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BioSphere Medical, Inc.

Annual Report 2007

BioSphere Medical

we will strive to continue to communicate these key messages directly to IRs and expect it will positively affect our efforts to increase the growth of the market. As noted above, in an increasingly cost-competitive health care environment, hospitals are becoming more inclined to adopt and promote new procedures that provide therapeutic benefit and deliver an attractive margin. Higher reimbursement for UFE could elevate the stature of IRs within the hospital setting, increasing their influence when seeking resources to build a women's health practice, including admitting privileges, human and space resources to manage and consult with patients, and discretionary marketing resources.

Gynecologists

In 2007 we redefined and we believe significantly enhanced our strategy to communicate to and educate ob/gyns about UFE. Ob/gyns are the treatment gatekeepers for a majority of women in the U.S., and thus we believe that a key focus for us should be educating these physicians about UFE and the benefits of collaborating with their IR colleagues. We have developed several tools to take the UFE message directly to gynecologists by gynecologists. In particular, we are promoting the clinical data supporting UFE as a frontline treatment option, and emphasizing analyses of the substantive economic benefit we believe an ob/gyn gains by working collaboratively with an IR, resulting in increased referrals for gynecology services, as well as emphasizing the lifetime value of a satisfied patient to an ob/gyn practice. We believe that as we seek to saturate this important physician specialty with the latest information, they will be better equipped to discuss with their increasingly better-informed patients how UFE fits into the fibroid treatment algorithm. Consequently, we expect our promotion activities aimed at gynecologists could, over time, increase the number of UFE procedures.

Patients

With an estimated five million women in the United States suffering from symptomatic uterine fibroids, and more than 500,000 of them receiving some form of procedural intervention, we believe that the demand for uterine-sparing UFE will continue to grow. Even a modest penetration of the market has the potential to yield substantial results. As noted in last year's letter, a November 2006 *Wall Street Journal* article reinforced our belief that women are becoming increasingly aware of their treatment options for symptomatic uterine fibroids. This article featured the findings of a survey BioSphere developed in partnership with The National Women's Health Resource Center, which found 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. In order to more effectively and efficiently reach this patient population, we have engaged a service provider with a successful track record of finding and connecting with targeted patients, assessing them based on predetermined geographic, psychographic, and other screening criteria, scheduling them with select physicians, and tracking and managing patient and physician interactions. We expect that as this multipronged initiative gets fully implemented, the number of UFE procedures in these markets will increase.

Sales Force

We must have adequate resources in the field to execute our strategies. Our current expansion of the U.S. sales force is the second such increase and third evolution of our sales organization in as many years. Approximately one year after our first expansion in 2005-06, our sales territories generated average annual revenues in excess of $1 million. These sales professionals did an excellent job at competitive product conversions. We are now focused on market growth and expansion. We believe that the combination of the new strategies we have developed for 2008 along with a larger sales force has the potential to positively impact revenues, and allow us to create new therapeutic demand for UFE and our suite of embolic products.

DuPont

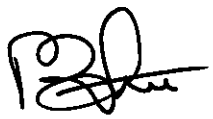
In December 2007, we announced a strategic collaboration agreement with DuPont Applied BioSciences under which the companies intend to evaluate potential peripheral vascular and embolotherapy research, development, and manufacturing engineering projects. The agreement establishes a nonbinding framework for the parties to consider and evaluate potential projects that target and deliver leading-edge solutions in embolotherapy. We believe that our collaboration agreement with DuPont has the potential to significantly impact BioSphere's future. We believe that our pipeline of, and applications for, BioSphere's proprietary microspheres have the potential to continue to evolve beyond the current therapeutic focus of interventional gynecology and interventional oncology. To that end, BioSphere and DuPont are working together to explore ways to potentially improve all aspects of our technology and processes, which, in turn, we expect could enhance the efficiency of our operations and operating results. In the coming months, we expect to move toward initiating key potential new product projects with DuPont that we believe can address the unmet needs of our customers and their patients whom we mutually serve, and increase shareholder value.

Interventional Oncology

Our interventional oncology franchise accounted for approximately 17% of our sales in 2007, up from 14% in 2006. United States and international embolic revenues grew by 41% in 2007. Our embolic products are cleared for sale in select geographies throughout the world, and are used by physicians for several clinical applications, including treating patients with hypervascularized, malignant tumors. The treatment of cancer patients with hypervascularized malignant tumors by image-guided embolization is evolving. Oncologists and interventionalists may seek to reduce tumor progression by "bland embolization" or "chemoembolization." Bland embolization is performed without adjunctive local chemotherapy. Chemoembolization is performed by injecting the local chemotherapeutic agents directly into the arterial supply of the tumor(s) followed by targeted embolization. Some physicians believe this procedure allows the dosage of the chemotherapeutic agent to be increased up to 20 to 200 times greater than if the chemotherapy was administered systemically. The dwell time of the chemotherapeutic agent is also thought to be increased. The side effects of chemoembolization have been demonstrated to be less severe than systemic chemotherapy due to the fact that the drugs are trapped locally and not circulated throughout the body. In the last few years, chemoembolization has been evolving into "drug-eluting chemoembolization" — the loading of drugs directly in or on the embolic. We are closely monitoring ongoing clinical studies of drug-eluting chemoembolization for the treatment of primary liver cancer, specifically those studies involving doxorubicin and our HepaSphere Microspheres. We believe this therapy, which is currently approved in territories outside of the U.S., but not yet approved in the U.S., would offer a new therapeutic alternative and new opportunities for revenue growth worldwide.

We believe that as we enter 2008, BioSphere Medical is in the best position in its history. We have a dominant position in UFE, a growing position in interventional oncology, an expanding global presence in select geographies, promising opportunities that we will seek to exploit through our collaboration with DuPont, and at present, the financial resources to pursue our current goals. To be sure, we have faced challenges this past year, but these have been opportunities to build the character of our organization. Acknowledging challenges and working to redirect our strategies to overcome hurdles is a testatment to the strength of our organization and I commend all of our employees for their many contributions. Together we are committed to increasing the value of our products and our practice-building expertise for our customers, and increasing the value of BioSphere Medical for 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

Letter to *Shareholders*

Dear BioSphere Shareholders:

Overview

For the third consecutive year, BioSphere Medical grew annual revenues, increased its gross margin, and narrowed its net loss. Revenues increased 18% to $26.9 million in 2007 when compared to 2006, driven by higher annual sales in each of our global geographies. Consolidated gross margin rose to 71% from 70% in the prior year, and our net loss narrowed to $2.4 million, or $0.14 per share. We achieved positive operating cash flow in 2007, and ended the year in a financial position that we believe was among the strongest in our history, highlighted by cash, cash equivalents, and marketable securities of $23.6 million.

In 2007, we were the beneficiary of new, published clinical studies that further demonstrated the safety, efficacy, and durability of uterine fibroid embolization ("UFE") and our Embosphere® Microspheres. We also expect to benefit from a decision made by the Centers for Medicare and Medicaid Services ("CMS") announced in November 2007 that reassigned UFE to a new Ambulatory Payment Classification code that significantly increased reimbursement for UFE in the **hospital outpatient setting**, effective January 1, 2008.

Most importantly, we were proactive in taking the steps we believe are necessary to achieve our goal of accelerating growth in 2008 and beyond, and to further advance embolotherapy as a first-line treatment modality for selected applications. We commenced the expansion of our U.S. sales force from 18 to 24 territories and from three regions to four toward the end of 2007, and nearly completed this expansion by the end of March 2008. We significantly strengthened our management team with the hiring of seasoned, functional executives in the areas of marketing and sales, regulatory, medical affairs and quality, and new product and business development. We obtained important regulatory clearances for our interventional oncology products, including the CE Mark for Transarterial Chemoembolization of Hepatocellular Carcinoma using HepaSphere™ Microspheres and doxorubicin, and approval in Brazil for HepaSphere Microspheres for clinical use in the treatment of primary and metastatic liver cancer. In early 2008, the State Food and Drug Administration of the People's Republic of China approved Embosphere Microspheres for clinical use for vascular embolizations, arteriovenous malformations, hypervascularized tumors, and symptomatic uterine fibroids, and we commenced shipment to China in March 2008. We also entered into a strategic collaboration with the Applied BioSciences group at DuPont, a relationship which we believe has the potential to increase our pipeline of new product candidates.

Market Leadership, Targeted Expansion

Based on the aforementioned achievements in 2007, the year just ended was, in many respects, the most successful and important in our history. As an organization we are very proud of our accomplishments. And, we remain confident about our long-term prospects and success. But, some trends in 2007 — particularly the slowing growth in U.S. UFE sales — were in fact disappointing. We believe that the primary reason for this slowdown was the large reduction in **physician** reimbursement that took effect January 1, 2007. We think this reduction rippled through the interventional radiology community and temporarily dampened physicians' interest in investing the time and other resources required to grow their UFE practices. While the large majority of interventional radiologists ("IRs") who performed UFE procedures prior to this change in reimbursement continued doing so, practice growth slowed.

Although UFE physician reimbursement declined in absolute dollars, the procedure remained, and is still, one of the most financially attractive for IRs to perform, as measured by revenue dollars per minute. So, we worked to take this message directly to the IRs during 2007, and we believe we enjoyed increasing success as the year progressed. However, the early headwinds created by this change were difficult to overcome during the year and we didn't see many signs of change until late in the year — too late to affect our 2007 results. But going forward, we do expect to see increasingly better growth in 2008.

Concurrent with our direct campaign to IRs in the U.S., we also reengineered other key marketing and sales strategies in order to accelerate growth of UFE in the U.S. in 2008. We believe the resulting programs are more robust and are designed to better promote minimally invasive, uterus-sparing UFE to our four key constituents — hospitals, IRs, gynecologists, and women with symptomatic fibroids. Thus, we are implementing a new, data-driven marketing and sales strategy in partnership with successful IRs, high-volume referring gynecologists, hospital administrators, reimbursement experts, the Society of Interventional Radiology ("SIR") and service providers skilled at educating physicians and targeting and channeling patients to appropriate physicians. This fresh approach is being funded primarily by a reallocation of resources that had been earmarked for our prior programs.

