ensure that manufacturers do not influence the CME content as a means of promoting their products for off-label uses.

We may in the future make modifications to our microspheres or their labeling which we determine do not necessitate the filing of a new 510(k) notification. However, if the FDA does not agree with our determination, it will require us to make additional 510(k) filings for the modification, and we may be prohibited from marketing the modified product or the new claims until we obtain FDA clearance. Similarly, if we obtain premarket approval, we may not be able to make product or labeling changes until we get further FDA approval.

If we fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions which could affect our ability to develop, market and sell our products and product candidates successfully and could harm our reputation and lead to decreased acceptances of our products by the market.

Even if we obtain the necessary FDA clearances or approvals, if we or our suppliers fail to comply with ongoing regulatory requirements our products could be subject to corrections, removals or recalls from the market or other enforcement action.

We are subject to the Medical Device Reporting, or MDR, regulations that require us to report to the FDA if our products may have caused or contributed to patient death or serious injury, or if our device malfunctions and a recurrence of the malfunction would likely result in a death or serious injury. We must also file reports of device corrections and removals and adhere to the FDA's rules on labeling and promotion. Our failure to comply with these or other applicable regulatory requirements could result in enforcement action by the FDA, which may include any of the following:

- untitled letters, warning letters, fines, product seizures, injunctions and civil penalties;
- administrative detention, which is the detention by the FDA of medical devices believed to be adulterated or misbranded;
- customer notification, or FDA orders for repair, replacement or refund;
- voluntary or mandatory recall of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusal to review premarket notification or premarket approval submissions;
- rescission of a substantial equivalence order or suspension or withdrawal of a premarket approval; and
- criminal prosecution.

If we are subject to an enforcement action, our ability to develop, market and sell our products successfully would be adversely affected, our reputation could be harmed and we may experience decreased market acceptance of our products.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and regulations and, if we are unable to fully comply with such laws, could face substantial penalties.

Our operations may be directly or indirectly affected by various broad state and federal healthcare fraud and abuse laws, including the federal Anti-Kickback Statute, which prohibit any person from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce or reward either the referral of an individual, or the furnishing or arranging for an item or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. If our past or present operations are found to be in violation of these laws, we and our officers may be subject to civil or criminal penalties, including large monetary penalties, damages, fines, imprisonment and exclusion from Medicare and Medicaid program participation. If enforcement action were to occur, our business and financial condition would be harmed.

Risks Relating to Our Intellectual Property

If we are unable to obtain patent protection for our products, their competitive value could decline.

We may not obtain meaningful protection for our technology and products with the patents and patent applications that we own or license relating to our microsphere technology or other ancillary products. In particular, the patent rights we possess or are pursuing generally cover our technologies to varying degrees, and these rights may not prevent others from designing products similar to or otherwise competitive with our Embosphere Microspheres and other products we commercialize. To the extent that our competitors are able to design products competitive with ours, we may experience less market penetration with our products and, consequently, we may have decreased revenues.

We do not know whether competitors have similar U.S. patent applications on file, since U.S. patent applications filed before November 28, 2000, or for which no foreign patents will be sought are secret until issued, and applications filed after November 28, 2000, are published approximately 18 months after their earliest priority date. Consequently, the United States Patent and Trademark Office could initiate interference proceedings involving our owned or licensed U.S. patent applications or issued patents. Further, there is a substantial backlog of patent applications at the United States Patent and Trademark Office, and the approval or rejection of patent applications may take several years.

We require our employees, consultants and advisors to execute confidentiality agreements. However, we cannot guarantee that these agreements will provide us with adequate protection against improper use or disclosure of confidential information. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants or advisors have prior employment or consulting relationships. Further, others may independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets. Our failure to protect our proprietary information and techniques may inhibit or limit our ability to exclude certain competitors from the market.

If we become involved in expensive patent litigation or other proceedings to enforce or defend our patent rights, we could incur substantial costs and expenses or substantial liability for damages or be required to stop our product development and commercialization efforts.

On January 13, 2005, we were notified of a Notice of Oppositions filed by Biocompatibles UK Limited on December 23, 2004, challenging the patentability of the claims in our granted European Patent 1128816, which relates to certain PVA microspheres, their use in embolization and methods of manufacture related to such PVA microspheres. We will continue defending our European PVA patent in this proceeding. While we are not able to predict the outcome of this patent opposition proceeding, it will not impact our ability to sell our Embosphere Microsphere, HepaSphere Microsphere or QuadraSphere Microsphere products, which are not comprised of PVA.

With the exception of the European Opposition proceeding just described, we are not currently involved in any other litigation or actions with third parties to enforce or defend our patent rights. However, in order to protect or enforce our patent rights, we may have to initiate legal proceedings against third parties, such as infringement suits or interference proceedings. By initiating legal proceedings to enforce our intellectual property rights, we may also provoke these third parties to assert claims against us and, as a result, our patents could be narrowed, invalidated or rendered unenforceable by a court. Furthermore, we may be sued for infringing on the intellectual property rights of others. We may find it necessary, if threatened, to initiate a lawsuit seeking a declaration from a court regarding the proprietary rights of others. Intellectual property litigation is costly and, even if we prevail, could divert management attention and resources away from our business.

The patent position of companies like ours generally is highly uncertain, involves complex legal and factual questions, and has recently been the subject of much litigation. We may not prevail in any patent-related proceeding. If we do not prevail in any litigation, we could be required to pay damages, stop the infringing activity, or obtain a license. Any required license might not be available to us on acceptable terms, or at all. In addition, some licenses may be nonexclusive, and therefore our competitors may have access to the same technology licensed to us. If we fail to obtain a required license or are unable to design around a patent, we may be prevented from selling some of our products, which could decrease our revenues.

If any of our licenses to use third-party technologies in our products are terminated, we may be unable to develop, market or sell our products.

We are dependent on various license agreements relating to each of our current and proposed products that give us rights under intellectual property rights of third parties. In particular, we have an agreement with L'Assistance Publique-Hopitaux De Paris, pursuant to which L'Assistance Publique-Hopitaux De Paris has granted us exclusive rights to use two jointly owned patents relating to Embosphere Microspheres. We also have an agreement with Dr. Shinichi Hori pursuant to which we have an exclusive royalty-bearing license to Japanese patent rights for our HepaSphere Microsphere product. We also have an agreement with Archimmed SARL pursuant to which we have an exclusive royalty-bearing license to patent rights for our MR Microsphere product, which is in development. Each of these agreements can be terminated on short notice by the licensor if we default on our obligations under the license and fail to cure such default after notice is provided. These licenses impose commercialization, sublicensing, royalty, insurance and other obligations on us. Our failure, or any third party's failure, to comply with the terms of any of these licenses could result in our losing our rights to the license, which could result in our being unable to develop, manufacture or sell products which contain the licensed technology.

Risks Relating to the Production and Supply of Our Products

If we experience manufacturing delays or interruptions in production, then we may experience customer dissatisfaction and our reputation could suffer.

If we fail to produce enough products at our own manufacturing facility or at a third-party manufacturing facility, we may be unable to deliver products to our customers on a timely basis, which could lead to customer dissatisfaction and could harm our reputation and ability to compete. We currently produce and package all of our microsphere products in one manufacturing facility in France. In the United States, we have engaged Brivant Medical Engineering and Radius Medical Technologies, Inc. to supply our guidewire products and Concert Medical to supply and package our catheter products. Either we or any third-party manufacturer would likely experience significant delays or cessation in producing our products if a labor strike, natural disaster, local or regional conflict or other supply disruption were to occur. If we are unable to manufacture and package our products at our facility in France, we may be required to enter into arrangements with one or more alternative contract manufacturing companies.

Even if we are able to identify alternative facilities to manufacture our products, if necessary, we may experience disruption in the supply of our products until such facilities are available. Although we believe we possess adequate insurance for damage to our property and the disruption of our business from casualties, such insurance may not be sufficient to cover all of our potential losses and may not be available to us on acceptable terms or at all. Our failure to deliver products on a timely basis could lead to customer dissatisfaction and damage our reputation. In addition, if we are required to depend on third-party manufacturers, our profit margins may be lower, which will make it more difficult for us to achieve profitability.

Medical device manufacturers must adhere to the Quality System Regulation, or QSR, 21 Code of Federal Regulation Part 820, which is enforced by the FDA through its inspection program. The manufacturers may not be able to comply or maintain compliance. If any third-party manufacturers we engage fail to comply, their noncompliance could significantly delay our receipt of new product premarket approvals or result in FDA enforcement action, including an embargo on imported devices. For a premarket approval device, if we change our manufacturing facility or switch to a third-party manufacturer, we will be required to submit a premarket approval application supplement before the change is implemented.

Because we rely on a limited number of suppliers, we may experience difficulty in meeting our customers' demands for our products in a timely manner or within budget.

We currently purchase key components and services with respect to our microspheres, catheters and guidewires from approximately ten third-party vendors, including Radius Medical, from whom we purchase guidewires for our Segway Guidewire product, Concert Medical, from whom we purchase catheters for our EmboCath Infusion Catheters and EmboCath Plus Infusion Microcatheter products, and Brivant Medical Engineering, from whom we purchase guidewires for our Sequitor Steerable Guidewire product. We generally do not have long-term agreements with any of our suppliers. Our reliance on our suppliers exposes us to risks, including:

- the possibility that one or more of our suppliers could terminate their services at any time without penalty;
- the potential inability of our suppliers to obtain required components;
- the potential delays and expenses of seeking alternative sources of supply;
- reduced control over pricing, quality and timely delivery due to difficulties in switching to alternative suppliers; and
- the possibility that one or more of our suppliers could fail to be compliant with Quality System Regulations, 21 CFR Part 820.

Consequently, in the event that our suppliers delay or interrupt the supply of components for any reason, our ability to produce and supply our products could be impaired, which could lead to customer dissatisfaction and be harmful to our reputation.

Risks Relating to Our Foreign Operations

If we are unable to meet the operational, legal and financial challenges that we encounter in our international operations, we may not be able to grow our business.

Our worldwide manufacturing and European sales operations are currently conducted primarily through our French subsidiary. Furthermore, we currently derive a portion of our revenues from the sale of our microspheres and other products in the European Union. For the years ended December 31, 2006 and 2005, approximately 24% and 27%, respectively, of our revenues were derived from sales of our

microspheres and other products in the European Union. We are increasingly subject to a number of challenges that specifically relate to our international business activities. Our international operations may not be successful if we are unable to meet and overcome these challenges, which would limit the growth of our business. These challenges include:

- failure of local laws to provide the same degree of protection against infringement of our intellectual property;
- protectionist laws and business practices that favor local competitors, which could slow our growth in international markets;
- the requirement that we obtain regulatory approval or clearance in each country in which we choose to offer and sell our products;
- in some jurisdictions, strict government regulated price controls;
- complex reimbursement procedures;
- potentially longer sales cycles to sell products, which could slow our revenue growth from international sales; and
- potentially longer accounts receivable payment cycles and difficulties in collecting accounts receivable.

Because we translate foreign currency from international sales into U.S. dollars and are required to make foreign currency payments, we may incur losses due to fluctuations in foreign currency exchange rates.

A significant portion of our business is conducted in the European Union Euro. We recognize foreign currency gains or losses arising from our operations in the period incurred. As a result, currency fluctuations between the U.S. dollar and the currencies in which we do business will cause foreign currency translation gains and losses, which may cause fluctuations in our future operating results. We do not currently engage in foreign exchange hedging transactions to manage our foreign currency exposure.

Risk Relating to Our Stock Price

Because the market price of our stock is highly volatile, investments in our stock could rapidly lose their value and we may incur significant costs from class action litigation.

The market price of our stock is highly volatile. From January 1, 2005 through March 1, 2007, the price of our common stock has ranged from a low of $3.50 to a high of $9.43. As a result of this volatility, investments in our stock could rapidly lose their value. In addition, the stock market often experiences extreme price and volume fluctuations, which affect the market price of many medical device companies and which are often unrelated to the operating performance of these companies.

When the market price of a stock has been as volatile as our stock price has been, holders of that stock may institute securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, we could incur substantial costs in defending the lawsuit. The lawsuit could also divert the time and attention of our management.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

We currently lease office and manufacturing facilities in Rockland, Massachusetts, and Roissy, France. Our Rockland, Massachusetts office includes approximately 13,000 square feet of corporate offices and laboratory space pursuant to a lease expiring on February 28, 2009 at a cost of $19,500 per month. Our Roissy, France facility, where we produce our Embosphere Microspheres, HepaSphere Microspheres and QuadraSphere Microspheres as well as some ancillary disposable devices, includes approximately 18,000 square feet of office, laboratory and manufacturing space and is leased through May 2010 at a cost of $25,000 per month.