Below are the highlights of our new approach regarding each of our constituencies:

Hospitals

Effective January 1, 2008, CMS increased the hospital outpatient reimbursement for UFE by 113%. UFE can be performed in an angio suite and typically requires a patient stay of less than 24 hours; more invasive procedures, such as hysterectomy and myomectomy, are performed in an operating room, which is a higher cost venue, and generally require a longer in-hospital stay. Based on our analysis of representative data following the CMS increase, we believe that UFE provides hospitals a potentially large service-line expansion opportunity that can achieve a significantly higher contribution margin than hysterectomy or myomectomy. In addition, because of UFE's lower costs, this increase in contribution margin can generally be achieved without constructing new facilities, purchasing additional capital equipment, or making other expensive or time-consuming capital investments. Thus, we believe we have a compelling new message to convey to service-line and hospital administrators. So far, we believe this message is being well received, and we expect that the utilization of UFE may increase as a result of our ongoing communication campaign. In addition, the SIR has recently partnered with The Advisory Board Company, a well-respected consultancy serving the CXO's of the leading hospitals in the U.S., to communicate the value of interventional radiology procedures and economics to hospitals. We believe that campaigns directed to administrators by us and the SIR reinforce a similar message and provide hospitals with a compelling clinical proposition for patients that is supported by attractive economics. In today's health care environment, that combination is rare.

Interventional Radiologists

Although physician (not hospital) reimbursement for UFE declined in 2007, the reimbursement for UFE on a revenue-per-minute basis exceeds other IR procedures by as much as 60%. Thus, we believe that UFE remains a financially attractive procedure for IRs, is clinically satisfying to perform, and has the potential to be a cornerstone for an IR's women's health service franchise. In 2008

"UFE is an important option for patients, and great for the hospital's bottom line. Patient stays are shorter, costs are lower than with surgical alternatives, and success rates are excellent."

Cassandra *Earley*

Hospital Administrator

"The success of my UFE practice depends on my strong relationships with gynecologists. I find that they're very willing to work with me to determine the best treatment option for their patients who suffer from fibroid symptoms."

Gary *Siskin* *MD*

Professor and Chairman, Department of Radiology
Professor of Obstetrics and Gynecology
Albany Medical Center

"Our local interventional radiologist and I have collaborated on a treatment algorithm so we both understand which patients are best served with UFE and those who are best served with surgery. For many of my fibroid patients, UFE is the best choice and when I refer a patient, I am confident that she will be in good hands."

Robert K. *Zurawin* *MD*

Associate Professor of Obstetrics and Gynecology
Baylor College of Medicine

"I couldn't be more satisfied with the results of my UFE. I had the procedure done on a Thursday, and I was hanging new cabinets in my kitchen the next Tuesday. And now, two years later, I am still free of fibroid symptoms."

Mary *Successfully treated with UFE in 2005*

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, 2007

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	**04-3**[illegible]**867**
(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, a non-accelerated filer or a smaller reporting company. See definition of "large accelerated filer," "accelerated filer," and "smaller reporting company" in rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐	Accelerated filer ☐	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	Smaller reporting company ☒

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 29, 2007, was $70,723,522 based on the closing price of the common stock as reported on the NASDAQ Global Market as of such date.

The Registrant had 18,296,834 shares of common stock outstanding as of March 1, 2008.

Documents incorporated by reference:

Portions of the information required by Part III of Form 10-K will appear in the registrant's definitive Proxy Statement on Schedule 14A for the 2008 Annual Meeting of Stockholders and are hereby incorporated by reference into this report.

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 revenue, 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; any statements about our expectations regarding market acceptance and market penetration for our products and product liability challenges with respect to 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 that use embolotherapy. 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 or destroy 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 of medical science, engineering principles and manufacturing methods. These core technologies are used to produce miniature spherical embolic particles, or microspheres, that are designed to have uniquely beneficial properties for a variety of medical applications.

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. Additionally, we offer these products to clinicians in calibrated size ranges so they can be selected to target occlusion of specific sized vessels. The use of appropriately sized microspheres is designed to produce predictable results and optimize therapeutic benefit.

Our principal focus is the treatment of symptomatic uterine fibroids, which are noncancerous, or benign, hypervascular 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. We believe that the selection of our Embosphere Microspheres product is gaining market acceptance in this procedure.

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 within the medical community there has been increased acceptance of UFE as an effective alternative for patients who are on drug therapy or are considering undergoing surgery, such as hysterectomy or myomectomy, for treatment of their uterine fibroids. As such, we anticipate that the number of UFE procedures will continue to increase. We were the first company to gain regulatory clearance to market a product for UFE in the United States. Over the past three years, we have focused on growing our Embosphere Microsphere business through the development of physician referral networks and patient awareness programs. We intend to 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 other hypervascularized tumors, such as primary liver cancer tumors. In November 2004, we received CE Mark approval to market our HepaSphere™ Microspheres in the European Union for the treatment of primary and metastatic liver cancer and in November 2007 we received CE Mark approval for transarterial chemoembolization, or TACE, of liver cancer using HepaSphere Microspheres and doxorubicin, an anticancer drug. CE Mark approval denotes conformity with European standards for safety and allows certified devices to be placed in the market in European Union countries. TACE refers to a two-stage process involving the injection of a concentrated dose of chemotherapeutic drugs, such as doxorubicin, directly into the blood vessels supplying a tumor, followed by the infusion of an embolic agent through a catheter and into the blood vessels that feed the tumor, thus selectively blocking its blood supply. In connection with the CE Mark approval of our HepaSphere Microspheres we intend to conduct a 100-patient, post-market study in 10 to 15 European centers. 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 been granted a worldwide exclusive royalty bearing license to make, use, sell and import HepaSphere Microspheres by its inventor, Dr. Shinichi Hori. 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 January 2008, the Medical Device Department of the State Food and Drug Administration of the People's Republic of China approved our Embosphere Microspheres for clinical use for vascular embolizations, arteriovenous malformations, hypervascularized tumors, and symptomatic uterine fibroids.

We believe that our microsphere technologies may have non-embolotherapy uses, including tissue bulking, for the treatment of gastroesophageal reflux disease and for use in cosmetic dermatology. We have a number of patent applications and 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, as such, we are not currently devoting significant resources to research in these areas, 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, Massachusetts 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 an Internet web site with the address www.biospheremed.com. We are not including the information contained in our web site 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 web site 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. Our code of business conduct and ethics and the charters of the audit committee, compensation committee, and nominating and corporate governance committee of our board of directors are all available on the corporate governance section of our web site. Stockholders may request a free copy of any of these documents by writing to Investor Relations, BioSphere Medical, Inc., 1050 Hingham Street, Rockland, Massachusetts, U.S.A. 02370 or submitting a request through the web site.

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. A hysterectomy may be performed as an open surgery with or without robotic assistance or as a laparoscopic procedure. 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 may mean 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.
- **Drug Therapy and "Watchful Waiting."** Drug therapies include nonsteroidal 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 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. Primary liver cancer is typically diagnosed at a stage that is too advanced to cure surgically. 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 or breast, 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 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.

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, Australia and 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 and Brazil
HepaSphere Microspheres	Transarterial chemoembolization, or TACE, of hepatocellular carcinoma in combination with doxorubicin.	European Union
QuadraSphere Microspheres . . .	Hypervascularized tumors and arteriovenous malformations	United States
Delivery System Products:		
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
Segway Guidewire	Peripheral embolization procedures	United States, Canada, European Union, Argentina, Brazil, Costa Rica, Panama and China

Embosphere Microspheres

Our Embosphere Microsphere and EmboGold Microsphere products are intended for use in embolotherapy to block or control the blood supply to certain tumors and other vascular malformations.

We believe that UFE will remain the principal application for our microsphere products for the foreseeable future. The majority of our revenue is 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 report that they 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 these 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 Microsphere product contains a product enhancement that 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 because of reports in 2003 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. 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, if at all.

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 four 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 the fourth quarter of 2007, we received CE Mark approval for transarterial chemoembolization, or TACE, of hepatocellular carcinoma, or primary liver cancer, using HepaSphere Microspheres and doxorubicin, an anticancer drug. Interventional Radiologists in the European Union who chose TACE for their patients with HCC, or primary liver cancer, now have alternative treatment options with our embolics: they may use either a drug-loaded embolic, HepaSphere Microspheres, or Embosphere Microspheres, in a conventional TACE protocol. TACE is a two-stage process involving the injection of a concentrated dose a of chemotherapeutic drug, such as doxorubicin, directly into the blood vessels supplying a tumor, followed by the infusion of an embolic agent through a catheter and into the blood vessels that feed the tumor, thus selectively blocking its blood supply. Because the blood vessels are blocked with embolic material, the chemotheraptic drug is thought to dwell in direct contact with the tumor longer and target the tumor more effectively than a systemic chemotherapeutic treatment would. Thus, with chemoembolization the drug concentration has been measured to be 20 to 200 times greater within the tumor, compared to chemotherapy administered systemically. The side effects of chemoembolization have been observed to be less severe than the standard systemic chemotherapy because chemoembolization is designed to trap the drug in the liver rather than allowing it to circulate throughout the body. TACE using HepaSphere loaded with doxorubicin is believed to further concentrate the chemotherapeutic drug's effect by embolizing the target tissue and delivering the drug over an extended time frame. As a follow-up to our CE Mark approval for TACE using HepaSphere Microspheres loaded with doxorubicin, we intend to conduct a 100-patient, post-market registry study in ten to 15 European centers.

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, for the treatment of hypervascularized tumors and arteriovenous malformations, does not include specific indications for the treatment of primary and metastatic liver cancer. The FDA requires 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 four 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, and coating technology to

the product lines. These products were also 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 other 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 interventionalists with characteristics such as:

- a durable atraumatic polymer tip that is designed to reduce the risk of vascular spasm but retain 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 9% and 11% of our revenue in 2007 and 2006, respectively, from these nonstrategic products, we expect these products to be a less significant component of our sales in 2008 as we intend to phase out of this nonstrategic business in 2008.