We believe that the leased facilities in Rockland, Massachusetts and in Roissy, France are suitable to meet our current requirements and that suitable additional or substitute space will be available to us on commercially reasonable terms, if needed in the future.

Item 3. LEGAL PROCEEDINGS

On August 17, 2005, a lawsuit commenced in the Circuit Court, Twenty-Second Judicial Circuit, St. Louis, Missouri captioned *Brett Pingel by next friend Dawn LaRose vs. BioSphere Medical, Inc., Bruce Kirke Bieneman, M.D., St. Louis University Hospital, John Stith, M.D and St. Louis University.* The lawsuit alleges, among other things, that a patient suffered permanent bilateral blindness as a result of the use of our Embosphere Microspheres or the negligence of the health care providers or both factors combined. All defendants have denied the allegations against them. Plaintiffs seek compensatory and punitive damages. We carry product liability insurance and this case is currently being defended by our insurer under reservation of rights with respect to the claim of punitive damages, for which an exclusion from coverage exists. We have filed an answer to this lawsuit in which we have denied the claims being made. We intend to defend against the claims vigorously. However, we cannot give any assurance that we will prevail, and we are currently unable to predict the impact, financial or otherwise, of this product liability litigation.

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

No matters were submitted to a vote of security holders of the Company, through solicitations of proxies or otherwise, during the quarter ended December 31, 2006.

EXECUTIVE OFFICERS

As of March 1, 2007, our executive officers, their respective ages and their positions are as follows:

Name	Age	Position
Richard J. Faleschini...	60	President and Chief Executive Officer
Gary M. Saxton	46	Executive Vice President and Chief Operating Officer
Martin J. Joyce.....	53	Executive Vice President and Chief Financial Officer
Peter C. Sutcliffe	57	Vice President, Manufacturing

Richard J. Faleschini has served as our President, and Chief Executive Officer since November 2004 and as a director of BioSphere Medical since March 2005. From 2003 to 2004, Mr. Faleschini served as Vice President and General Manager of the gynecology division at American Medical Systems Holdings, Inc., a supplier of medical devices to physicians specializing in the treatment of urological and gynecological disorders. From 1999 to 2003, Mr. Faleschini was Vice President of Marketing and Sales for American Medical Systems Holdings, Inc. From 1995 to 1999, he held executive marketing and general management positions at Medtronic Inc., a medical technology company, with responsibilities in several sectors of their cardiac rhythm management, cardiac surgery, and interventional vascular businesses. His previous experience also includes executive marketing and sales management responsibilities at Cordis

Corporation, Biomagnetic Technologies, and ATL/ADR Ultrasound. Mr. Faleschini received his B.S. in biology and M.S. in physiology from Michigan Technological University.

Gary M. Saxton has served as our Executive Vice President and Chief Operating Officer since January 16, 2006. He served as our Senior Vice President and General Manager from March 2005 until January 2006, and served as our Vice President of Marketing and Sales from November 2004 to March 2005. From 2001 to 2004, Mr. Saxton was a strategy consultant in the medical device industry. From 1999 to 2001, he was the Vice President of Sales and Marketing at Symphonix Devices, Inc. and the Vice President of Marketing at CardioGenesis Corporation, both publicly traded medical device companies. Mr. Saxton also previously held several marketing and strategy positions within Medtronic, Inc., both in the United States and Japan, including Director, Strategic Plan and Market Development Manager. He began his private sector career with IBM Corporation in a variety of sales, marketing and finance roles. Before IBM, he served as a Captain in the U.S. Army. Mr. Saxton holds a B.S. degree from the United States Military Academy, West Point, New York, and an M.B.A. from Harvard University, Cambridge, Massachusetts.

Martin J. Joyce has served as our Executive Vice President and Chief Financial Officer since January 16, 2006. He served as our Chief Financial Officer and Vice President from September 2004 to January 2006. From 2000 to 2004, Mr. Joyce served as Managing Partner of Stratex Group LLC, a provider of biopharmaceutical executive services to early-stage companies and venture investors. From 1996 to 2000, Mr. Joyce was North American Chief Financial Officer for Serono Inc. a biotechnology company. Prior to serving as North American Chief Financial Officer, Mr. Joyce held a variety of senior level positions within Serono, in finance, sales, marketing and manufacturing. Mr. Joyce was previously employed at Millipore Corporation and Bose Corporation focusing on strategic planning, product rationalization and return on investment analysis. Mr. Joyce received a B.S. in finance from Northeastern University and an M.B.A. from Suffolk University, Boston, Massachusetts.

Peter C. Sutcliffe has served as our Vice President, Manufacturing since October 2002. From 2001 to 2002, Mr. Sutcliffe served as the Vice President for North American Manufacturing for Whatman, Plc., a life science filtration company. From 1996 to 2001, he was the Chief Operating Officer for HemaSure Inc., a manufacturer and supplier of blood filters. From 1982 to 1996, Mr. Sutcliffe held the position of Vice President of Manufacturing for Corning Costar Company, a life science products company. Prior to Costar, he held manufacturing management positions with Millipore Corporation, a high technology bioscience company. Mr. Sutcliffe holds a B.S. in biology from the University of Richmond in Virginia and an M.B.A. from Sul Ross State University of Texas, Fort Bliss, Texas.

PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock trades on the NASDAQ Global Market under the symbol "BSMD". On March 1, 2007, the last reported sale price of our common stock on the NASDAQ Global Market was $6.80 and there were approximately 110 stockholders of record. This number does not include stockholders for whom shares are held in "nominee" or "street" name.

The following table shows the range of high and low sales prices per share of our common stock for the last two fiscal years as reported on the NASDAQ Global Market since July 1, 2006 and prior to that, the NASDAQ National Market.

	2006	
	High	Low
First Quarter	$9.43	$6.79
Second Quarter	$8.20	$5.56
Third Quarter	$7.20	$4.84
Fourth Quarter	$7.66	$5.89

	2005	
	High	Low
First Quarter	$4.25	$3.50
Second Quarter	$5.00	$3.50
Third Quarter	$6.20	$4.27
Fourth Quarter	$8.60	$4.57

We have not paid any cash dividends on our common stock since our inception and do not intend to pay any cash dividends in the foreseeable future.

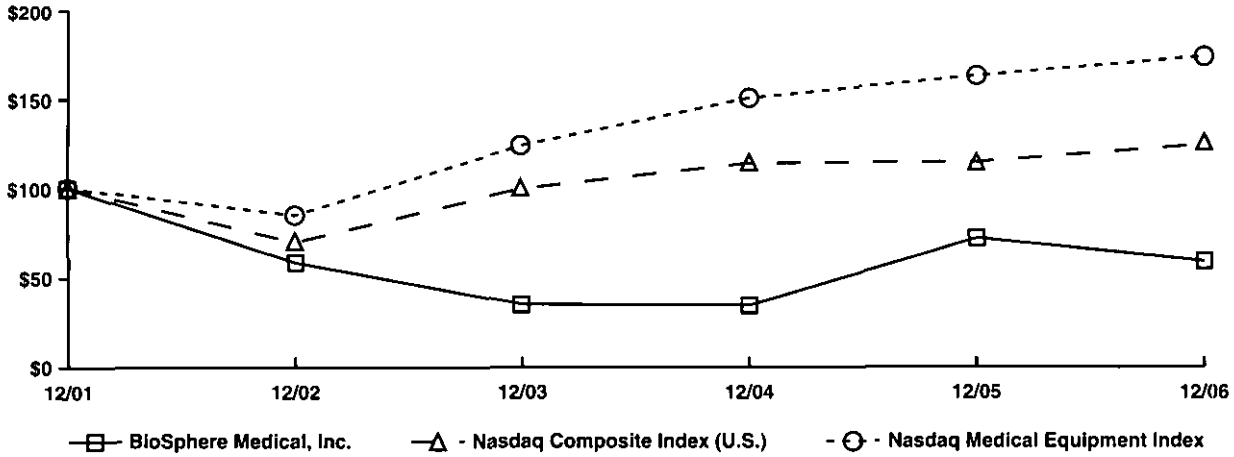
Comparative Stock Performance

The following graph compares the cumulative total stockholder return on our common stock for the last five fiscal years with the cumulative total return on (i) the Total Return Index for the Nasdaq Stock Market (US Companies) (the "Nasdaq Market Index (U.S.)") and (ii) the Nasdaq Medical Equipment Index (the "Nasdaq Medical Composite Index"). This graph assumes the investment of $100 on December 31, 2001 in our common stock and each of the indices listed above, and assumes dividends are reinvested. We have not paid any dividends on our common stock and no dividends are included in the representation of our performance. The stock price performance shown in the below graph is not necessarily indicative of future price performance. Measurement points are the last trading day of the fiscal years ended December 31, 2002, 2003, 2004, 2005 and 2006.

The graph and table below are not "soliciting material," are not deemed filed with the SEC and are not to be incorporated by reference in any filing of ours under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
AMONG BIOSPHERE MEDICAL, INC., THE NASDAQ COMPOSITE INDEX (U.S.)
AND THE NASDAQ MEDICAL EQUIPMENT INDEX

	12/02	12/03	12/04	12/05	12/06
BioSphere Medical, Inc.	58.47	35.05	34.52	71.87	59.27
Nasdaq Composite Index (U.S.)	69.66	99.71	113.79	114.47	124.20
Nasdaq Medical Equipment Index	84.83	123.84	150.14	162.67	173.54



* $100 invested on December 31, 2001 in our common stock or in either the Nasdaq Composite Index (U.S.) or Nasdaq Medical Equipment Index, including reinvestment of dividends.

Item 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes to those statements and other financial information included elsewhere in this annual report on Form 10-K. Historical results are not necessarily indicative of future results.

Year Ended December 31, (in thousands, except per share amounts)	2006	2005	2004	2003	2002
Statement of Operations Data:					
Revenues:					
Product sales	$22,787	$18,484	$14,058	$12,803	$12,152
License revenues	104	—	100	—	—
Total revenues	22,891	18,484	14,158	12,803	12,152
Costs and expenses:					
Costs of product sales	6,958	6,303	6,646	5,558	3,261
Research and development	2,290	2,359	2,113	2,344	3,714
Sales	7,583	5,807	5,271	5,881	4,985
Marketing	3,666	2,458	2,279	3,681	3,074
General, administrative and patent	5,561	4,219	4,154	3,359	4,263
Litigation costs	—	—	874	—	—
Total costs and expenses	26,058	21,146	21,337	20,823	19,297
Loss from operations	(3,167)	(2,662)	(7,179)	(8,020)	(7,145)
Other income (expense):					
Interest income	938	225	92	135	398
Interest expense	(15)	(15)	(16)	(27)	(29)
Other	(80)	(442)	379	583	214
Loss before income taxes	(2,324)	(2,894)	(6,724)	(7,329)	(6,562)
Income tax benefit (provision)	—	93	(117)	(23)	181
Net loss	(2,324)	(2,801)	(6,841)	(7,352)	(6,381)
Preferred stock dividends	(525)	(495)	(68)	—	—
Net loss applicable to common stockholders	$ (2,849)	$ (3,296)	$ (6,909)	$ (7,352)	$ (6,381)
Basic and diluted net loss per share applicable to common stockholders	$ (0.17)	$ (0.22)	$ (0.49)	$ (0.55)	$ (0.49)
Basic and diluted weighted average number of common shares outstanding	17,027	14,653	14,152	13,462	12,988

As of December 31, (in thousands)	2006	2005	2004	2003	2002
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$22,119	$ 8,774	$10,222	$ 7,575	$14,738
Working capital	24,719	10,832	12,391	10,704	17,008
Total assets	32,079	17,495	19,391	17,002	23,928
Long-term debt and deferred licensing revenue	190	101	192	171	270
Stockholders' equity	26,965	13,088	14,835	13,525	20,259

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

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes included elsewhere in this report. Some of the information contained in this discussion and analysis and set forth elsewhere in this report, including information with respect to our plans and strategy for our business includes forward-looking statements that involve risks and uncertainties. You should review the section titled "Risk Factors" for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We develop, manufacture and market products for medical procedures using embolotherapy techniques. Embolotherapy is the therapeutic introduction of various biocompatible substances into a patient's circulatory system to occlude a blood vessel, either to arrest or prevent hemorrhaging or to devitalize the structure or organ by occluding its blood supply. Our core technologies consist of patented bioengineered polymers, which are chemical compounds that we create through the application to medical science of engineering principles and manufacturing methods. These core technologies are used to produce miniature spherical particles, or microspheres, with unique properties for a variety of applications. In a typical embolotherapy procedure using our products, an interventional radiologist injects our microspheres through a catheter into the blood vessels that feed these target areas. By selectively blocking the target tissue's blood supply, the deprived tissue will either become destroyed or devitalized, designed to result in therapeutic benefit.

We currently market and sell four microsphere products: our Embosphere® Microspheres, which are marketed for uterine fibroids, hypervascularized tumors and other arteriovenous malformations in the United States, the European Union and several other foreign markets; our EmboGold® Microspheres, which are marketed for hypervascularized tumors and other arteriovenous malformations in the United States, the European Union and several other foreign markets; our QuadraSphere™ Microspheres, which are marketed for the treatment of hypervascularized tumors and other arteriovenous malformations in the United States; and HepaSphere™ Microspheres, which are marketed in the European Union for primary and metastatic liver cancer and are also sold in limited quantities in Japan to Dr. Shinichi Hori for clinical evaluation and use in treating liver cancer pursuant to Japanese private import regulations. Our QuadraSphere Microspheres are identical in all respects to our HepaSphere Microspheres. For the fiscal years ended December 31, 2006, and December 31, 2005, we generated revenues primarily from product sales of our Embosphere Microspheres in North America and the European Union. We also generated revenues from product sales in other geographic territories, including the Middle East, Africa, South America and Asia. Product revenues also include the sale of accessory embolotherapy devices such as our EmboCath® Infusion Catheter, EmboCath® Plus Infusion Microcatheter, Segway® Guidewire and our Sequitor™ Guidewire, as well as our barium delivery kits and other ancillary medical devices sold exclusively in Europe. We currently derive a majority of our revenues in the United States and the European Union from the sale of Embosphere Microspheres for use in the treatment of symptomatic uterine fibroids, which are noncancerous (benign) tumors growing within or on the wall of the uterus, using a procedure called uterine fibroid embolization, or UFE.

Our principal focus is on growing our embolotherapy business worldwide through increases in UFE and hypervascularized tumor embolization procedures. Our marketing strategy is to promote the UFE procedure for patients suffering with uterine fibroids through our ask4UFE.com® awareness and education program and also to specifically promote our Embosphere Microspheres as the product of choice for the UFE procedure. Our success will depend upon the continued acceptance by the medical

community, patients and third-party payers of the UFE procedure, our Embosphere Microsphere product and our other products, as safe, medically therapeutic and cost effective.

We have experienced operating losses in each fiscal period since our inception. As of December 31, 2006, we had approximately $22.12 million in cash, cash equivalents and marketable securities, and an accumulated deficit of approximately $81.65 million. Most of our expenditures to date have been for sales and marketing activities, general and administrative expenses and research and development activities. We expect to continue to incur operating losses in 2007 as we seek to execute on our business plan, including continuing to establish sales and marketing capabilities and conducting research and development activities.

On February 22, 2006, we sold 2,075,000 shares of our common stock at a price of $7.00 to several investors in a private placement. We received net proceeds of approximately $13.50 million.

In March 2006, we instituted a voluntary recall of our HepaSphere Microspheres in Europe and Japan to correct a packaging defect that we identified while conducting aging studies routinely performed on all of our product packaging. HepaSphere Microspheres, which are used in the treatment of primary and metastatic liver cancer, are contained in a prefilled vial that was in turn initially packaged inside a paper pouch. We determined that a defect in the paper pouch could compromise the sterility of the outside of the vial. If the sterility of the outside of the vial was not maintained, there was the risk that a physician's hands could become contaminated when handling the vial. We are not aware of any adverse events resulting from the defects in the paper packaging. We recognized an inventory charge of approximately $30,000 related to the recall of HepaSphere Microspheres during 2006. Sales of HepaSphere Microspheres outside of the United States resumed in the paper pouch packaging with a shortened shelf life during the second quarter, and we launched the new plastic packaging configuration for HepaSphere Microspheres in the third quarter of 2006.

Research and Development

The following table identifies each of the programs for which we have incurred research and development expenses in the years ended December 31, 2006, and 2005 and the current development phase of each.

Product / Product Candidate	Development Status
Embosphere® Microspheres	Marketed for uterine fibroids, hypervascularized tumors and other arteriovenous malformations in the United States, Canada, European Union, Argentina, Brazil, Columbia, Costa Rica, Ecuador, Panama, Peru, Uruguay, Hong Kong, Taiwan and Australia; clinical evaluation in China
EmboGold® Microspheres	Marketed for hypervascularized tumors and arteriovenous malformations in the United States, Canada, European Union, Argentina, Brazil, Columbia, Costa Rica, Ecuador, Panama, Peru, Uruguay, Hong Kong, Taiwan and Australia
HepaSphere™ Microspheres(1)	Marketed in the European Union for primary and metastatic liver cancer
QuadraSphere™ Microspheres(2)	Received market clearance from the FDA for embolization of hypervascularized tumors and peripheral arteriovenous malformations
EmboCath® Infusion Catheter	Marketed for infusion of various diagnostic, embolic and therapeutic agents and super-selective angiography within peripheral and coronary vasculature in the United States, Canada, European Union, Argentina, Brazil, Costa Rica, Ecuador, Panama and China
Segway® Guidewire	Marketed for placement of catheters within peripheral and coronary vasculature in the United States, Canada, European Union, Argentina, Brazil, Costa Rica, Ecuador, Panama and China
EmboCath® Plus Infusion Microcatheter	Received market clearance from the FDA, and Health Canada, and received a CE Mark in the European Union for infusion of various diagnostic, embolic and therapeutic agents and super-selective angiography within peripheral vasculature
Sequitor™ Steerable Guidewire	Marketed in the United States, Canada, and in the European Union for various diagnostic and interventional procedures within peripheral vasculature
MR Microspheres (magnetic resonance visible)	Preclinical research—animal studies
Resorbable Microspheres	Preclinical research—feasibility stage

(1) Pursuant to our CE Mark approval in the European Union, HepaSphere Microspheres are indicated for use in the embolization of blood vessels for therapeutic or preoperative purposes in the following procedures: embolization of hepato-cellular carcinoma and the embolization of hepatic metastasis. Hepato-cellular carcinoma refers to cancer which originates in the liver and hepatic metastasis refers to cancer which has spread to the liver from other sites in the body. We have exclusive worldwide rights to the HepaSphere Microsphere technology under a license from Dr. Shinichi Hori, subject only

to Dr. Hori's right to conduct clinical trials on our behalf in Japan, treat patients at Rinku Medical Center and Osaka Medical Center in Japan and engage in research at Osaka University.

(2) In November 2006, we received marketing clearance in the United States from the FDA for our QuadraSphere Microsphere product candidate for the treatment of hypervascularized tumors and peripheral arteriovenous malformations. Although our QuadraSphere Microspheres are identical in all technical respects to our HepaSphere Microspheres, our QuadraSphere Microspheres are not specifically indicated for use in hepato-cellular carcinoma and hepatic metastasis. FDA regulations require that we conduct formal clinical trials prior to seeking to claim the use of the QuadraSphere Microspheres for the treatment of a specific disease or condition, such as hepato-cellular cancer or hepatic metastasis, while European Union regulations do not mandatorily require it for this class of medical devices. Accordingly, in order for us to seek FDA clearance to promote the use of QuadraSphere Microspheres for the embolization of hepato-cellular carcinoma and hepatic metastasis in the United States, we will be required to undertake clinical trials.

Research and development expenses relate primarily to:

- research to identify and evaluate new and innovative embolotherapy products based on our platform microsphere technology, such as our MR Microspheres;
- preclinical testing and clinical trials of our HepaSphere Microsphere, Sequitor Steerable Guidewire, EmboCath Plus Infusion Microcatheter, and our QuadraSphere Microsphere products;
- development related to improving manufacturing processes; and
- product and production facilities validation processes under FDA Good Manufacturing Practices.

Our research and development functions typically work on a number of projects concurrently. In addition, except for clinical expenses, a substantial amount of fixed research and development costs such as salary and salary-related benefits, rent, equipment depreciation, utilities, insurance and maintenance are shared among various programs. Accordingly, we have not historically tracked specific costs for each of our research and development projects.

The successful development of our product candidates is highly uncertain. We cannot reasonably estimate or know the nature, timing and estimated costs of the efforts necessary to complete the development of, or the period in which material net cash inflows are expected to commence from, any of our product candidates due to the numerous risks and uncertainties associated with developing medical devices, including the uncertainty of:

- the scope, rate of progress and cost of clinical trials and other research and development activities undertaken by us;
- future clinical trial results;
- the cost, timing and success of regulatory approvals;
- the cost, timing and success of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our product candidates and any products that we may develop;
- the effect of competing technological and market developments; and
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

Any failure to complete the development of our product candidates in a timely manner, or at all, could have a material adverse effect on our operations, financial position and liquidity. A discussion of the risks and uncertainties associated with completing our projects on schedule, or at all, and some consequences of failing to do so, are set forth in "Risk Factors."

Critical Accounting Policies

The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, revenues and expenses, and related disclosure at the date of our financial statements. The significant accounting policies which we believe are most critical in gaining an understanding of our financial statements include policies and judgments relating to revenue recognition, stock-based compensation, accounts receivable and inventories. Actual results could differ materially from these estimates. Our significant accounting policies are summarized in Note 2 of the notes to our consolidated financial statements. The significant accounting policies which we believe are the most critical to gaining a full understanding of and evaluating our reported financial results include the following:

Revenue Recognition

We apply the revenue recognition guidelines summarized in Staff Accounting Bulletin, or SAB, No. 104, "Revenue Recognition." We recognize revenue when products are shipped and the customer or distributor, takes ownership and assumes risk of loss, collection of the relevant receivable is reasonably assured, persuasive evidence of an arrangement exists (a valid purchase order from an approved customer), the sales price is fixed or determinable, payment is not contingent on resale and we do not have any continuing obligations to ensure resale. Revenue from licensing agreements is recognized ratably over the expected service period. We establish reserves for potential sales returns and evaluate the adequacy of those reserves based upon realized experience and expectations. Any significant change in product satisfaction and any resulting credit returns could have a material adverse impact on our revenues and operating results for the period or periods in which such returns materialize.

Stock Based Compensation

We adopted the provisions of Statement of Financial Accounting Standards, No. 123R, "Share-Based Payment", or SFAS 123R, beginning January 1, 2006, using the modified prospective transition method. This statement requires us to measure the cost of employee services in exchange for an award of equity based on the grant-date fair value of the award and to recognize cost over the requisite service period. Under the modified prospective transition method, financial statements for periods prior to the date of adoption are not adjusted for the change in accounting. However, we recognize compensation expense for (a) all share-based payments granted after the effective date and (b) all awards granted to employees prior to the effective date that remain unvested on the effective date. We recognize compensation expense on fixed awards with pro rata vesting on a straight-line basis over the awards' vesting period.

Prior to January 1, 2006, we used the intrinsic value method to account for stock-based employee compensation under Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and therefore we did not recognize compensation expense in association with options granted at or above the market price of our common stock at the date of grant.

As a result of adopting the new standard, stock-based compensation charges during the fiscal year ended December 31, 2006 increased by approximately $1.28 million. Net loss applicable to common stockholders for the year ended December 31, 2006, increased by $0.07 per basic and diluted share.

However, the amount of stock compensation expense recognized in any future period cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. The adoption of SFAS 123R did not require any cumulative adjustments to our financial statements.

We estimate the fair value of each option grant on the date of grant using the Black-Scholes option-pricing model, which requires the consideration of several subjective assumptions, including the expected dividends on our common stock, the expected volatility of our common stock, the risk-free interest rate for the expected option term and the expected term of the option. Equity instrument valuation models, such as the Black-Scholes valuation model, are highly subjective. Any significant changes in any of our estimates and judgments, including those used to select the inputs for the Black-Scholes valuation model, could have a significant impact on the fair value of the equity instruments granted or sold and the associated compensation charge, if any, we record in our financial statements.

Accounts Receivable

We continuously monitor collections and payments from our customers and maintain a provision for estimated credit losses based upon our historical payment experience and any specific customer collection issues that we have identified. While such credit losses have historically been within our expectations and the provisions established, we cannot guarantee that we will continue to experience the same credit loss rates that we have in the past. Substantially all of our receivables are due from hospitals, distributors, health care clinics, and managed care systems located throughout the United States, Canada, Europe, Asia and South America. A significant portion of products sold, both foreign and domestic, is ultimately funded through government reimbursement programs. As a consequence, changes in these programs can have an adverse impact on our operating results and cash flows.