MANUFACTURING AND SUPPLY

We currently produce and package all of our microsphere products at our facility located in Roissy, France. Manufacturing of our 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 the EmboCath Plus Infusion Microcatheter, Segway Guidewire and Sequitor Steerable Guidewire are all accomplished by medical device contract manufacturers in both the United States and Europe. We currently purchase key components and services with respect to our microspheres, catheters and guidewires from approximately ten third-party vendors, including third-parties from whom we purchase guidewires for our Segway Guidewire product; catheters for our EmboCath Plus Infusion Microcatheter product; and guidewires for our Sequitor Steerable Guidewire product.

MARKETING AND SALES

We currently market our embolotherapy and delivery systems products through a direct sales force covering 24 territories in the United States and two territories in France and through distributors in Europe, Asia, Canada, the Middle East, Africa, South America and other parts of the world. Approximately 86% of our product revenue was generated through our direct sales force in 2007.

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, practice building, 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 2007. Our principal source of revenue in each of the last three fiscal years was from sales of our microspheres products. For the years ended December 31, 2007, 2006 and 2005, revenue from the sale of our microspheres products accounted for 85%, 85% and 83% respectively, of our total revenue.

RESEARCH AND DEVELOPMENT

Research and development expenses as a percentage of total revenue for the years ended December 31, 2007, 2006 and 2005 were 9%, 10% and 13%, respectively. Research and development expenses in these periods relate primarily to:

- research to identify and evaluate new and innovative embolotherapy products based on our platform microsphere technology, including our Resorbable Microsphere and our MR Microsphere product candidates, both of which are in preclinical development;
- further preclinical testing and clinical trials to support initial and/or additional marketing approvals for our Embosphere Microspheres, HepaSphere Microspheres, QuadraSphere Microspheres, Sequitor Steerable Guidewire and EmboCath Plus Infusion Microcatheter, all of which products are currently approved and marketed in specified indications and in specified geographic locations; and
- improving our manufacturing processes for our currently marketed products.

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.

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. We are aware of other companies with active development programs for embolics targeted to uterine fibroid applications. CeloNova, a U.S. company, currently markets an embolic product in Europe that is being used for UFE procedures. CeloNova's embolic is not yet approved for use in any application in the U.S. 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.

UFE competes with other treatments that are used to address symptoms related to fibroids. Endometrial ablation is a technique for addressing excessive uterine bleeding (menorrhagia) in women. Endometrial ablation is not indicated for use in treatment of fibroids; however, obstetricians and gynecologists may use this procedure to resolve symptoms secondary to fibroids. Robotic surgery is an option that offers a less invasive alternative to a full surgical hysterectomy. These procedures require purchase of an expensive piece of equipment and disposables required for the procedure,. Although robotic surgery generally requires a smaller incision and therefore reduced time for healing, these procedures are still a surgical procedure requiring the removal of either the tumor or entire uterus.

In the United States our QuadraSphere Microspheres product competes with Biocompatible's LC bead. Biocompatible's LC bead is distributed by AngioDynamics. Market clearance for both our QuadraSphere Microspheres and Biocompatible's LC bead in the United States is for the treatment of hypervascularized tumors and arteriovenous malformations.

In drug delivery microspheres our primary competition in Europe is Biocompatibles. In Europe we have CE Mark approval for HepaSphere Microspheres for drug delivery for hepatocellular carcinoma. Biocompatibles in Europe has CE Mark approval for DC bead.

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 the Quality System Regulation (21CFR Part 820).

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 Practice / Quality System Regulation and Reporting. The Federal Food, Drug, and Cosmetic Act requires us to comply with Current Good Manufacturing Practice 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 Practice / Quality Systems Regulation 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 Practice 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, withdrawal of market clearance or approval, injunctions, product 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 health-care program Anti-Kickback Statute prohibits persons from, among other things, knowingly and willfully offering or paying remuneration, directly or indirectly, to a person to induce the purchase, order, lease, or recommending of a good or service for which payment may be made in whole or part under a federal health-care 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 intended 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 health-care programs, the statute has been violated. The law contains several 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 health-care programs. Exclusion of a manufacturer would preclude any federal health-care program from paying for its products. In addition, some courts have held 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 health-care 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, 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 health-care 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 pharmaceutical, medical device, and other health-care 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 health-care 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 anti-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 health-care 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 associate 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 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 agreement or provisions where appropriate. We have implemented a patent strategy designed to maximize our intellectual property rights. We are pursuing patent rights 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-Hôpitaux de Paris, referred to as AP-HP, pursuant to which AP-HP has granted us the exclusive license to 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 of 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-based license to Japanese patent rights relating to our HepaSphere Microsphere product. These patent rights expire in 2012. We continue to develop this technology and related 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 this technology and any licenses, if obtained, may not be on terms that are favorable 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 technologies and uses thereof. For example, we have at least five U.S. and eleven foreign patents, and five U.S. and five 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 U.S. and foreign counterpart patents expire at various dates between 2019 and 2020. We also have ten issued foreign patents and at least four U.S. and four 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 U.S. applications or U.S. patents, or that a third party will not oppose any granted patent in Europe. There can be no guarantee that a third party will not file an opposition or the like against any of our foreign patents or pending patent applications. 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 the 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 a 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 filed a response to the Notice of Opposition in August 2005. Biocompatibles UK Limited subsequently filed a response in 2006. On December 10, 2007, the European Patent Office upheld the claims of our patent in amended form. The European Patent Office rendered its formal written decision on December 27, 2007. We and Biocompatibles have appealed this decision. We intend to continue defending our European PVA patent. While we are not able to predict the outcome of this proceeding, it will not impact our ability to sell our Embosphere Microsphere or HepaSphere Microsphere products in Europe.

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.

SEGMENT INFORMATION

We develop microspheres and other ancillary embolotherapy products for use in the treatment of uterine fibroids, other hypervascularized tumors and arteriovenous malformations. We operate exclusively in the medical devise business, which we consider as one business segment pursuant to Statement of Financial Accounting Standards No. 131, "*Disclosures About Segments of an Enterprise and Related Information*." Further segment information can be found in Note 11 of the notes to our consolidated financial statements, included elsewhere in this annual report on form 10-K.

EMPLOYEES

As of December 31, 2007, we had approximately 80 employees. Of these employees, five are primarily engaged in research, development and clinical activities, 24 are engaged in manufacturing, 39 are engaged in sales and marketing, and the remainder are engaged in finance and administration. Of these 80 employees, 44 are located in the United States and 36 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, 2007, had an accumulated deficit of approximately $84.06 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 2008, 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 2008.

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

- produce and manufacture our products;
- expand our United States sales force;
- 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 ongoing 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, unanticipated changes in the amount of revenue 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; the outcome of product liability challenges, including the current product liability lawsuit described below under "Item 3—Legal Proceedings," for which any adverse judgment against us may not be adequately covered by product liability insurance; 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 may also need

additional funds for possible strategic acquisitions of synergistic businesses, products and/or technologies.

We will require substantial additional cash to fund our planned, and any unplanned, near- and long-term expenses. If adequate funds are not available, we could be required to reduce our capital expenditures, scale back or eliminate some or all of our research, development, sales and marketing initiatives, reduce our workforce, and license to others products or technologies that we otherwise would seek to commercialize ourselves. We may seek additional funding through a combination of collaborative arrangements, debt financing, or the sale of additional equity securities. We may not receive such additional funding on reasonable terms, or at all. Any sales of equity or debt securities are likely to dilute our existing stockholders, and the new securities may have rights, preferences or privileges senior to those of existing holders of our capital stock. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or products, or grant licenses on terms that are not favorable to us.

If our 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;
- the introduction or announcement of competitive products;
- regulatory approvals;
- product recalls;
- successful product liability challenges against our products;
- turnover in our direct sales force;
- the timing and amount of expenses;
- timing of orders by our distributors;
- the effectiveness of new marketing and sales programs;
- changes in management;
- negative publicity; and
- general economic conditions.

In addition, a large portion of our expenses, including expenses for facilities, equipment and personnel, are relatively fixed. Accordingly, if our revenue declines or does not grow as much as we anticipate, we might not be able to improve our operating margins. Failure to achieve anticipated levels of revenue could therefore significantly harm our operating results for a particular fiscal period. 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.

Compliance with changing regulation of corporate governance and public disclosure as well as potential new accounting pronouncements are likely to impact our future financial position or results of operations.

Changing laws, regulations and standards relating to corporate governance and public disclosure, new SEC regulations and NASDAQ Global Market rules are creating uncertainty for companies such as ours. These new or changed laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. In addition, future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our financial position or results of operations. New accounting pronouncements and varying interpretations of pronouncements have occurred with frequency in the past and may occur again in the future and as a result we may be required to make changes in our accounting policies, for example the 2006 requirement under Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment* to expense stock options.

Our efforts to comply with evolving laws, regulations and standards have resulted in, and are likely to continue to result in, increased general and administrative expenses and management time related to compliance activities. We expect these efforts to require the continued commitment of significant resources. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, our reputation may be harmed and we might be subject to sanctions or investigation by regulatory authorities, such as the SEC. Any such action could adversely affect our financial results and the market price of our common stock.

Failure to maintain effective internal controls in accordance with section 404 of the Sarbanes-Oxley act could have a material adverse effect on our business and stock price.

Section 404 of the Sarbanes-Oxley Act of 2002 requires management's annual review and evaluation of our internal controls, and we expect will require attestation of the effectiveness of our internal controls by our independent auditors beginning as early as the fiscal year ended December 31, 2008. This process could require us to implement significant measures to improve our internal controls, may require us to hire additional personnel and outside advisory services and will result in significant accounting and legal expenses. Any failure by us to maintain effective internal controls could have a material adverse effect on our business, operating results and stock price.