Inventories

We value our inventory at the lower of the actual cost to purchase or manufacture the inventory or the market value for such inventory. We regularly review inventory quantities in process and on hand and record a provision for production loss and obsolete inventory based primarily on actual loss experience and on our estimated forecast of product demand. A significant decrease in demand could result in an increase in the amount of excess inventory quantities on hand. In the future, if our inventory is determined to be overvalued, we would be required to recognize such costs in our costs of product sales at the time of such determination. Although we make every effort to ensure the accuracy of our production process and forecasts of future product demand, any significant unanticipated changes in production yield or product demand could have a significant impact on the value of our inventory and our reported operating results.

Results of Operations

Years Ended December 31, 2006 and 2005

Revenue and Margin Overview

(in thousands)	For the Years Ended December 31, 2006	2005	Increase/ (Decrease) ($)	Increase/ (Decrease) (%)
Total revenues	$22,891	$18,484	$4,407	24%
Costs of product sales	6,958	6,303	655	10%
Gross margin	$15,933	$12,181	$3,752	31%
Gross margin %	70%	66%	4%	

Revenues. Total revenues increased for the year ended December 31, 2006 as compared to the year December 31, 2005 primarily due to the following:

- an increase in revenues from Embosphere and EmboGold microsphere sales in the United States of approximately $3.68 million, or 30%, on increased demand for use in the treatment of uterine fibroids and liver tumors. This volume growth is partially due to the addition of five new sales territories in 2006 and, we believe, to increased awareness of the UFE procedure resulting from additional local advertising and marketing;
- an increase in revenues from Embosphere and EmboGold microsphere sales outside of the United States of approximately $330,000, or 10%, on increased product volumes. Revenues in 2006 included sales of approximately $60,000 to our distributor located in the People's Republic of China, for use in clinical evaluations, which were the first sales of Embospheres Microspheres to this distributor in China. We are still awaiting regulatory approval of Embospheres in the People's Republic of China;
- An increase in revenues from the sale of our new HepaSphere Microsphere product outside of the United States, which was first introduced in December 2005, and from the initial sales of our new QuadraSphere Microspheres product, which was approved in the United States for the treatment of hypervascularized tumors and peripheral arterial venous malformations in November 2006, which on a combined basis totaled $182,000 in 2006;
- revenue from a licensing agreement signed in October 2006 related to non-core intellectual property, which totaled $104,000 in 2006; and
- changes in foreign exchange rates during 2006 as compared to 2005 increased revenues approximately $51,000 as sales from our French subsidiary increased due to the weakening of the U.S. dollar versus the Euro, which averaged 1.25 dollars to the Euro during 2006 as compared to 1.24 dollars to the Euro during 2005.

Revenues from our delivery system and other products, which include barium delivery kits and other ancillary products, were consistent with 2005.

Cost of Product Sales. Cost of product sales for the year ended December 31, 2006 increased from the year ended December 31, 2005 primarily due to higher Embosphere Microsphere sales volume and, to a lesser extent, the recognition of equity compensation costs of approximately $185,000 resulting from the adoption of SFAS 123R in January 2006 and costs associated with an increase in write downs for excess inventory of $180,000. During our routine quarterly review of our inventory we determined that approximately $71,000 and $66,000 of inventory related to our ancillary business in France and to our older generation delivery systems, respectively, would not be realized due to our decision to phase these products out in 2007.

The gross margin improvement of 4% as a percentage of revenues for 2006 as compared to 2005 was primarily attributable to the increase in sales in 2006 of Embosphere Microspheres in the United States, which provide our highest profit margins. Offsetting these improvements were equity compensation costs and the increase in inventory write downs.

We expect that future gross margin will be highly correlated with the following factors:

- revenue growth;
- mix of products sold;
- production levels;
- foreign exchange rate movements;

- terms and conditions of subcontracted manufacturer and supplier agreements; and
- future inventory reserve requirements.

Expense Overview

(in thousands)	For the Years Ended December 31, 2006	2005	Increase/ (Decrease) ($)	Increase/ (Decrease) (%)
Research and development	$ 2,290	$ 2,359	$ (69)	(3)%
Sales	7,583	5,807	1,776	31%
Marketing	3,666	2,458	1,208	49%
General, administrative and patent	5,561	4,219	1,342	32%
Total operating expenses	$19,100	$14,843	$4,257	

Research and Development Expense. Total research and development expense in 2006 was essentially unchanged when compared to 2005 as a decrease in overhead expenses and a reduction in spending on product development projects related to our new delivery systems, which were released in 2006, was offset by an increase in clinical studies and equity compensation. Research and development expense included $72,000 of equity compensation costs in 2006 due to the adoption of SFAS 123R beginning in January 2006. We expect research and development expenses will increase as we increase our focus on the development of embolotherapy products for clinical oncology.

Sales Expense. Sales expense for 2006 increased over 2005 primarily due to increased recruiting, payroll and related expenses incurred with the expansion of the sales force in the United States. We ended 2006 with 18 sales professionals in the United States, led by three regional sales managers. This represents a 50% increase in the sales organization compared to 2005. In addition, sales expense included $325,000 of equity compensation costs in 2006 due to the adoption of SFAS 123R beginning in January 2006.

Marketing Expense. Marketing expense for 2006 increased from 2005 primarily due to increased local promotional activities, in an effort to build physician and patient demand for UFE in the United States and to the addition of resources to manage this increase in marketing programs.

General, Administrative and Patent Expense. General, administrative and patent expenses for 2006 increased from 2005 primarily due to an increase in compensation and consulting costs. Included in general, administrative and patent expense in 2006 is $680,000 of equity compensation costs due to the adoption of SFAS 123R beginning in January 2006. In addition, we incurred approximately $155,000 in consulting costs to help us position the company for continued growth and approximately $45,000 in costs related to regulatory compliance.

Interest Income, Net. For the year ended December 31, 2006, interest income, net of interest expense, increased to $923,000 as compared to $210,000 in 2005. The increase in 2006 as compared to 2005 was due primarily to higher average daily-invested cash balances and to a lesser extent to higher interest rates on available investment grade assets.

Foreign Exchange Losses, Net. Foreign exchange gains and losses primarily result from Euro to U.S. dollar foreign currency fluctuations on Euro denominated intercompany trade accounts. The foreign exchange losses during the year ended December 31, 2006 totaled approximately $102,000 compared to the foreign exchange losses of approximately $444,000 in the comparable period of 2005. The decrease in the loss was primarily the result of lower Euro denominated intercompany trade receivable and payable balances and to the fluctuation of the U.S. dollar as compared to the Euro.

Years Ended December 31, 2005 and 2004

Revenue and Margin Overview

(in thousands)	For the Years Ended December 31, 2005	2004	Increase/ (Decrease) ($)	Increase/ (Decrease) (%)
Total revenues	$18,484	$14,158	$4,326	31%
Costs of product sales	6,303	6,646	(343)	-5%
Gross margin	$12,181	$ 7,512	$4,669	62%
Gross margin %	66%	53%	13%	

Revenues. Revenues increased 31% in 2005 as compared to 2004 primarily due to the following:

- an increase in revenues from microspheres and delivery systems in the United States of approximately $3.68 million, or 41%, as Embosphere Microsphere sales volume levels continued to increase as we execute our strategies to grow the UFE business in the United States;
- an increase in revenues from microspheres and delivery systems outside the United States of $635,000, or 22%, driven by an increase in Embosphere Microsphere sales volumes in France, Germany and the United Kingdom. In April 2005, we began a year-long patient awareness program in France targeted at potential UFE patients through medical gynecologists' offices, which we believe has contributed to the increase in sales volumes; and
- an increase in revenues from other products, which include barium delivery kits and other ancillary products, of approximately $100,000, or 4%, as a result of the timing of several hardware sales in the first quarter of 2005.

Offsetting these increases was a decrease in licensing revenue of $100,000 as a result of the conclusion of a five-month agreement for the development of Embosphere Microspheres for the use in the prevention of gastroesphageal reflex disease, or GERD, which began in 2004 and did not renew in 2005.

Cost of Product Sales. Cost of product sales for the year ended December 31, 2005 decreased from the year ended December 31, 2004 primarily due to the $1.13 million write-off for work-in-process inventory disposals in 2004 due to manufacturing process improvements, and product replacements resulting from shelf life limitations that we recorded during 2004 and did not occur in 2005.

The gross margin improvement of 13% as a percentage of revenues for 2005 as compared to 2004 was primarily attributable to the additional costs in 2004 related to the inventory write-off and the increase in sales in 2005 of Embosphere Microspheres in the United States, which provide our highest profit margins. Offsetting these improvements were costs associated with the initial production of our HepaSphere Microsphere product, which we introduced commercially in 2005, and the decrease in licensing revenue.

Expense Overview

(in thousands)	For the Years Ended December 31, 2005	2004	Increase/ (Decrease) ($)	Increase/ (Decrease) (%)
Research and development	$ 2,359	$ 2,113	$ 246	12%
Sales	5,807	5,271	536	10%
Marketing	2,458	2,279	179	8%
General, administrative and patent	4,219	4,154	65	2%
Litigation costs	—	874	(874)	—
Total operating expenses	$14,843	$14,691	$ 152	

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of BioSphere Medical, Inc.:

We have audited the accompanying consolidated balance sheets of BioSphere Medical, Inc. as of December 31, 2006 and 2005, and the related consolidated statements of operations, stockholders' equity and comprehensive income (loss), and cash flows for each of the three years in the 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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purposes of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and 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 consolidated financial position of BioSphere Medical, Inc. at December 31, 2006 and 2005, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment" using the modified prospective transition method.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 20, 2007

BIOSPHERE MEDICAL, INC.
CONSOLIDATED BALANCE SHEETS

(in thousands except share data)	December 31, 2006	December 31, 2005
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 8,913	$ 8,774
Marketable securities	13,206	—
Account receivable, net of allowance for doubtful accounts of $218 and $233 as of December 31, 2006 and 2005, respectively	4,082	3,521
Inventories	2,830	2,435
Prepaid and other current assets	612	407
Total current assets	29,643	15,137
Property and equipment, net	929	858
Goodwill	1,443	1,443
Other assets	64	57
Total Assets	$ 32,079	$ 17,495
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,366	$ 1,146
Accrued compensation	1,935	1,830
Other accrued liabilities	1,483	1,203
Current portion of capital lease obligations and long-term debt	57	127
Current portion of deferred licensing revenue	83	—
Total current liabilities	4,924	4,306
Long-term debt and capital lease obligations	44	101
Long-term portion of deferred licensing revenue	146	—
Total Liabilities	5,114	4,407
Commitments and contingencies (Note 9 and 16)		
Stockholders' equity:		
Preferred stock; $.01 par value; 1,000,000 shares authorized:		
6% series A convertible preferred stock, 12,000 authorized shares, 8,950 and 8,434 shares issued and outstanding, as of December 31, 2006 and 2005, respectively (aggregate liquidation preference including accrued dividends of $9,083 at December 31, 2006)	7,970	7,449
Common stock; $.01 par value; 50,000,000 shares authorized; 17,957,964 and 15,006,005 shares issued and outstanding as of December 31, 2006 and 2005, respectively	180	150
Additional paid-in capital	100,275	84,471
Deferred compensation	—	(41)
Accumulated deficit	(81,648)	(78,799)
Accumulated other comprehensive income (loss)	188	(142)
Total stockholders' equity	26,965	13,088
Total Liabilities and Stockholders' Equity	$ 32,079	$ 17,495

The accompanying notes are an integral part of these consolidated financial statements.

BIOSPHERE MEDICAL, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands except per share data)	For the Years Ended December 31, 2006	2005	2004
Revenues:			
Product sales	$22,787	$18,484	$14,058
Licensing revenues	104	—	100
Total revenues	22,891	18,484	14,158
Costs and expenses:			
Costs of product sales	6,958	6,303	6,646
Research and development	2,290	2,359	2,113
Sales	7,583	5,807	5,271
Marketing	3,666	2,458	2,279
General, administrative and patent	5,561	4,219	4,154
Litigation costs	—	—	874
Total costs and expenses	26,058	21,146	21,337
Loss from operations	(3,167)	(2,662)	(7,179)
Interest income	938	225	92
Interest expense	(15)	(15)	(16)
Foreign exchange (loss) gains, net	(102)	(444)	389
Other income (expense), net	22	2	(10)
Loss before income tax benefit (provision)	(2,324)	(2,894)	(6,724)
Income tax benefit (provision)	—	93	(117)
Net loss	(2,324)	(2,801)	(6,841)
Preferred stock dividends	(525)	(495)	(68)
Net loss applicable to common stockholders	$ (2,849)	$ (3,296)	$ (6,909)
Net loss per common share applicable to common stockholders			
Basic and diluted	$ (0.17)	$ (0.22)	$ (0.49)
Weighted average number of common shares outstanding			
Basic and diluted	17,027	14,653	14,152

The accompanying notes are an integral part of these consolidated financial statements.