Changes to our performance in each jurisdiction in which we operate, resulting from either changes in our business or as a result of routine tax audits, could materially impact our deferred tax asset or could materially impact our future financial position or results of operations.

We use 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 in each tax jurisdiction in which we operate. 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. Due to the size of the net operating loss carryforward in relation to our history of unprofitable operations, we have not recognized any of our net deferred tax assets. However, future improvements in operational performance, while not guaranteed, could result in increased certainty of our ability to apply deferred tax assets against taxable income, which could, in turn, result in a significant impact on the value of our deferred tax assets and reported operating results.

Risks Relating to Our Industry, Business and Strategy

A significant portion of our revenue is derived from sales of our Embosphere Microspheres for UFE, and if we do not successfully commercialize and achieve widespread market acceptance of our Embosphere Microspheres for UFE, our business will be materially harmed and our stock price will decline.

The majority of our revenue in the United States for the year ended December 31, 2007, was derived from the sale of Embosphere Microspheres for use in UFE. Our principal business focus is to grow our embolotherapy business through increases in the utilization rate for UFE procedures verses other procedures to treat uterine fibroids and in the employment by medical providers of our Embosphere Microspheres in such procedures in lieu of competing products. We began marketing and selling Embosphere Microspheres for UFE in 2002, but to date we have not achieved widespread market acceptance for our products. Our ability to grow our product revenue is substantially dependent upon growth in UFE procedures and our ability to achieve widespread acceptance of the use of Embosphere Microspheres for the treatment of UFE. If growth in UFE procedures does not occur and if we do not achieve such market acceptance, our product revenue, and our prospects for future profitability and success will be materially adversely affected. We face a number of significant risks relating to our ability to successfully commercialize Embosphere Microspheres for use in UFE, including risks relating to:

- our ability to successfully market and sell Embosphere Microspheres for use in UFE with our limited sales force;
- the success of our sales and marketing strategies for Embosphere Microspheres for use in UFE, including our ask4UFE campaign, in which we are seeking to increase awareness among patients, referring physicians, interventional radiologists and third-party payers of UFE as an alternative treatment for fibroids;
- our ability to recruit and train our sales force and the effectiveness of our sales force in influencing referral behavior with gynecologists and other health care providers;
- favorable reimbursement treatment from government and third-party insurers for our Embosphere Microspheres for UFE;
- long-standing use of other treatment options for uterine fibroids;
- our ability to gain market acceptance of Embosphere Microspheres as a safe, effective and medically necessary treatment for UFE;
- the availability of substantial amounts of cash to fund our commercialization plans;
- competitive factors;
- our ability to effectively develop adequate marketing, manufacturing, and distribution capabilities;
- our ability to maintain the necessary patent protection and regulatory approvals required to market and sell Embosphere Microspheres for UFE; and
- the various other factors discussed in detail throughout this section titled "Risk Factors."

If the market concludes that our products are not safe or effective, we will not achieve widespread market acceptance of our microsphere products, and our business prospects will be seriously harmed.

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 UFE. We began to market and sell our HepaSphere Microspheres in the

European Union in the fourth quarter of 2005 and received marketing clearance from the FDA for our QuadraSphere Microspheres in November 2006. Although we have been selling and marketing our microsphere products since 2000 and our Embosphere Microspheres for specific use in UFE procedures since 2002, we have not achieved widespread market acceptance for our products. 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 products may not gain widespread market acceptance for a variety of reasons including:

- 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.
- To use our microspheres correctly for a particular medical procedure, trained physicians must correctly evaluate the subject vasculature, select and use the proper size and quantity of the product and carry out appropriate placement of the product. Physician error could potentially have significant adverse health effects on the patient, including death.
- 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.
- 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.
- Product liability claims could create a perception that our products are unsafe. For example, in August 2005 we were named as a defendant in a product liability lawsuit in which the plaintiff claims that he was rendered blind in both eyes as a result of the use of our EmboGold Microspheres or the negligence of the health-care providers or both factors combined. See "Risk Factors—We are a defendant in a product liability lawsuit, the outcome of which is uncertain, could result in a judgment substantially in excess of our product liability coverage and could harm our business, reputation and financial condition."
- Many health care providers, including obstetricians and gynecologists, use other forms of treatment for patients with uterine fibroids that do not require referral to an interventional radiologist.
- We have only recently received approval to use our HepaSphere Microspheres to treat liver cancer using procedures such as targeted liver embolotherapy and transarterial chemoembolization. Physicians may not use our product for such procedures until further clinical data demonstrate its safety and efficacy as compared to other treatments. Physicians may also not elect to use our HepaSphere Microspheres to treat liver cancers for a number of other reasons, including, without limitation, unfavorable reimbursement, the effectiveness of our competitors in marketing their products, and our failure to convince physicians that our HepaSphere Microspheres have greater benefits than existing products or therapies.

Other factors could also affect market acceptance of our products, including, without limitation, the introduction of competing products, unfavorable reimbursement from third-party payers, safety concerns with similar products marketed by others, ineffective sales, marketing and distributions support and significant warranty claims.

If our products fail to achieve widespread market acceptance we will not be able to grow our revenue and achieve profitability, which would adversely affect our business prospects and cause our stock price to decline.

If gynecologists, obstetricians, interventional radiologists and other health-care providers do not recommend and endorse our products, and if health-care providers do not make the necessary referrals to interventional radiologists who administer our embolotheraphy products, our sales may decline or we may be unable to increase our sales and profits.

Our ability to establish and maintain favorable relationships with gynecologists, obstetricians, interventional radiologists and other health-care providers is critical to our continued growth. We believe that the success of these relationships is, and will be, based on, among other things, the quality of our products, such providers' perceptions concerning our 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 health-care professionals and cause our growth to be limited and our business to be harmed.

In order for us to sell our products, health-care professionals must recommend and endorse them. For example, our embolotherapy techniques are administered by interventional radiologists. In the treatment of uterine fibroids, we believe that the UFE procedure utilizing our Embosphere Microspheres has 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 revenue is from the sale of our Embosphere Microspheres for UFE and, 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. We have not achieved widespread market acceptance for our products. Acceptance of our products, and our ability to obtain the necessary endorsements and referrals, depend 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 health-care 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 health-care 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 and growing the sales, distribution and marketing capabilities necessary to successfully commercialize our products, we will have difficulty maintaining and seeking to increase our sales.

We continue to develop sales, distribution and marketing capabilities primarily in the United States, the European Union, Asia and South America to promote UFE awareness and the benefits of our product for the treatment of uterine fibroids. It has been, and we expect it will continue to be, expensive and time-consuming for us to seek to develop a global sales and marketing force. At December 31, 2007, we had a sales and marketing force of 39 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 incentives to maintain our sales and marketing force or to attract new sales and marketing personnel 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 ensure 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 39 third-party distributors and we may choose, or find it necessary to enter into additional third-party agreements to sell, distribute or market our products in the future. Any third party with whom we have established a sales, distribution and/or marketing relationship may not devote sufficient time to the marketing and sales of our products, thereby adversely affecting our planned revenue and exposing us to potential expenses in terminating such distribution agreements. 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 may not achieve profitability and our stock price could decline.

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, including, without limitation, our product candidates, MR Microspheres and Resorbable Microspheres, both of which are still in preclinical development. Our products under development 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, as well as 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.

If we do not develop and introduce new products, our business may not grow and our future prospects may be adversely affected.

We derived approximately 9% of our revenue for the period ended December 31, 2007 from the sale of nonstrategic medical products that we expect will constitute a declining portion of our revenue on an ongoing basis as we intend to phase out of this business in 2008. 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, a portion of our revenue for the year ended

December 31, 2007 was 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. Accordingly, in order to grow our revenue in future periods 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, our position in, and share of, the markets in which we participate and our business, financial condition, results of operations or future prospects may be adversely affected.

We are a defendant in a product liability lawsuit, the outcome of which is uncertain, could result in an adverse judgment substantially in excess of our product liability coverage and could harm our business, reputation and financial condition.

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 case is presently set for trial on October 27, 2008. The lawsuit alleges, among other things, that a patient suffered permanent bilateral blindness as a result of the use of our EmboGold Microspheres or the negligence of the health-care providers or both factors combined. Plaintiffs seek compensatory and punitive damages. Although we currently maintain product liability insurance coverage, certain claims asserting medical product liability have in the past resulted in substantial damages awards for plaintiffs. As such, our insurance may not cover, or provide us with adequate coverage against, a judgment against us. For example, although our product liability insurer has agreed to vigorously defend us with regard 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 our coverage. Our insurer has also advised us that it does not waive any other defenses to coverage that may apply. Moreover, our insurance is subject to a cap on the maximum amount our insurer is required to pay.

We cannot predict the outcome of this matter, including whether we may prevail in the trial. If we do not prevail in this matter, we could be required to pay substantially more in damages than the amount we may seek to recover from our product liability insurer, which would have a material adverse effect on our financial condition, results of operations and liquidity. Moreover, an adverse outcome could harm our reputation and market acceptance of our products.

We may be exposed to product liability claims, and if we are unable to obtain or maintain adequate product liability insurance, then we may incur substantial costs and expenses in defending such claims and 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 physicians do not use our products properly, 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 such as the Pingel Claim described above. 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 not covered in whole or in part by our insurance or 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.

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.

If we are required to recall any of our products we may experience a decrease in the market acceptance of our products and our reputation may be harmed, hindering our ability to generate revenue from sales of our 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. 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. In the third quarter of 2006 we launched a new plastic packaging configuration for our HepaSphere MicroSphere product designed to correct this defect. 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.

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

Our success depends upon our ability to develop and maintain a competitive position in both the embolotherapy and related delivery systems markets. 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. 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., Terumo Corporation and CeloNova BioSciences, Inc. Many of our competitors may 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. For example, in recent years we have experienced increasing competition from products that compete with Embosphere Microspheres products for UFE. Moreover, some of our competitors have provided free or reduced-price samples of competing forms of microspheres for the treatment of medical procedures for which our Embosphere Microspheres are indicated. We believe the availability of these free or reduced-price samples may have had, and if this practice recurs our product revenue may be adversely effected. 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. The medical device market is characterized by extensive research and development, and rapid technological change. Developments by other companies of new or improved products, processes or technologies, in particular in the market for treating UFE, may make our products or proposed products obsolete or less competitive and may negatively impact our revenue.

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.

As a result of these and other factors, 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.

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 health-care 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 January 1, 2007, the Centers for Medicare and Medicaid Services, or CMS, issued a rule 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 historically received by physicians. We believe that some physicians have shifted their procedural mix away from UFE in response to this change in reimbursement, which has and may continue to negatively affect our sales growth. 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 health-care costs, including price regulation, are underway in the United States and other major health-care markets. For example, these proposals include prescription drug benefit legislation recently enacted in the United States, and health-care 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 health-care 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. Disruptions in our business could result in the near term as a result of such departure. 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, 2008, 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, one of our directors is a director of Sepracor and another of our directors is an executive officer 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 the extent such dividends are 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.

Our employees may engage in misconduct or other improper activities, including insider trading.

We are exposed to the risk that employee fraud or other misconduct could occur. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state health-care fraud and abuse laws and regulations, to accurately report financial information or data or to disclose unauthorized activities to us. Employee misconduct could also involve the improper use of customer information or information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses.

In addition, during the course of our operations, our directors, executives and employees may have access to material, non public information regarding our business, our results of operations or potential transactions we are considering. Despite the adoption of an Insider Trading Policy, we may not be able to prevent a director or employee from trading in our common stock on the basis of or while having access to material, non public information. If a director or employee was to be investigated, or an action was to be brought against a director or employee, for insider trading, it could have a negative impact on our reputation and our stock price. Such a claim, with or without merit, could also result in substantial expenditures of time and money, and divert attention of our management team from other tasks important to the success of our business.

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 or clearance 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 hepatocellular carcinoma and hepatic metastasis, our QuadraSphere Microspheres are not specifically indicated for use in hepatocellular carcinoma and hepatic metastasis. FDA regulations require that we conduct clinical trials prior to submitting an application to claim the use of the QuadraSphere Microspheres for the treatment of a specific disease or condition, such as hepatocellular 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 hepatocellular carcinoma and hepatic metastasis, we will be required to undertake clinical trials. If the FDA believes our advertisements or labeling, or statements made by our sales representatives or other company officials, improperly promote our products for unapproved indications, the FDA could allege that our promotional activities misbrand or adulterate 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 health-care providers. The FDA also could take enforcement action, including seizure of product, injunction or criminal prosecution against us and our officers or employees or seek civil penalties.

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. We must also comply with the FDA's Good Manufacturing Practice regulations. 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.

Recently enacted legislation may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to produce, market and distribute products after approval.

On September 27, 2007, the president signed the Food and Drug Administration Amendments Act of 2007, or FDAAA. The FDAAA grants a variety of new powers to the FDA, many of which are aimed at improving the safety of drug products before and after approval. Under the FDAAA, companies that violate the new law are subject to substantial civil monetary penalties. While we expect the FDAAA to have a substantial effect on the medical device industry, the extent of that effect is not yet known. As the FDA issues regulations, guidance and interpretations relating to the new legislation, the impact on the industry, as well as our business, will become clearer. The new requirements and other changes that the FDAAA imposes may make it more difficult, and likely more costly, to obtain approval of new medical device products and to produce, market and distribute products after approval.

We may be subject, directly or indirectly, to federal and state health-care 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 health-care 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 health-care 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 revenue. The patent laws involving medical devices and life sciences technologies such as our microspheres are complex and vary from country to country. Thus, we cannot predict whether we will secure patent protection from any of our existing patent applications in the United States or abroad, although we have a current policy of pursuing patent protection wherever possible for our new technologies. Nor can we predict whether such coverage will be meaningful.

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. On December 10, 2007, the European Patent Office upheld the claims of BioSphere's patent in amended form. The European Patent Office rendered its formal written decision on December 27, 2007. We and Biocompatibles have appealed this decision. We intend to continue to defend our European patent in this appeal. While we are not able to predict the outcome of this patent opposition proceeding, we do not believe it will impact our ability to sell our Embosphere Microsphere or HepaSphere Microsphere products in Europe.

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, opposition proceedings 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. As we introduce new products into the market, we may be accused of infringing the patent rights of third parties. If we do not prevail in such a patent litigation brought against one of our products or its use, we may be required to pay damages, stop selling our product or obtain a royalty-bearing license if one is obtainable. 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 revenue.

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-Hôpitaux de Paris, pursuant to which L'Assistance Publique-Hôpitaux de Paris has granted us exclusive rights to use two United States patents and their foreign counterparts that we jointly own with L 'Assistance Publique-Hôpitaux de Paris relating to Embosphere Microspheres. We also have an agreement with Dr. Shinichi Hori pursuant to which we have an exclusive royalty-bearing license relating to patent rights for our HepaSphere Microsphere and QuadraSphere Microsphere products. 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. We have contracted with two suppliers for our guidewire products, and are currently in negotiation to extend an existing contract with a third-party to supply and package our catheter product. Either we or any third-party manufacturer would likely experience significant delays or cessation in producing our products if we or they experience manufacturing process, quality control process, equipment calibration, process-critical equipment or in any other process necessary for the manufacture of our products, a labor-based error or omission, or a labor strike, natural disaster, local or regional conflict or any

disruption in supply. 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 current Good Manufacturing Practices and Quality System Regulations which are enforced by the FDA through its inspection program. We and other third-party manufacturers 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. In addition, medical device manufacturing laws are also in effect in the many countries outside of the U.S. We or our third-party manufacturers may not be able to comply or maintain compliance. If we or any third-party manufacturers we engage fail to comply, such noncompliance could significantly delay our receipt of new product premarket approvals, result in FDA enforcement action, including an embargo on imported devices or otherwise cause delays and disruptions in the manufacture and supply of our products, any of which would harm our reputation and could materially adversely affect our operating results.

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 a third-party, from whom we purchase guidewires for our Segway Guidewire product; a third party from whom we purchase catheters for our EmboCath Plus Infusion Microcatheter product; and a third-party, from whom we purchase guidewires for our Sequitor Steerable Guidewire product. 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 revenue from the sale of our microspheres and other products in the European Union. For the years ended December 31, 2007 and 2006, approximately 23% and 24%, respectively, of our revenue was 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, 2006 through March 1, 2008, the price of our common stock has ranged from a low of $3.78 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.

Securities analysts may not initiate coverage for our common stock or may issue negative reports, and this may have a negative impact on the market price of our common stock.

Securities analysts may elect not to provide research coverage of our common stock. If securities analysts do not cover our common stock, the lack of research coverage may adversely affect the market price of our common stock. The trading market for our common stock may be affected in part by the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts who elect to cover us downgrades our stock, our stock price could decline. If one or more of these analysts ceases coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline. In addition, rules mandated by the Sarbanes-Oxley Act and a global settlement reached in 2003 between the Securities and Exchange Commission, or SEC, other regulatory agencies and a number of investment banks have led to a number of fundamental changes in how analysts are reviewed and compensated. In particular, many investment banking firms will be required to contract with independent financial analysts for their stock research. It may be difficult for companies such as ours, with smaller market capitalizations, to attract independent financial analysts that will cover our common stock. This could have a negative effect on the market price of our stock.

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 approximately $21,000 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 approximately $33,000 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 EmboGold 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. Some pretrial discovery has been completed, but no party has disclosed any expert opinions. The case is presently set for trial on October 27, 2008. We intend to defend against the claims vigorously. However, we cannot give any assurance that we will prevail, or that all or any part of

our liability, if any, would be covered by its product liability insurance. Accordingly, we are currently unable to predict the financial impact 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, 2007.

EXECUTIVE OFFICERS

As of March 1, 2008, our executive officers, their respective ages and their positions are as follows:

Name	Age	Position
Richard J. Faleschini. . .	61	President and Chief Executive Officer
Martin J. Joyce	54	Executive Vice President and Chief Financial Officer
Melodie R. Domurad . .	50	Vice President of Regulatory, Medical Affairs, and Quality Systems
Willard W. Hennemann.	53	Vice President of New Product and Business Development
Peter C. Sutcliffe	58	Vice President of Manufacturing
Joel B. Weinstein	57	Vice President of Global Marketing and Sales

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.

Martin J. Joyce has served as our Executive Vice President and Chief Financial Officer since January 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.

Melodie R. Domurad has served as our Vice President of Regulatory, Medical Affairs, and Quality Systems since January 2008. From 1997 to 2007, Ms. Domurad served as Vice President of Clinical, Regulatory, and Quality Affairs for Matritech, Inc., a developer of proteomics-based diagnostic products for the early detection of cancer. From 1994 to 1997, Ms. Domurad held the position of Director of Clinical Research and Clinical Research Manager at Ergo Science, Inc., where she focused on therapeutics for diabetes, obesity, and cancer. Prior to joining Ergo Science Inc., Ms. Domurad held leadership roles at the Center for the Study of Nutrition and Medicine at the New England Deaconess

Hospital, and the Cambridge Center for Holistic Health. Ms. Domurad holds a B.A. from Cornell University and a Ph.D. from the University of Cincinnati.

Willard W. Hennemann has served as our Vice President of New Product and Business Development since February 2008. From 2006 to early 2008, Dr. Hennemann served as Vice President of Intravascular Systems/Marketing for Medeikon Corporation, an early-stage developer of proprietary disposable technologies to treat cardiovascular disease. From 2000 to 2006, Dr. Hennemann held the position of Vice President of Research and Development/Interventional Vascular at CryoCath Technologies, a leader in catheter-based products for the cryotherapeutic treatment of cardiovascular disease. From 1998 to 1999, Dr. Hennemann served as Director of Marketing and Product Development for Intervascular (a division of Datascope), which produces a broad line of vascular grafts. From 1996 to 1998, Dr. Hennemann served as Director of Marketing/International Clinical Studies of the Global Stent Business Unit for Medtronic, Inc., a medical technology company. Prior to Medtronic, Dr. Hennemann assumed roles of increasing responsibility over a 12-year period with Cordis Corporation, a pioneer in developing innovative diagnostic and therapeutic devices for interventional vascular medicine. Dr. Hennemann received his B.A. from the University of Maryland and a Ph.D. from the University of Florida.