BIOSPHERE MEDICAL, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE INCOME (LOSS)

(in thousands)	Preferred Stock	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
Balance at December 31, 2003	$ —	13,841	$138	$ 81,952	$ —	$(68,594)	$ 28	$13,524
Comprehensive loss:								
Net loss	—	—	—	—	—	(6,841)	—	(6,841)
Unrealized loss on marketable securities	—	—	—	—	—	—	(6)	(6)
Translation adjustment	—	—	—	—	—	—	(210)	(210)
Total Comprehensive loss								(7,057)
Issuance of convertible preferred stock and warrants	6,945	—	—	846	—	—	—	7,791
Dividends on convertible preferred stock	—	—	—	—	—	(68)	—	(68)
Issuance of common stock under employee benefit and incentive plans	—	453	5	640	—	—	—	645
Balance at December 31, 2004	6,945	14,294	143	83,438	—	(75,503)	(188)	14,835
Comprehensive loss:								
Net loss	—	—	—	—	—	(2,801)	—	(2,801)
Unrealized gain on marketable securities	—	—	—	—	—	—	7	7
Translation adjustment	—	—	—	—	—	—	39	39
Total Comprehensive loss								(2,755)
Issuance costs of convertible preferred stock and warrants	(59)	—	—	—	—	—	—	(59)
Dividends on convertible preferred stock	563	—	—	—	—	(495)	—	68
Issuance of common stock under employee benefit and incentive plans	—	697	7	974	—	—	—	981
Issuance of restricted stock	—	15	—	59	(59)	—	—	—
Amortization of stock based compensation	—	—	—	—	18	—	—	18
Balance at December 31, 2005	7,449	15,006	150	84,471	(41)	(78,799)	(142)	13,088
Comprehensive loss:								
Net loss	—	—	—	—	—	(2,324)	—	(2,324)
Unrealized loss on marketable securities	—	—	—	—	—	—	(4)	(4)
Translation adjustment	—	—	—	—	—	—	334	334
Total Comprehensive loss				—	—	—	—	(1,994)
Dividends on convertible preferred stock	525	—	—	—	—	(525)	—	—
Dividends paid in cash in lieu of partial shares	(4)	—	—	—	—	—	—	(4)
Issuance of common stock		2,075	21	13,477	—	—	—	13,498
Issuance of common stock under employee benefit and incentive plans	—	462	5	943	—	—	—	948
Issuance of restricted stock	—	415	4	—	—	—	—	4
Reclassification of deferred compensation upon adoption of SFAS 123R	—	—	—	(41)	41	—	—	—
Non-cash stock-based compensation	—	—	—	1,425	—	—	—	1,425
Balance at December 31, 2006	$7,970	17,958	$180	$100,275	$ —	$(81,648)	$ 188	$26,965

The accompanying notes are an integral part of these consolidated financial statements.

BIOSPHERE MEDICAL, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)	For the Years Ended December 31, 2006	2005	2004
Cash flows from operating activities:			
Net loss	$ (2,324)	$(2,801)	$(6,841)
Adjustments to reconcile net loss to net cash used in operating activities:			
(Recovery of) Provision for doubtful accounts	(8)	66	80
Write down for inventory obsolescence	231	54	1,384
Depreciation	445	509	625
Realized loss on available-for-sale investments	—	5	4
Stock-based compensation	1,425	18	—
Changes in operating assets and liabilities:			
Accounts receivable	(437)	(725)	(510)
Inventories	(449)	593	(938)
Prepaid and other current assets	(169)	(213)	129
Accounts payable	144	149	212
Accrued compensation	39	(3)	799
Other accrued expenses	399	89	(182)
Net cash used in operating activities	(704)	(2,259)	(5,238)
Cash flows from investing activities:			
Purchase of property and equipment	(464)	(325)	(200)
Purchase of marketable securities	(16,575)	—	(255)
Proceeds from the sale and maturity of marketable securities	3,364	764	5,016
Net cash (used in) provided by investing activities	(13,675)	439	4,561
Cash flows from financing activities:			
Proceeds from issuance of convertible preferred stock and warrants, net	—	(59)	7,791
Proceeds from issuance of common stock, net	13,498	—	—
Proceeds from issuance of common stock under employee benefit and incentive plans	952	981	645
Proceeds from capital lease obligations	—	43	210
Payment of cash dividends in lieu of partial shares	(4)	—	—
Principal payments under long-term debt and capital lease obligations	(124)	(163)	(185)
Net cash provided by financing activities	14,322	802	8,461
Effect of exchange rate changes on cash and cash equivalents	196	332	(367)
Net increase (decrease) in cash and cash equivalents	139	(686)	7,417
Cash and cash equivalents at beginning of year	8,774	9,460	2,043
Cash and cash equivalents at end of year	$ 8,913	$ 8,774	$ 9,460

The accompanying notes are an integral part of these consolidated financial statements.

1. Nature of the Business

BioSphere Medical, Inc. (the "Company") was incorporated in Delaware in December 1993. The Company is focused on applying its proprietary Embosphere® Microspheres and other ancillary embolotherapy products for use in treating uterine fibroids, hypervascularized tumors and arteriovenous malformations. The Company's wholly owned subsidiary, BioSphere Medical S.A. ("BMSA"), a French société anonyme, holds the license to the embolotherapy technology that is the main focus of the Company's business.

The Company believes that its existing working capital as of December 31, 2006, together with anticipated proceeds from sales of microspheres, delivery systems and other products will be sufficient to fund operating and capital requirements, as currently planned through at least 2007. In the longer term, the Company expects to fund its operations and sustain capital requirements through a combination of expected proceeds from product sales and capital equipment financing. However, cash requirements may vary materially from those now planned due to a number of factors, including the Company's failure to achieve expected revenue amounts, costs associated with changes in its uterine fibroid embolization ("UFE") marketing programs, unanticipated research and development expenses, the scope and results of pre-clinical and clinical testing, changes in the focus and direction of research and development programs, competitive and technological advances, the timing and results of regulatory review at the United States Food and Drug Administration ("FDA") or comparable regulatory agencies in other countries and the market's acceptance of any approved products, including Embosphere Microspheres for UFE, HepaSphere Microspheres and QuadraSphere Microspheres.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries BMSA, BioSphere Medical Japan, Inc. and BSMD Ventures, Inc. All intercompany balances and transactions have been eliminated in consolidation.

Translation of Foreign Currencies

The functional currency of each of the Company's foreign subsidiaries is their local currency. The assets and liabilities of the Company's foreign subsidiaries are translated into U.S. dollars using the exchange rates in effect as of each balance sheet date. Revenue and expense items are translated into U.S. dollars at average exchange rates prevailing during each reporting period. Resulting translation adjustments are recorded in the cumulative translation adjustment account in stockholders' equity. Aggregate foreign exchange transaction gains and losses resulting from Euro to U.S. dollar foreign currency fluctuations on Euro-denominated intercompany trade accounts are included in the accompanying statement of operations.

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 following: (1) the reported amounts of assets and liabilities, (2) the disclosure of contingent assets and liabilities at

the date of the financial statements, and (3) the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

Cash, Cash Equivalents and Marketable Securities

The Company considers all highly liquid investments with an original maturity of ninety days or less, as of the date of purchase, to be cash equivalents. As of December 31, 2006 and 2005, approximately $8.39 million and $8.36 million respectively, of cash and cash equivalents held by financial institutions in the United States exceeded Federal Deposit Insurance Corporation insured amounts.

Concentration of Credit Risk and Off-Balance Sheet Risk

The Company has no material concentrations of credit risk, nor is it a party to any financial instruments with material off-balance sheet risk. Financial instruments that potentially subject the Company to concentration of credit risk consist primarily of cash, cash equivalents, marketable securities and trade accounts receivable. The estimated fair value of the Company's financial instruments approximates their carrying value. Concentrations of credit risk with respect to trade accounts receivable are limited due to the large number of customers and their dispersion across many geographic areas. No single customer accounted for greater than 10% of the outstanding receivables on December 31, 2006 or 2005, and no single customer accounted for greater than 10% of revenues in 2006, 2005 or 2004.

The Company places its cash, cash equivalents and marketable securities with high credit quality financial institutions. In accordance with the Company's investment policy, surplus cash is invested in investment grade corporate and U.S. government debt as well as certain asset-backed securities. At December 31, 2006, all marketable securities were classified as available-for-sale, since the Company had the intent to use such securities to satisfy current liabilities as needed. Available-for-sale marketable securities are carried at their fair value with unrealized gains and losses included in accumulated other comprehensive income (loss) in the accompanying balance sheet.

Accounts Receivable and Allowance for Doubtful Accounts

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses in its existing accounts receivable. The Company determines the allowance based on the credit worthiness of customers, age of receivables and on historical write-off experience and future expectations by location. The Company reviews its allowance for doubtful accounts monthly. Account balances are charged off against the allowance when the Company feels it is probable the receivable will not be recovered. The Company does not have any off-balance-sheet credit exposure related to its customers.

Property and Equipment

Property and equipment are stated at cost. The Company provides for depreciation based upon expected useful lives using the straight-line method over the following estimated useful lives:

Office equipment	3-5 years
Laboratory and manufacturing equipment	3-5 years
Leasehold improvements	Shorter of lease term or estimated useful life

Maintenance and repairs are charged to expense as incurred. Upon retirement or sale, the cost of disposed assets and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to the statement of operations.

Goodwill and Other Assets

Goodwill represents the difference between the purchase price and the fair value of the tangible and identifiable intangible assets acquired net of liabilities assumed when accounted for in accordance with the purchase method of accounting. Between February 1999 and November 2001, the Company recorded goodwill upon the periodic step-acquisitions of BMSA.

The Company performs annual impairment reviews of its goodwill or whenever events or changes in circumstances indicate that the carrying value of the assets may not be recoverable. Goodwill was derived from the step acquisition of BMSA, the consolidated subsidiary that holds the license to the embolotherapy platform device that is the main focus of the Company's business. In performing the review, the Company utilizes the two-step approach prescribed under the Financial Accounting Standards Board, or FASB, Statement No. 142, Goodwill and Other Intangible Assets. The first step requires a comparison of the carrying value of the reporting units, as defined, to the fair value of these units. If the carrying value of a reporting unit exceeds its fair value, the Company will perform the second step of comparing the implied fair value of the reporting unit's goodwill to its carrying value. For purposes of performing the Goodwill impairment review, management considers itself to be one reporting unit. Based upon the Company's review, the Company has not recorded any impairment charges.

Impairment of Long-Lived Assets

The Company periodically evaluates the potential impairment of its long-lived assets in accordance with Statement of Financial Accounting Standards, or SFAS, SFAS 144, "Accounting for the Impairment or Disposal of Long-lived Assets," to determine whether events or changes in circumstances may indicate that the carrying amount of a recorded asset may not be recoverable. Based on management's assessment as of December 31, 2006, the Company has determined that no impairment of long-lived assets exists.

Revenue Recognition

The Company applies the revenue recognition guidelines summarized in Staff Accounting Bulletin, or SAB, No. 104, "Revenue Recognition." The Company recognizes revenue when products are shipped and the customer or distributor takes ownership and assumes risk of loss, collection of the relevant receivable is reasonably assured, persuasive evidence of an arrangement exists (a valid purchase order from an approved customer), the sales price is fixed or determinable, payment is not contingent on resale and the Company does not have any continuing obligations to ensure resale. The Company establishes reserves for potential sales returns and evaluates the adequacy of those reserves based upon realized experience and expectations. Any significant change in product satisfaction and any resulting credit returns could have a material adverse impact on the Company's revenues and operating results for the period or periods in which such returns materialize. Shipping and handling costs are included in costs of product sales.

In September 2006, the Company entered into an agreement to license certain patent technologies to a third party in exchange for an upfront lump-sum payment of $250,000 and an additional 4% royalty on future net sales of the licensed products. Under the agreement, the third party is required to pay a minimum royalty of $1.00 million over the first three years of the agreement. The Company will recognize both the lump-sum payment and the minimum royalties over the estimated useful life of the patent. The Company recognized approximately $104,000 as licensing revenue during the year ending December 31, 2006.

In June 2004, the Company entered into an exclusive five-month development agreement with a third party for the use of Embosphere Microspheres for gastroesophegal reflex disease. In exchange for this development agreement, the Company received a payment of $100,000. The Company recognized $100,000 as licensing revenue over the life of the contract, which concluded in November 2004.

Research and Development

Research and development costs include payroll, building costs, administrative expenses, and third party costs related to developing new products, making technological improvements to existing products and production methods are expensed in the period incurred. Preclinical testing of product candidates and clinical trials and product validation costs associated with recently released products are also included in research and development expenses.

Deferred Income Taxes

The Company uses the asset and liability accounting method whereby deferred tax assets and liabilities are recognized based on temporary differences between the financial statements and tax bases of assets and liabilities using current statutory tax rates. A valuation allowance against net deferred tax assets is recorded if, based on the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. Management evaluates, on a quarterly basis, the ability to recover the deferred tax assets and the level of the valuation allowance. Due to the size of the net operating loss carry forward in relation to the Company's history of unprofitable operations, the Company has not recognized any of its net deferred tax assets. However, future improvements in operational performance could result in the increased certainty of the ability to apply deferred tax assets against taxable income, which could, in turn, result in a significant impact on the value of the Company's deferred tax assets and reported operating results.

Comprehensive Income (Loss)

Other comprehensive income (loss) includes certain changes in equity that are excluded from net loss, specifically, the effects of foreign currency translation adjustments and unrealized gains and losses on available-for-sale marketable securities, which are reflected separately in stockholders' equity in accumulated other comprehensive income (loss). The components of accumulated other comprehensive income (loss) are as follows:

(in thousands)	December 31, 2006	December 31, 2005
Foreign exchange currency translation	$192	$(142)
Unrealized losses on investments	(4)	—
Total accumulated other comprehensive income/(loss)	$188	$(142)

Net Loss Per Share

Basic net loss per share is calculated based on the weighted average number of common shares outstanding during the period. Diluted net loss per share incorporates the dilutive effect of common stock equivalent options, warrants and other convertible securities. Shares used to compute dilutive net loss per share exclude the following common share equivalents as their inclusion would have an antidilutive effect.

(in thousands)	For the years ended December 31, 2006	2005	2004
Shares issuable upon exercise of stock options	2,627	2,623	3,054
Shares issuable upon conversion of convertible securities	2,271	2,140	2,017
Shares issuable upon exercise of outstanding warrants	400	400	563
Unvested restricted stock awards	430	15	—
	5,728	5,178	5,634

Stock Options

The Company adopted the provisions of Statement of Financial Accounting Standards No. 123R, "Share-Based Payment" ("SFAS 123R"), beginning January 1, 2006, using the modified prospective transition method. This statement requires the Company to measure the cost of employee services in exchange for an award of equity instruments based on the grant-date fair value of the award and to recognize cost over the requisite service period. Under the modified prospective transition method, the Company has not adjusted its financial statements for periods prior to the date of adoption for the change in accounting. However, the Company will recognize compensation expense for (a) all share-based payments granted after the effective date and (b) all awards granted to employees prior to the effective date that remain unvested on the effective date. The Company recognizes compensation expense on fixed awards with pro rata vesting on a straight-line basis over the awards vesting period.

Prior to January 1, 2006, the Company used the intrinsic value method to account for stock-based employee compensation under Accounting Principles Board Opinion No. 25, "*Accounting for Stock Issued to Employees*," and, therefore, the Company did not recognize compensation expense in association with employee options granted at or above the market price of the Company's common stock at the date of grant.

As a result of adopting SFAS 123R, stock-based compensation charges during the year ended December 31, 2006 increased by approximately $1.28 million. Net loss applicable to common stockholders for the year ended December 31, 2006 increased as compared to the same periods in 2005 by $0.07 per basic and diluted share.

At December 31, 2006, there was $3.15 million and $579,000 of unrecognized compensation cost, net of estimated forfeitures, related to non-vested options and restricted stock awards, respectively, which the Company expects to recognize over weighted-average periods of 3.70 years and 3.24 years, respectively. However, the amount of stock compensation expense recognized in any future period cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. The adoption of SFAS 123R did not require any cumulative adjustments to the Company's financial statements.

The following table presents the stock-based compensation expense for the year ended December 31, 2006:

(in thousands)	For the Year Ended December 31, 2006
Cost of product sales	$ 195
Research and development	72
Sales	346
Marketing	18
General, administrative and patent	794
	$1,425

The fair value of options granted during the year ended December 31, 2006, 2005 and 2004 are estimated on the date of the grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	For the Years Ended December 31,		
	2006	2005	2004
Options granted (in thousands)	620	483	1,101
Weighted average exercise price	$7.01	$4.49	$ 2.89
Weighted average grant date fair value	$5.21	$3.19	$ 2.09
Assumptions:			
Dividend yield	0%	0%	0%
Expected volatility	83%	84%	93%
Risk-free interest rate	4.85%	3.77%	3.63%
Expected term (years)	6.25	5.71	5.09

Historical Company information was the primary basis for the expected volatility and the expected term assumptions. Based on the analysis of the historical forfeitures, the Company utilized an estimated forfeiture rate of 13% for the year ended December 31, 2006. Prior to January 1, 2006, forfeitures were recorded on an actual basis.

The following table presents a reconciliation of reported net loss and per share information to pro forma net loss and per share information that would have been reported if the fair value method had been used to account for stock-based employee compensation for all periods prior to January 1, 2006:

(in thousands, except per share amounts)	For the Years Ended December 31, 2005	2004
Net loss applicable to common stockholders		
As reported	$(3,296)	$(6,909)
Pro forma compensation expense	(872)	(894)
Pro forma net loss	$(4,168)	$(7,803)
Basic and diluted loss per share		
As reported	$ (0.22)	$ (0.49)
Pro forma	$ (0.28)	$ (0.55)

Reclassifications

Certain reclassifications have been made to prior year's consolidated financial statements to conform to the current year presentation. In connection with preparation of the accompanying consolidated financial statements, the Company concluded that it was appropriate to classify local advertising campaigns initiated by the sales force as marketing expenses. Previously, such advertising costs were classified as selling expenses. This revision in classification does not affect total operating costs and expenses.

New Accounting Pronouncements

In June 2006, the FASB issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes—an Interpretation of FASB Statement No. 109", or Interpretation. The Interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes.* The Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This Interpretation also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and

transition. The Interpretation is effective for fiscal years beginning after December 15, 2006. The Company has not completed its evaluation of the Interpretation, but does not currently believe that adoption will have a material impact on its results of operations, financial position or cash flows.

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, "Fair Value Measurements", or SFAS 157. SFAS 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles in the United States, or GAAP, and expands disclosures about fair value measurements. SFAS 157 applies under other accounting pronouncements that require or permit fair value measurements, the FASB having previously concluded in those accounting pronouncements that fair value is the relevant measurement attribute. Accordingly, SFAS 157 does not require any new fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years, with earlier adoption permitted. The provisions of SFAS 157 should be applied prospectively as of the beginning of the fiscal year in which it is initially applied, with limited exceptions. The Company does not believe the adoption of SFAS 157 will have a material impact on its results of operations, financial position or cash flows.

3. Goodwill

Goodwill, comprised entirely of the unamortized purchase price paid in excess of the net BMSA assets acquired, equaled $1.44 million as of December 31, 2006 and 2005.

4. Marketable Securities

All current fixed maturity securities are classified as "available-for-sale" and are reported at fair value. The Company has determined its investment securities are available to support current operations and, accordingly, has classified such marketable securities as current assets without regard for contractual maturities. The unrealized gains or losses on these securities are included in accumulated other comprehensive income as a separate component of stockholders' equity unless the decline in value is deemed to be other-than-temporary, in which case securities are written down to fair value and the loss is charged to income. The Company evaluates its investment securities for other-than-temporary declines based on quantitative and qualitative factors.

The Company's available-for-sale marketable securities, including accrued interest receivable, as of December 31, 2006 are as follows:

(in thousands)	Amortized Cost	Unrealized Gains/ (losses)	Estimated Fair Value
United States Treasury securities	$ 2,014	$(13)	$ 2,001
Corporate obligations	6,465	8	6,473
Bank obligations	4,599	1	4,600
Mortgage-backed obligations	132	—	132
Total marketable securities	$13,210	$ (4)	$13,206

The Company's cash and cash equivalents as of December 31, 2005 were comprised of cash and money market funds.

As of December 31, 2006, the contractual maturities of marketable securities are as follows:

(in thousands)	Estimated Fair Market Value
Due within one year:	
United States Treasury securities	$ 2,001
Corporate obligations	2,655
Bank obligations	4,600
Mortgage-backed obligations	132
Due between one and five years:	
Corporate obligations	3,818
Total	$13,206

No material realized gains or losses on the Company's marketable securities were recognized during the years ended December 31, 2006, 2005 and 2004.

5. Inventories

Inventories are stated at the lower of cost (first-in, first-out) or market and consist of the following as of:

(in thousands)	December 31, 2006	2005
Finished goods	$1,793	$1,348
Work in progress	793	878
Raw material	244	209
Total inventory	$2,830	$2,435

6. Property and Equipment

Property and equipment consists of the following:

(in thousands)	December 31, 2006	2005
Office equipment	$ 1,080	$ 976
Laboratory and manufacturing equipment	2,608	2,166
Leasehold improvements	211	189
Total property and equipment	3,899	3,331
Less: accumulated depreciation	(2,970)	(2,473)
Net property and equipment	$ 929	$ 858

Property and equipment under capital lease agreements, net of accumulated depreciation, which are included in the table above, at December 31, 2006 and 2005, were $87,000 and $210,000, respectively.

Depreciation expense, including amortization on capital leases, was $445,000, $509,000 and $625,000 for the years ended December 31, 2006, 2005 and 2004, respectively.

7. Accrued Compensation

Accrued compensation consists of the following:

(in thousands)	December 31, 2006	2005
Accrued payroll, vacation and incentive compensation	$1,840	$1,559
Accrued severance	—	14
Accrued relocation	95	257
	$1,935	$1,830

At December 31, 2006 and December 31, 2005, there was $95,000 and $257,000, respectively, remaining of costs accrued to relocate two new executives, who were hired during 2004.

8. Accrued Expenses

Accrued expenses consist of the following:

(in thousands)	December 31, 2006	2005
Accrued royalties	$1,016	$ 702
Accrued other	467	501
	$1,483	$1,203

9. Debt and Lease Obligations

Debt consists of the following:

(in thousands)	December 31, 2006	2005
Capital lease obligations	$101	$ 228
Less: current portion	(57)	(127)
Total long-term debt and capital lease obligations	$ 44	$ 101

The Company currently has a credit facility with a bank under which it may borrow up to $3.00 million for general working capital and corporate purposes. The credit facility expires in June 2007. There were no borrowings outstanding under this agreement as of December 31, 2006 or 2005. Each available 30-, 60-, 90- or 180- day advance will bear interest at a per annum rate, at the Company's option, equal to either (i) a variable rate as determined by the bank or (ii) a rate equal to the corresponding 30-, 60-, 90- or 180-day LIBOR rate (5.33% as of December 31, 2006) plus a LIBOR advance rate spread as determined by certain current working capital balances at the time of the advance. In connection with the credit facility, the Company entered into a security agreement pursuant to which the Company has pledged to the bank all of the Company's U.S. assets, excluding our equity ownership of our subsidiaries including BMSA, as collateral. Letters of credit issued in the ordinary course of business totaled $448,000 as of December 31, 2006, and were collateralized by the Company's credit facility noted above.

The Company leases approximately 13,000 square feet of office and laboratory space at its Rockland, Massachusetts facility under an operating lease expiring in February 2009 for approximately $234,000 per year, exclusive of periodic operating and maintenance expenses. BMSA leases approximately 18,000 square feet of manufacturing and office space in Roissy, France through May 2010 for approximately €230,000 per year (approximately $300,000 as of December 31, 2006). The Company also has several operating leases covering certain pieces of manufacturing and office equipment through 2010.

During 2005 and 2004, the Company entered into several capital lease agreements in connection with the acquisition of certain manufacturing, computer and communication equipment. The leases have initial terms of 36 to 60 months with interest rates of 4.6% to 8.7%. All equipment leased under these agreements serves as pledged capital.

Future minimum lease payments under non-cancelable operating leases and capital leases in effect as of December 31, 2006, are as follows:

(in thousands)	Operating Leases	Capital Leases
2007	$ 696	$ 62
2008	649	29
2009	402	10
2010	151	8
Thereafter	—	—
Total lease commitments	$1,898	109
Less amount representing interest		(8)
Present value of net minimum capital lease payments		$101

Total facility rental expense for the years ended December 31, 2006, 2005 and 2004 was approximately $540,000, $431,000 and $509,000, respectively.