Peter C. Sutcliffe has served as our Vice President of 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.

Joel B. Weinstein has served as our Vice President of Global Marketing and Sales since January 2008. Prior to joining Biosphere Medical, Mr. Weinstein founded and led several medical device companies, and founded his own firm, which provided strategic counsel to medical device companies and venture capital firms. From 1987 to 1998, Mr. Weinstein served as Vice President of Marketing and Business Development for Hologic, Inc., a medical device company focused on women's health. Prior to Hologic, Mr. Weinstein had progressively greater management responsibilities over a seven-year period with Advanced Technology Laboratories, a multi-modality diagnostic ultrasound company. He received his bachelor's degree in Electrical Engineering from City College of New York and an M.B.A. from Western New England College.

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, 2008, the last reported sale price of our common stock on the NASDAQ Global Market was $3.91, and there were approximately 94 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.

	2007	
	High	Low
First Quarter	$7.70	$5.88
Second Quarter	$8.02	$6.39
Third Quarter	$7.79	$4.32
Fourth Quarter	$6.33	$4.15

	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

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.

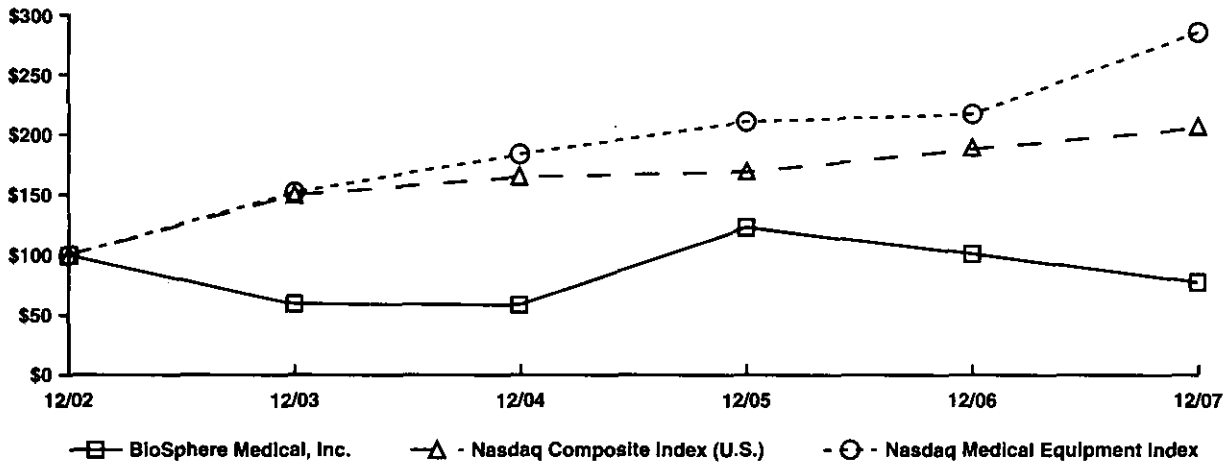
Comparative Stock Performance

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 (U.S. Companies), which we refer to as the NASDAQ Composite Index (U.S.) and (ii) the NASDAQ Medical Equipment Index, which we refer to as the NASDAQ Medical Equipment Index. This graph assumes the investment of $100 on December 31, 2002 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, 2003, 2004, 2005, 2006 and 2007.

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

	12/03	12/04	12/05	12/06	12/07
BioSphere Medical, Inc.	$ 59.94	$ 59.03	$122.91	$101.37	$ 77.85
NASDAQ Composite Index (U.S.)	$149.75	$164.64	$168.60	$187.83	$205.22
NASDAQ Medical Equipment Index	$151.86	$183.56	$210.66	$217.12	$285.24



* $100 invested on December 31, 2002 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)	2007	2006	2005	2004	2003
Statement of Operations Data:					
Revenue:					
Product sales	$26,483	$22,787	$18,484	$14,058	$12,803
License revenue	417	104	—	100	—
Total revenue	26,900	22,891	18,484	14,158	12,803
Costs and expenses:					
Costs of product sales	7,768	6,958	6,303	6,646	5,558
Research and development	2,342	2,290	2,359	2,113	2,344
Sales	7,671	7,550	5,792	5,251	5,876
Marketing	5,290	3,699	2,473	2,299	3,686
General, administrative and patent	6,439	5,560	4,219	4,154	3,359
Litigation costs	—	—	—	874	—
Total costs and expenses	29,510	26,057	21,146	21,337	20,823
Loss from operations	(2,610)	(3,166)	(2,662)	(7,179)	(8,020)
Other income (expense):					
Interest income	1,017	938	225	92	135
Interest expense	(17)	(15)	(15)	(16)	(27)
Other	(244)	(81)	(442)	379	583
Loss before income taxes	(1,854)	(2,324)	(2,894)	(6,724)	(7,329)
Income tax benefit (provision)	—	—	93	(117)	(23)
Net loss	(1,854)	(2,324)	(2,801)	(6,841)	(7,352)
Preferred stock dividends	(557)	(525)	(495)	(68)	—
Net loss applicable to common stockholders	$(2,411)	$(2,849)	$(3,296)	$(6,909)	$(7,352)
Basic and diluted net loss per share applicable to common stockholders	$ (0.14)	$ (0.17)	$ (0.22)	$ (0.49)	$ (0.55)
Basic and diluted weighted average number of common shares outstanding	17,647	17,027	14,653	14,152	13,462

As of December 31, (in thousands)	2007	2006	2005	2004	2003
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$23,579	$22,119	$ 8,774	$10,222	$ 7,575
Working capital	26,555	24,719	10,832	12,391	10,704
Total assets	34,759	32,079	17,495	19,391	17,002
Long-term debt and deferred licensing revenue	80	190	101	192	171
Stockholders' equity	29,109	26,965	13,088	14,835	13,525

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 "Item 1A—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 that use embolotherapy. 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 or destroy 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 embolic particles, or microspheres, with uniquely beneficial properties for a variety of applications. We currently market and sell four microsphere products:

- Embosphere Microspheres, which are marketed for hypervascularized tumors and arteriovenous malformations in the United States, the European Union and several other foreign markets;
- EmboGold Microspheres, which are marketed for hypervascularized tumors and arteriovenous malformations in the United States, the European Union and several other foreign markets;
- HepaSphere Microspheres, which are marketed in the European Union and Brazil for primary and metastatic liver cancer;
- QuadraSphere Microspheres, which are marketed for the treatment of hypervascularized tumors and arteriovenous malformations in the United States. Our QuadraSphere Microspheres are identical in all respects to our HepaSphere Microspheres. However, the clearance from the FDA for QuadraSphere Microspheres does not include specific indications for the treatment of primary and metastatic liver cancer. FDA regulations require that we conduct clinical trials prior to submitting an application 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 preclearance clinical trials for this class of medical device on an indication-by-indication basis. 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 November of 2007 we received CE Mark approval for transarterial chemoembolization of hepatocellular carcinoma, or primary liver cancer, using HepaSphere Microspheres and doxorubicin, an anticancer drug. CE Mark approval denotes conformity with European standards for safety and allows certified devices to be placed in the market in European Union countries. In connection with the CE Mark approval of our HepaSphere Microspheres, we intend to conduct a 100-patient, post-market study in ten to 15 European centers. In January 2008, the Medical Device Department of the State Food and Drug Administration of the People's Republic of China approved our Embosphere Microspheres for clinical use for vascular embolizations, arteriovenous malformations, hypervascularized tumors, and symptomatic uterine fibroids.

For the fiscal years ended December 31, 2007 and 2006, we primarily generated revenue from product sales of our embolic products in North America and the European Union. We also recognized revenue from product sales in other geographic territories, including the Middle East, Africa, South America and Asia. Product revenue also includes the sale of accessory embolotherapy devices such as our EmboCath Plus and EmboCath hydrophilic Infusion Catheters, Sequitor Guidewire and Segway Guidewire, as well as our nonstrategic barium delivery kits and other ancillary medical devices sold exclusively in Europe. We currently derive a majority of our revenue in the United States and the European Union from the sale of Embosphere Microspheres for use in the treatment of uterine fibroids, using a procedure called UFE.

Our principal focus is on growing our embolotherapy business worldwide through increases in UFE and other hypervascularized tumor embolization procedures. Our marketing strategy is to promote the UFE procedures 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 procedures. Our success will depend upon the continued acceptance by the medical community, patients and third-party payers of the UFE procedures, and acceptance of 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, 2007, we had approximately $23.58 million in cash, cash equivalents and marketable securities, and an accumulated deficit of approximately $84.06 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 2008 as we seek to execute on our business plan, including continuing to establish sales and marketing capabilities and conducting research and development activities.

Research and Development

Research and development expenses as a percentage of total revenue for the fiscal years ended December 31, 2007, 2006 and 2005 were 9%, 10% and 13%, respectively. Research and development expenses in these periods relate primarily to:

- research to identify and evaluate new and innovative embolotherapy products based on our platform microsphere technology, including our product candidates, Resorbable Microspheres and MR Microspheres, both of which are in preclinical development;
- further clinical testing and clinical trials to support our Embosphere Microspheres, HepaSphere Microspheres, QuadraSphere Microspheres, Sequitor Steerable Guidewire and EmboCath Plus Infusion Microcatheter, all of which products are currently approved and marketed in specified indications and in specified geographic locations; and
- improving manufacturing processes for our currently marketed products.