10. Income Taxes

As of December 31, 2006, the Company had federal net operating loss ("NOL") carry forwards of approximately $71.71 million, which will expire through the year 2026, state NOL carry forwards of approximately $37.04 million, which will expire through the year 2011, and foreign NOL carry forwards of approximately $4.01 million, which do not expire. The difference between the federal and state NOL carry forwards and the deferred tax asset related to NOL carry forwards is attributable to the tax deduction for stock option exercises during the year ended December 31, 2006, which totaled $2.21 million. As of December 31, 2006, the Company has $187,000 of research and development credit carry forwards to offset future income taxes, which will expire through the year 2018. The components of the Company's net deferred tax asset at December 31, 2006 and 2005 are as follows:

(in thousands)	December31, 2006	2005
Assets derived from the following:		
NOL carry forwards	$ 26,981	$ 26,890
Tax credit carry forwards	186	187
Other	374	171
Subtotal	27,541	27,248
Valuation allowance	(27,541)	(27,248)
Net deferred tax asset	$ —	$ —

As discussed in Note 2, the Company adopted SFAS 123R effective January 1, 2006 for stock-based compensation plans. Generally, tax return deductions are allowable on such arrangements but may arise in different amounts and periods from compensation costs recognized on financial statements. Pursuant to SFAS 123R, if the tax return deduction for an award exceeds the cumulative compensation cost recognized on the financial statements, any excess tax benefit shall be recognized as additional paid-in-capital when the deduction reduces taxes payable. Prior to adoption, the Company recognized deferred tax assets, along with an offsetting valuation allowance, for net operating loss carry forwards that included deductions for

excess tax benefits from stock-based compensation. The net tax amount of unrealized excess tax benefits as of December 31, 2006, included and disclosed as a deferred tax asset, is approximately $7.64 million.

The Company has established a full valuation allowance against its deferred tax assets as of December 31, 2006 as it considers the realizable value of any tax benefit against future taxable income to be uncertain. The change in the valuation allowance from December 31, 2005 to December 31, 2006 is a result of the increase in NOL carry forwards from the inclusion of the current period loss offset by a decrease in state NOL carry forwards due to carry forward limitations.

The 2005 income tax benefit of $93,000 primarily represents the realization of income tax benefits, as a portion of the 2001 taxes paid in France were recovered.

For the years ended December 31, 2006, 2005, and 2004, the increase in the valuation allowance relating to losses not resulting in a current period tax benefit is the primary difference between the income tax provision (benefit) recorded by the Company and the amount of the income tax benefit would be at statutory income tax rates.

The components of the Company's pre-tax income (loss) by tax jurisdiction, net of any intercompany transactions, are as follows:

	For the years ended December 31,		
(in thousands)	2006	2005	2004
United States	$(2,815)	$(3,100)	$(4,996)
France	491	206	(1,728)
Pretax loss	$(2,324)	$(2,894)	$(6,724)

11. Segment Information

The Company develops microspheres and other ancillary embolotherapy products for use in the treatment of uterine fibroids, hypervascularized tumors and arteriovenous malformations. The Company operates exclusively in the medical device business, which the Company considers as one business segment pursuant to SFAS No. 131, "Disclosures About Segments of an Enterprise and Related Information". Financial information by geographic area, attributed to countries according to the location of customers and equipment, is as follows:

	For the years ended December 31,		
(in thousands)	2006	2005	2004
Revenues:			
United States	$16,458	$12,663	$ 9,080
France	3,516	3,382	2,883
Other European Union countries	1,855	1,658	1,408
Other foreign countries	1,062	781	787
Total revenues	$22,891	$18,484	$14,158
Long- lived assets:			
United States	$ 385	$ 297	$ 425
France	544	561	709
Total long- lived assets	$ 929	$ 858	$ 1,134

12. Stockholders' Equity

Common Stock

On February 22, 2006, the Company sold 2,075,000 shares of common stock at a price per share of $7.00 to several investors in a private placement. Upon payment of all offering expenses, the Company received net proceeds of approximately $13.50 million. The common stock was issued in reliance upon the

exemptions from registration under Section 4(2) of the Securities Act of 1933, as amended, and Regulation D promulgated thereunder, relative to sales by an issuer not involving any public offering. The proceeds are being used to fund current operations.

Preferred Stock

Under the certificate of incorporation of the Company, the Board of Directors has the authority to issue up to 1,000,000 shares of $0.01 par value preferred stock from time to time in one or more series with such preferences terms and rights as the Board of Directors may determine without further action by the stockholders of the Company. Accordingly, the Board of Directors has the power to establish the provisions, if any, relating to dividends, voting rights, redemption rates, liquidation preferences and conversion rights for any series of preferred stock issued in the future.

6% Series A Convertible Preferred Stock

In November 2004, the Company completed a private placement of $8.00 million of its series A convertible preferred stock ("series A preferred stock") and warrants to purchase common stock with Sepracor Inc. and affiliates of Cerberus Capital Management, L.P., two existing investors. These investors purchased a total of 8,000 shares of series A preferred stock, which are initially convertible into 2,000,000 shares of common stock based upon a conversion price of $4.00 per share. In addition, The Company has the right to convert the series A preferred stock into common stock, or redeem it, under specified circumstances. The series A preferred stock has a 6% dividend, which is payable quarterly in either cash or additional shares of series A preferred stock, at the Company's election. Additionally, the investors were issued warrants to purchase an aggregate of 400,000 shares of common stock. These warrants expire five years from the date of issuance and have an initial exercise price of $4.00 per share. These warrants were assigned a value of $850,000 using the Black-Scholes option-pricing model. Through December 31, 2006, the Company issued 950 shares of series A preferred stock for payment of series A preferred stock dividends.

13. Stock Plans

Stock Option Plans

As of December 31, 2006, the Company has granted options and/or restricted stock awards under the following four stock-based compensation plans: (i) the 2006 Stock Incentive Plan (the "2006 Plan"), which was adopted by the Company's Board of Directors on March 9, 2006 and was approved by the Company's stockholders on May 10, 2006 and which authorizes the issuance of up to an aggregate of 2,000,000 shares of common stock to officers, directors, advisors, consultants and employees of the Company; (ii) the 1997 Stock Option Plan (the "1997 Plan"), which expires in March 2007 and is intended to be replaced by the 2006 Plan, (iii) the 1994 Stock Option Plan (the "1994 Plan"), which expired in January 2004 and, accordingly, has no shares available for future grant and (iv) the 1994 Director Option Plan (the "Director Plan"), which expired in January 2000 and, accordingly, has no shares available for future grant. The Company's 2006 Plan, 1997 Plan and 1994 Plan each provide for the grant of Incentive Stock Options ("ISOs") to officers and employees and Non-Statutory Stock Options ("NSOs") to officers, directors, advisors, consultants and employees of the Company. Options granted under such plans generally become exercisable in five equal annual installments beginning on the first anniversary of the date of the grant and have a maximum term of ten years from the date of grant. The Company's Director Plan provided for the grant of NSOs to directors of the Company who are not officers or employees of the Company or any subsidiary of the Company. Options granted under the Director Plan vest in either two or five equal installments beginning on the first anniversary of the date of the grant depending on the nature of the grant and have a maximum term of ten years from the date of grant. At December 31, 2006 there were 1,575,000 and 20,000 shares available for future grant under 2006 Plan and 1997 Plan, respectively.

The 2006 Plan and 1997 Plan also provide for the grant of restricted stock awards to officers, directors, advisors, consultants and employees of the Company. Generally, the restricted stock awards are subject to a right of repurchase by the Company if service is terminated prior to specified dates and/or if specified performance conditions are not met, which right of repurchase lapses over time. Ownership of restricted stock cannot be transferred, except under specified circumstances, until the foregoing repurchase restrictions have lapsed. In connection with restricted stock grants, the Company records compensation expense based on the fair value of the shares at the time of grant. This stock compensation is amortized on a straight-line basis over the vesting periods.

On June 1, 2006, the Board of Directors awarded an aggregate of 400,000 shares of restricted common stock to the Company's executive officers under the 2006 Plan. The shares of restricted common stock are subject to a right of repurchase by the Company, which lapses on June 1, 2010, subject to the achievement by the Company of specified stockholder returns on its common stock. If on June 1, 2010, the four-year cumulative total stockholder return on the Company's common stock is equal in dollar amount to the four-year cumulative total return for the NASDAQ Medical Equipment Index ("NASDAQ Index"), 25% of the restricted stock award will vest and no longer be subject to the repurchase option. An additional 1.6304% of the restricted stock award will vest and become free of the repurchase option for each one percentage that the four-year cumulative total stockholder return on the Company's common stock exceeds the four-year cumulative total return for the NASDAQ Index. The aggregate intrinsic value of the 400,000 shares of the Company's common stock underlying the restricted stock awards was $2.40 million, based on the closing price of the Company's common stock on the NASDAQ National Market on the date of grant. The Company utilized a Monte-Carlo simulation to estimate a range of possible future stock prices over the four-year period for the Company's common stock and the NASDAQ Index to estimate the number of restricted shares that may vest based upon such simulation. Using the Monte-Carlo simulation method, the Company calculated an aggregate compensation cost of $580,000 at the time of the grant. The Company is recognizing this compensation cost over the four-year service period whether or not the market condition is actually satisfied. However, in the event one or more of the participants voluntarily terminates before the end of the four year period, some amounts of the charge will be reversed. In the event that a qualifying change in the control of the Company occurs prior to June 1, 2010, the Company's repurchase option will fully lapse, and the Company will then recognize a compensation change equal to the full $2.40 million intrinsic value less any previously recognized compensation expense.

Pursuant to the Company's 2000 Employee Stock Purchase Plan, the Company may issue and sell to its eligible employees up to an aggregate of 100,000 shares of common stock at a purchase price equal to 85% of the lower of the fair market value on the first or last day of each six-month offering period. Eligible employees may elect to have up to a maximum of 10% of their regular compensation withheld through payroll deductions to pay the purchase price of the shares at the end of the offering period, subject to limitations specified in the plan.

15. Valuation and Qualifying Accounts

The Company monitors the creditworthiness of its trade customers based upon historical payment experience. The allowance for doubtful accounts activity for the years ended December 31, 2006, 2005 and 2004 is as follows:

(in thousands)	Balance, Beginning of Period	Charged to Costs and Expenses	Deductions	Balance, End of Period
Year ended December 31, 2006	$233	$(8)	$ (7)	$218
Year ended December 31, 2005	$184	$66	$(17)	$233
Year ended December 31, 2004	$180	$80	$(76)	$184

16. Contingencies

On August 17, 2005, a lawsuit commenced in the Circuit Court, Twenty-Second Judicial Circuit, St. Louis, Missouri captioned *Brett Pingel by next friend Dawn LaRose vs. BioSphere Medical, Inc., Bruce Kirke Bieneman, M.D., St. Louis University Hospital, John Stith, M.D. and St. Louis University.* The lawsuit alleges, among other things, that a patient suffered permanent bilateral blindness as a result of the use of the Company's Embosphere Microspheres or the negligence of the healthcare providers or both factors combined. All defendants have denied the allegations against them. Plaintiffs seek compensatory and punitive damages. The Company carries product liability insurance and this case is currently being defended by the Company's insurer under reservation of rights with respect to the claim of punitive damages, for which an exclusion from coverage exists. The Company has filed an answer to this lawsuit in which it has denied the claims being made. The Company intends to defend against the claims vigorously. However, the Company cannot give any assurance that it will prevail and it is currently unable to predict the financial impact, of this product liability litigation.

17. Quarterly Financial Data (Unaudited)

The following is a summary of quarterly financial results:

(in thousands except per share amounts)	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Net revenues				
2006	$ 5,269	$ 5,637	$5,644	$6,341
2005	4,429	4,489	4,412	5,154
Gross profit				
2006	3,578	3,968	3,936	4,451
2005	2,888	2,990	2,866	3,437
Net loss applicable to common stockholders				
2006	(901)	(1,115)	(500)	(333)
2005	(1,346)	(1,159)	(519)	(272)
Basic and diluted net loss per share				
2006	$ (0.06)	$ (0.06)	$ (0.03)	$ (0.02)
2005	(0.09)	(0.08)	(0.04)	(0.02)

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

None.

Item 9A. CONTROLS AND PROCEDURES

Our management, with the participation of the Company's chief executive officer and chief financial officer, evaluated the effectiveness of the Company's disclosure controls and procedures as of December 31, 2006. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2006, the Company's chief executive officer and chief financial officer concluded that, as of such date, the Company's disclosure controls and procedures were effective at the reasonable assurance level.

No change in our internal control over financial reporting occurred during the fiscal quarter ended December 31, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

None.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors and Executive Officers

Information regarding our directors will be included in the definitive proxy statement for the 2007 Annual Meeting of Stockholders under "Nominees for Director" and is herein incorporated by reference.

Information regarding our executive officers is included in Part I, Item 4, under the heading "EXECUTIVE OFFICERS."

Audit Committee

We have a separately-designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. Additional information regarding the Audit Committee will be included in the definitive proxy statement for the 2007 Annual Meeting of Stockholders under "Board and Committee Meetings" and "Report of the Audit Committee" and is herein incorporated by reference.

Audit Committee Financial Expert

The Board of Directors has determined that William M. Cousins, Jr. and John H. MacKinnon are each an "audit committee financial expert" as defined by Item 401(h) of Regulation S-K of the Exchange Act and has determined that they are independent within the meaning of Item 7(d)(3)(iv) of Schedule 14A of the Exchange Act.

Section 16(a) Beneficial Ownership Reporting Compliance

Information regarding Section 16(a) Beneficial Ownership Reporting Compliance will be included in the definitive proxy statement for the 2007 Annual Meeting of Stockholders under "Section 16(a) Beneficial Ownership Reporting Compliance" and is herein incorporated by reference.

Code of Ethics

We have adopted a code of business conduct and ethics that applies to our directors, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions) as well as our employees, a copy of which is listed as an exhibit to this annual report on Form 10-K. A copy of our code of ethics is also available on the Company's website at *www.biospheremed.com*.

Item 11. EXECUTIVE COMPENSATION

The response to this item will be included in the definitive proxy statement for the 2007 Annual Meeting of Stockholders under "Compensation of Executive Officers" and is herein incorporated by reference.

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

The response to this item will be included in the definitive proxy statement for the 2007 Annual Meeting of Stockholders under "Stock Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" and is herein incorporated by reference.

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

The response to this item will be included in the definitive proxy statement for the 2007 Annual Meeting of Stockholders under "Certain Relationships and Related Transactions" and is herein incorporated by reference.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The response to this item will be included in the definitive proxy statement for the 2007 Annual Meeting of Stockholders under "Report of the Audit Committee" and "Independent Accountants, Fees and Other Matters" and is herein incorporated by reference.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) (1) The following consolidated financial statements of BioSphere Medical, Inc. and subsidiaries are filed as part of this Form 10-K:

Statement

Report of Independent Registered Public Accounting Firm
Consolidated Balance Sheets—December 31, 2006 and 2005
Consolidated Statements of Operations—Years ended December 31, 2006, 2005 and 2004
Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss)—Years ended December 31, 2006, 2005 and 2004
Consolidated Statements of Cash Flows—Years ended December 31, 2006, 2005 and 2004
Notes to Consolidated Financial Statements

(a) (2) All schedules are omitted because they are not applicable or the required information is shown in the Financial Statements or notes thereto.

(a) (3) Exhibits included or incorporated herein:

See Exhibit Index

Exhibit No.	Description
10.24	Securities Purchase Agreement, dated as of November 10, 2004, by and among BioSphere Medical, Inc. and the investors named therein. (Incorporated herein by reference to the Company's Current Report on Form 8-K filed on November 15, 2004 (File No. 000-23678)).
10.25	Investor Rights Agreement, dated as of November 10, 2004, by and among BioSphere Medical, Inc. and the investors named therein. (Incorporated herein by reference the Company's Current Report on Form 8-K filed on November 15, 2004 (File No. 000-23678)).
10.26	Warrant No. 2004-1, dated as of November 10, 2004, issued to Cerberus Partners, L.P. (Incorporated herein by reference to the Company's Current Report on Form 8-K filed on November 15, 2004 (File No. 000-23678)).
10.27	Warrant No. 2004-2, dated as of November 10, 2004, issued to Sepracor Inc. (Incorporated herein by reference to the Company's Current Report on Form 8-K filed on November 15, 2004 (File No. 000-23678)).
10.28	Restrictive Covenants Agreement, dated as of December 23, 2004, by and among BioSphere Medical, Inc., Cerberus Partners, L.P. and Sepracor Inc. (Incorporated herein by reference to the Company's Current Report on Form 8-K filed on December 30, 2004 (File No. 000-23678)).
10.29	Amendment No. 1 to Warrant No. 2004-1, dated December 23, 2004, issued to Cerberus Partners, L.P. (Incorporated herein by reference to the Company's Current Report on Form 8-K filed on December 30, 2004 (File No. 000-23678)).
10.30	Amendment No. 1 to Warrant No. 2004-2, dated December 23, 2004, issued to Sepracor Inc. (Incorporated herein by reference to the Company's Current Report on Form 8-K filed on December 30, 2004 (File No. 000-23678)).
10.31	Second Amendment to Lease between BioSphere Medical, Inc. and Thomas J. Teuten and John H. Spurr, Jr., Trustees of 1050 Hingham Street Realty Trust, dated January 24, 2005. (Incorporated herein by reference to the Company's Current Report on Form 8-K filed on January 27, 2005 (File No. 000-23678)).
10.32	Third Amendment to Lease between BioSphere Medical, Inc. and Thomas J. Teuten and John H. Spurr, Jr., Trustees of 1050 Hingham Street Realty Trust, dated February 24, 2006. (Incorporated herein by reference to the Company's Current Report on Form 8-K filed on February 28, 2006 (File No. 000-23678)).
10.33(1)	Compensation Program for Non-Employee Directors of BioSphere Medical, Inc. (Incorporated herein by reference to the Company's Current Report on Form 8-K filed on August 9, 2006 (File No. 000-23678)).
10.34(1)	Letter Agreement between BioSphere Medical, Inc. and Martin J. Joyce, dated June 14, 2005. (Incorporated herein by reference to the Company's Current Report on Form 8-K filed on June 17, 2005 (File No. 000-23678)).
10.35(1)	Letter Agreement between BioSphere Medical, Inc. and Peter C. Sutcliffe, dated June 14, 2005. (Incorporated herein by reference to the Company's Current Report on Form 8-K filed on June 17, 2005 (File No. 000-23678)).
10.36	Securities Purchase Agreement, dated as of February 17, 2006, by and among BioSphere Medical, Inc. and the investors named therein. (Incorporated herein by reference to the Company's Current Report on Form 8-K filed on February 21, 2006 (File No. 000-23678)).
10.37	Registration Rights Agreement, dated as of February 17, 2006, by and among BioSphere Medical, Inc. and the investors named therein. (Incorporated herein by reference to the Company's Current Report on Form 8-K filed on February 21, 2006 (File No. 000-23678)).

Exhibit No.	Description
10.38	BioSphere Medical, Inc. 2006 Stock Incentive Plan (Incorporated herein by reference to the Company's Current Report on Form 8-K filed on May 16, 2006).
10.39	Form on Incentive Stock Option Agreement Granted Under BioSphere Medical, Inc. 2006 Stock Incentive Plan (Incorporated herein by reference to the Company's Current Report on Form 8-K filed on May 16, 2006).
10.40	Form of Nonstatutory Stock Option Agreement Granted Under BioSphere Medical, Inc. 2006 Incentive Plan (Incorporated herein by reference to the Company's Current Report on Form 8-K filed on May 16, 2006).
10.41	Form of Restricted Stock Agreement Granted Under BioSphere Medical, Inc. 2006 Stock Incentive Plan (Incorporated herein by reference to the Company's Current Report on Form 8-K filed on May 16, 2006).
10.42	Amendment No. 1 to 2006 Stock Incentive Plan. (Incorporated herein by reference to the Company's Current Report on Form 8-K filed on August 9, 2006 (File No. 000-23678)).
14.1	Code of Business Conduct and Ethics of the Company. (Incorporated herein by reference to the Company's Form 10-K for the year ended December 31, 2003 (File No. 000-23678)).
21.1	Subsidiaries of the Company. (Incorporated herein by reference to the Company's Annual Report on Form 10-K for the year ended December 31, 2000 (File No. 000-23678)).
23.1*	Consent of Ernst & Young LLP.
31.1*	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a)/Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated March 26, 2007.
31.2*	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a)/Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated March 27, 2007.
32.1*	Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated March 26, 2007.
32.2*	Certification of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated March 27, 2007.

(1) Management contract or compensatory plan or arrangement filed as an exhibit to this Form 10-K pursuant to Items 14(a) and 14(c) of Form 10-K.

\+ Confidential treatment requested as to certain portions.

* Filed herewith.

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.

BIOSPHERE MEDICAL, Inc.

By: /s/ RICHARD J. FALESCHINI
Richard J. Faleschini
President and Chief Executive Officer

Date: March 26, 2007

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ RICHARD J. FALESCHINI **Richard J. Faleschini**	Director, President and Chief Executive Officer (Principal Executive Officer)	March 26, 2007
/s/ MARTIN J. JOYCE **Martin J. Joyce**	Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 27, 2007
/s/ TIMOTHY J. BARBERICH **Timothy J. Barberich**	Director	March 23, 2007
/s/ WILLIAM M. COUSINS, JR. **William M. Cousins, Jr.**	Director	March 27, 2007
/s/ MARIAN L. HEARD **Marian L. Heard**	Director	March 27, 2007
/s/ ALEXANDER M. KLIBANOV, Ph.D. **Alexander M. Klibanov, Ph.D.**	Director	March 27, 2007
/s/ JOHN H. MACKINNON **John H. MacKinnon, CPA**	Director	March 27, 2007
/s/ RICCARDO PIGLIUCCI **Riccardo Pigliucci**	Director	March 27, 2007
/s/ DAVID P. SOUTHWELL **David P. Southwell**	Director and Chairman of the Board	March 27, 2007

Officers

Richard J. Faleschini
President and
Chief Executive Officer

Gary M. Saxton
Executive Vice President
and Chief Operating Officer

Martin J. Joyce
Executive Vice President and
Chief Financial Officer

Peter C. Sutcliffe
Vice President,
Manufacturing

Board of Directors

David P. Southwell
Chairman of the Board,
BioSphere Medical, Inc.
Executive Vice President
and Chief Financial Officer,
Sepracor Inc.

Richard J. Faleschini
President and
Chief Executive Officer,
BioSphere Medical, Inc.

Timothy J. Barberich
Chairman and
Chief Executive Officer,
Sepracor Inc.

William M. Cousins, Jr.
President,
William M. Cousins, Jr., Inc.

Marian L. Heard
President and CEO,
Oxen Hill Partners

Alexander M. Klibanov, Ph.D.
Professor of Chemistry,
Massachusetts Institute
of Technology

John H. MacKinnon
Retired Partner,
Pricewaterhouse-
Coopers LLP

Riccardo Pigliucci
Management Consultant

Market for Common Stock

The Common Stock of
BioSphere Medical, Inc.
is traded on the Nasdaq
Global Market under the
symbol BSMD.

Transfer Agent and Registrar

American Stock Transfer
and Trust Company
59 Maiden Lane
Plaza Level
New York, NY 10038
212-936-5100

General Counsel

Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, MA 02109
617-526-6000

Auditors

Ernst & Young LLP
200 Clarendon Street
Boston, MA 02116
617-266-2000

Annual Meeting

The Annual Meeting of Stockholders will be held at 9:00 AM on May 10, 2007, at Wilmer Cutler Pickering Hale and Dorr LLP, 60 State Street, Boston, MA 02109.

This Annual Report to stockholders contains forward-looking statements that are subject to risks and uncertainties, including statements regarding expected future business, financial and operating performance and results. There are a number of important factors that could cause BioSphere's actual results to differ materially from such forward-looking statements, including, without limitation, those set forth under the heading "Risk Factors" in BioSphere's Annual Report on Form 10-K for the fiscal year ended December 31, 2006, which is filed with the Securities and Exchange Commission. These statements should not be relied upon as representing BioSphere's expectations of beliefs as of any date subsequent to the date of the Annual Report.

BioSphere™
Medical

www.biospheremed.com

www.ask4ufe.com

Corporate Headquarters
BioSphere Medical, Inc.
1050 Hingham Street
Rockland, MA 02370
USA
800.394.0295

European Headquarters
BioSphere Medical, S.A.
Bat A - Parc des Nations
Paris Nord 2
383, rue de la Belle Etoile
BP50289 Roissy en France
95958 Roissy CDG Cedex
France
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