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, facility costs, equipment depreciation and maintenance are shared among various programs. Accordingly, we have not historically tracked specific costs for each of our research and development projects.

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 that are currently in the development or from any of our approved products for which we are seeking expanded marketing approvals in selected

indications or geographic regions, 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;
- market acceptance of our approved products;
- 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 "Part I, Item 1A -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, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, revenue 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, "*Revenue Recognition,*" or SAB, No. 104. 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 credit returns could have a material adverse impact on our revenue 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, or SFAS, 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, or APB, No. 25, "*Accounting for Stock Issued to Employees*," or APB No. 25, 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.

We estimate the fair value of each option 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, 2007 and 2006

Revenue and Margin Overview

(in thousands)	For the Years Ended December 31, 2007	2006	Increase/ (Decrease) ($)	Increase/ (Decrease) (%)
Total revenue	$26,900	$22,891	$4,009	18%
Costs of product sales	7,768	6,958	810	12%
Gross margin	$19,132	$15,933	$3,199	20%
Gross margin %	71%	70%	1%	

Revenue. Total revenue increased for the year ended December 31, 2007 as compared to the year ended December 31, 2006, primarily due to an increase in sales of our microsphere products for interventional gynecology and interventional oncology procedures.

- product revenue from sales of our microspheres for use in interventional gynecology for UFE increased $2.03 million, or 13% from the year ended December 31, 2006, primarily on higher sales of our Embosphere Microspheres in the United States. During the year ended December 31, 2007, sales of our microsphere products in the United States increased $1.63 million, or 12%. We believe the increase in product revenue from microsphere sales for use in interventional gynecology for UFE is due to increased awareness of the UFE procedure among symptomatic women resulting from our additional local marketing activities and to an increase in average selling prices. Sales outside the United States increased $400,000, or 16%, principally due to higher foreign exchange rates and increased demand in Europe.
- product revenue from microsphere sales used in interventional oncology, primarily for use in treating liver cancer, increased $1.34 million, or 41% from the year ended December 31, 2006 on increased demand for our Embosphere Microspheres and our new expandable microsphere products, which were released during 2006. During the year ended December 31, 2007, sales of our Embosphere Microspheres for use in interventional oncology increased $599,000, or 19% and sales of our recently approved QuadraSphere Microsphere product and our HepaSphere Microsphere product for use in interventional oncology increased $742,000 from the year ended December 31, 2006.

Additional increases in revenue during the year ended December 31, 2007, as compared to 2006, were due to increased sales of our delivery systems, licensing revenue and changes in foreign exchange rates. Product revenue from the sales of our delivery system products increased $290,000, or 36% from the year ended December 31, 2006 on increased demand outside the United States. Revenue from our licensing agreement increased $313,000 during the year ended December 31, 2007 compared to 2006 as we recognized a full year of revenue from the licensing of nonstrategic intellectual property to a third party in 2007 compared to one quarter of revenue in 2006.

Included in the increase in revenue noted above is the effect of changes in foreign exchange rates. During the year ended December 31, 2007, as compared to the same period in 2006, revenue increased $529,000, due to changes in foreign exchange rates as sales from our French operations increased due to the weakening of the U.S. dollar versus the euro.

Sale of nonstrategic gastric products in Europe, which include, among other things, barium and drainage kits, were of $2.47 million and $2.44 million for the years ended December 2007 and 2006, respectively. We intend to phase out of this nonstrategic business in 2008.

Cost of Product Sales. Cost of product sales for the year ended December 31, 2007 increased from the year ended December 31, 2006 primarily due to higher Embosphere Microsphere sales volume and, to a lesser extent, higher inventory obsolescence charges, which increased $91,000 in 2007 as compared to 2006, primarily resulting from phase out of our nonstrategic products and the release of our new expandable microsphere products.

The gross margin improvement of 1% as a percentage of revenue for 2007 as compared to 2006 was primarily attributable to the favorable product and geography mix of sales due to the increase in sales in 2007 of Embosphere Microspheres in the United States, which provide our highest profit margins. Offsetting these improvements were 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, 2007	2006	Increase/ (Decrease) ($)	Increase/ (Decrease) (%)
Research and development	$ 2,342	$ 2,290	$ 52	2%
Sales	7,671	7,550	121	2%
Marketing	5,290	3,699	1,591	43%
General, administrative and patent	6,439	5,560	879	16%
Total operating expenses	$21,742	$19,099	$2,643	

Research and Development Expense. Total research and development expense in 2007 increased over 2006 due to the change in foreign exchange rates offset by lower employee costs. Our research and development activities located in France, which are denominated in euros, cost $85,000 more during 2007 as compared to 2006 due to the weakening of the U.S. dollar versus the euro. Offsetting these increases were lower employee costs resulting from open positions in 2007. We expect research and development expenses will increase as we expand the management team to focus on the development of new products and increase the support of recently released products in 2008.

Sales Expense. Sales expense for 2007 increased over 2006, primarily due to an increase in consulting activities and to the change in foreign exchange rates offset by lower employee costs related to a open executive position through the second half of 2007. In 2007, we engaged an external resource to analyze our customer base and territory potential to optimize our planned expansion of the U.S sales force in 2008. In addition, our sales organization located in France, was $141,000 more during 2007 as compared to 2006 due to the weakening of the U.S. dollar versus the euro. Offsetting these increases were a decrease in net employee expenses resulting from temporary management vacancies during 2007. We expect sales expense will increase in 2008 as we increase our sales force coverage in the United States to four regions covering 24 territories.

Marketing Expense. Marketing expense for 2007 increased from 2006, primarily due to increased local marketing programs in the United States, which represented $1.10 million of the increase and

salary and other compensation expenses related to the expansion of the employee base during the latter half of 2006 to manage the increase in marketing activities. These local marketing activities, which included, among other channels, targeted print, radio, television, public transit advertising, and public relations, are designed to build physician and patient awareness and demand for UFE in the United States. In addition, during 2007 we engaged a market research consultant to perform a strategic analysis of the interventional oncology market, representing approximately $200,000 of the increase.

General, Administrative and Patent Expense. General, administrative and patent expenses for 2007 increased from 2006, primarily due to an increase in equity compensation, consulting and headcount increases. During 2007 we recognized higher equity compensation costs totaling approximately $380,000 due to the attainment of revenue targets on performance based awards and to the full year costs of previously awarded equity compensation. Expenses associated with headcount expansion and consulting costs related to our preparation for compliance with Section 404 of the Sarbanes—Oxley Act of 2002 were approximately $209,000 higher in 2007 as compared to 2006. In addition, the cost of our general and administrative function located in France, cost approximately $82,000 more during 2007 as compared to 2006 due to the weakening of the U.S. dollar versus the euro.

Interest Income. Interest income increased to $1.02 million in 2007 as compared to $938,000 in 2006. The increase in 2007 as compared to 2006 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 resulted from euro-to-U.S. dollar foreign currency fluctuations on euro-denominated short-term intercompany trade accounts. The foreign exchange losses during the year ended December 31, 2007 totaled approximately $238,000 compared to the foreign exchange losses of approximately $102,000 in the comparable period of 2006. The increase in the loss was primarily the result of higher euro-denominated intercompany trade payable balances during 2007.

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 revenue	$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%	

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

- an increase in revenue from Embosphere Microsphere 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 revenue from Embosphere Microsphere and EmboGold Microsphere sales outside of the United States of approximately $330,000, or 10%, on increased product volumes. Revenue 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. In January 2008, we received regulatory approval of Embospheres in the People's Republic of China;

- An increase in revenue from the sale of our HepaSphere Microsphere product outside of the United States, which was first introduced in December 2005, and from the initial sales of our 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, which increased revenue 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.

Revenue in 2006 from our delivery system and other products, which include barium delivery kits and other ancillary products, was 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 out these products.

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

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	7,550	5,792	1,758	30%
Marketing	3,699	2,473	1,226	50%
General, administrative and patent	5,560	4,219	1,341	32%
Total operating expenses	$19,099	$14,843	$4,256	

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.

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 represented 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. 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 payable balances and to the fluctuation of the U.S. dollar as compared to the euro.

Liquidity and Capital Resources

As of December 31, 2007, we had $23.58 million of cash, cash equivalents and marketable securities, an increase of $1.46 million from $22.12 million at December 31, 2006. This increase was primarily the result of the proceeds from stock option exercises by former employees. We have historically funded our operations from net proceeds provided by public and private equity offerings, net revenue, bank financing and equipment financing leases and, to a lesser extent, the exercise of stock options.

The net cash provided in operating activities was $327,000 and includes a net loss of $1.85 million and $645,000 in working capital changes, offset by noncash charges primarily related to stock-based compensation and depreciation. Accounts receivable decreased $192,000 as a result of a three-day improvement in days sales outstanding, which decreased to 55 days from 58 days at December 31, 2006. Inventory increased $1.13 million to meet demand of higher sales of our microsphere products.

During 2007, we spent $565,000 to purchase manufacturing equipment to support the expansion of our manufacturing capabilities, additional laboratory equipment, and other equipment to support our sales and marketing expansion and our existing infrastructure.

Net cash provided by financing activities was $1.58 million during 2007, which included $1.65 million from the exercise of stock options and purchases under our employee stock purchase plan, offset by scheduled principal payments, such as those on existing lease arrangements.

Borrowing Arrangements

At December 31, 2007, we had a credit facility with a bank under which we may borrow up to $3.00 million. We may use amounts borrowed under the agreement for general working capital and corporate purposes, subject to limitations defined in the agreement. This agreement expires in June

2009. There were no borrowings outstanding under this agreement as of December 31, 2007. Each available 30-, 60-, 90- or 180-day advance will bear interest at a per annum rate, at our 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 (5.02% as of December 31, 2007) 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, we entered into a security agreement pursuant to which we have pledged to the bank all of our U.S. assets, excluding our equity ownership of BioSphere Medical SA, a wholly owned subsidiary, as collateral.

Other Contractual Obligations

As of December 31, 2007, we are party to two operating leases for our facilities in Rockland, Massachusetts, and Roissy, France. The Roissy, France, operating lease expires in May 2010. On February 24, 2006, we amended the lease for the office and laboratory facility that we currently occupy in Rockland, Massachusetts. Pursuant to that amendment, the term of the lease was extended from March 31, 2007 to February 28, 2009. We are party to several non-cancelable capital lease agreements with various equipment-financing companies, related to the acquisition during 2002 and 2004 of certain manufacturing and computer equipment. The equipment leases have initial terms of 36 to 60 months with interest rates of 4.6% to 8.7%. Equipment leased under these arrangements serves as pledged capital with respect to each capital lease agreement.

Future cash payments, including interest, under contractual obligations in effect as of December 31, 2007, are as follows:

	Payments Due by Period			
(in thousands)	Less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
Operating leases	$ 725	$651	$—	$—
Capital leases	29	18	—	—
Other contractual obligations	1,563	53	40	15
Total	$2,317	$722	$40	$15

We believe that the $23.58 million in cash, cash equivalents and marketable securities that we have as of December 31, 2007, together with anticipated proceeds from sales of our microspheres, delivery systems and other products will be sufficient to fund our operating and capital requirements, as currently planned through at least 2008. In the longer term, we expect to fund our operations and sustain capital requirements through a combination of expected proceeds from product sales and capital equipment financing.

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

- produce and manufacture our products;
- expand our United States sales force;
- 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 ongoing 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, unanticipated changes in the amount of revenue 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; the outcome of product liability challenges, including the current product liability lawsuit described under the heading "Part 1, Item 3—Legal Proceedings," for which an adverse judgment against us may not be adequately covered by product liability insurance; 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 may also need additional funds for possible strategic acquisitions of synergistic businesses, products and/or technologies.

We will require substantial additional cash to fund our planned, and any unplanned, near- and long-term expenses. We may seek additional funding through a combination of collaborative arrangements, debt financing, or the sale of additional equity securities. We may not receive such additional funding on reasonable terms, or at all. Any sales of equity or debt securities are likely to dilute our existing stockholders, and the new securities may have rights, preferences or privileges senior to those of existing holders of our capital stock. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration and licensing arrangements with third-parties, we may have to relinquish valuable rights to our technologies or products, or grant licenses on terms that are not favorable to us. If adequate funds are not available, we could be required to reduce our capital expenditures, scale back or eliminate some or all of our research, development, sales and marketing initiatives, reduce our workforce, and license to others products or technologies that we otherwise would seek to commercialize ourselves.

Related Party Transactions

We did not have any related party transactions during 2007.

Off-Balance Sheet Arrangements

We do not have any material off-balance sheet arrangements.

Inflation

We believe that the effects of inflation generally do not have a material adverse impact on our operations or financial condition.

New Accounting Pronouncements

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 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. We do not believe the adoption of SFAS 157 will have a material impact on our results of operations, financial position or cash flows.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, "*The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment of FASB*

Statement No. 115," or SFAS 159. SFAS 159 permits entities to choose to measure eligible financial assets or liabilities, which include marketable securities available-for-sale and equity method investments, at fair value at specified election dates and report unrealized gains and losses on items for which the fair value option has been elected in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007. We have not completed our evaluation of the Interpretation, but do not currently believe the adoption of SFAS 159 will have a material impact on our results of operations, financial position or cash flows.

In June 2007, the FASB ratified Emerging Issue Task Force, or EITF, No. 07-3, "*Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*," or EITF 07-3. The EITF concluded that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. If an entity's expectations change such that it does not expect it will need the goods to be delivered or the services to be rendered, capitalized nonrefundable advance payments should be charged to expense. EITF 07-3 is effective for fiscal years beginning after December 15, 2007, including interim periods within those years. We have not completed our evaluation of the EITF, but do not currently believe the adoption will have a material impact on our results of operations, financial position or cash flows.

In December 2007, the FASB issued Statement of Financial Accounting Standards No. 141(R), "*Business Combinations,*" or SFAS 141R, a replacement of Statement of Financial Accounting Standards No. 141, "*Business Combinations,*" or SFAS 141. SFAS 141R applies to all transactions and other events in which an entity obtains control over one or more other businesses. The statement changes the principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree. The statement also provides guidance for recognizing and measuring goodwill acquired in the business combination and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. This statement is effective prospectively, except for certain retrospective adjustments to deferred tax balances, for fiscal years beginning after December 15, 2008. We do not believe the adoption of SFAS 141R will have a material impact on our results of operations, financial position or cash flows.

In December 2007, the FASB issued Statement of Financial Accounting Standards No. 160, "*Noncontrolling Interests in Consolidated Financial Statements: an amendment of Accounting Research Bulletin No. 51,*" or SFAS 160. SFAS 160 establishes new accounting and reporting standards for noncontrolling interest (formally referred to as "minority interests") in a subsidiary and for the deconsolidation of a subsidiary. Specifically the statement requires the recognition of a noncontrolling interest as equity in the consolidated financial statements and separate from the parent's equity. The amount of net income attributable to a noncontrolling interest will be included in consolidated net income on the face of the income statement. SFAS 160 clarifies that changes in a parent's ownership interest in a subsidiary that do not result in deconsolidation are equity transactions if the parent retains its controlling financial interest. In addition, SFAS 160 requires that a parent recognize a gain or loss in net income when a subsidiary is deconsolidated. Such gains or losses will be measured using the fair value of the noncontrolling equity investment on the deconsolidation date. SFAS 160 also includes expanded disclosure requirements regarding the interests of the parent and its noncontrolling interest. SFAS 160 is effective for fiscal years and interim periods within those fiscal years, beginning on or after December 15, 2008, with early adoption prohibited. We do not believe the adoption of SFAS 160 will have a material impact on our results of operations, financial position or cash flows.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Derivative Financial Instruments, Other Financial Instruments, and Derivative Commodity Instruments

As of December 31, 2007, we did not participate in any derivative financial instruments or other financial and commodity instruments. However, in the future, we may consider certain financing instruments, including foreign currency forward contracts, or alternative instruments, which may be considered derivative in nature.

Primary Market Risk Exposures

Our primary market risk exposure is in the area of foreign currency exchange rate risk. We are exposed to currency exchange rate fluctuations related to our operations in France. Our operations in France are denominated in the euro, and as of December 31, 2007, approximately euro 1.90 million, or $2.79 million, remained outstanding within the intercompany trade accounts. We have not engaged in formal currency hedging activities to date, but do have a limited natural hedge in that both our revenue and expenses in France are primarily denominated in the euro. We also attempt to minimize exchange rate risk by converting non-U.S. currency to U.S. dollars as often as practicable. We generally view our investment in foreign subsidiaries operating under a functional currency (the euro) other than our reporting currency (the U.S. dollar) as long term. Our investment in foreign subsidiaries is sensitive to fluctuations in foreign currency exchange rates. The effect of a change in foreign exchange rates on our net investment in foreign subsidiaries is reflected in the "Other accumulated comprehensive loss" component of stockholders' equity. Because our foreign currency exchange rate risk is not material, no quantitative tabular disclosure has been provided.

The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may have market risk. This means that an increase in prevailing interest rates may cause the principal amount of the investment to decrease. To minimize this risk in the future, we maintain our portfolio of cash equivalents and short-term investments in a variety of securities, including commercial paper, investment-grade asset-backed corporate securities, money market funds and government and nongovernment debt securities. Due to the conservative nature of our investments, the relatively short duration of their maturities, our ability to convert some or all of our long-term investments to less interest rate-sensitive holdings and our general intent to hold most securities until maturity, we believe interest rate risk is mitigated. A hypothetical 100-basis-point increase or decrease in interest rates would not have a material impact on the fair value of our short-term investments as of December 31, 2007. As of December 31, 2007, approximately 55% of the $7.97 million classified as available-for-sale marketable securities will mature within one year.

BioSphere Medical, Inc.

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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, 2007 and 2006, 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, 2007. 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, 2007 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the consolidated financial statements, effective January 1, 2007, the Company adopted FASB Interpretation No. 48 "Accounting for Uncertainty in Income Taxes," and effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123R, "Share-Based Payments" using the modified prospective transition method.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 20, 2008

BIOSPHERE MEDICAL, INC.
CONSOLIDATED BALANCE SHEETS

(in thousands except share data)	December 31, 2007	2006
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 15,608	$ 8,913
Marketable securities	7,971	13,206
Account receivable, net of allowance for doubtful accounts of $160 and $218 as of December 31, 2007 and 2006, respectively	4,097	4,082
Inventories	3,836	2,830
Prepaid and other current assets	613	612
Total current assets	32,125	29,643
Property and equipment, net	1,124	929
Goodwill	1,443	1,443
Other assets	67	64
Total Assets	$ 34,759	$ 32,079
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,970	$ 1,366
Accrued compensation	1,674	1,935
Other accrued liabilities	1,816	1,483
Current portion of capital lease obligations and long-term debt	27	57
Current portion of deferred licensing revenue	83	83
Total current liabilities	5,570	4,924
Long-term debt and capital lease obligations	17	44
Long-term portion of deferred licensing revenue	63	146
Total Liabilities	5,650	5,114
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, 9,495 and 8,950 shares issued and outstanding, as of December 31, 2007 and 2006, respectively (aggregate liquidation preference including accrued dividends of $9,636 at December 31, 2007)	8,523	7,970
Common stock; $.01 par value; 50,000,000 shares authorized; 18,287,834 and 17,957,964 shares issued and outstanding as of December 31, 2007 and 2006, respectively	183	180
Additional paid-in capital	103,753	100,275
Accumulated deficit	(84,059)	(81,648)
Accumulated other comprehensive income	709	188
Total stockholders' equity	29,109	26,965
Total Liabilities and Stockholders' Equity	$ 34,759	$ 32,079

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, 2007	2006	2005
Revenue:			
Product sales	$26,483	$22,787	$18,484
Licensing revenue	417	104	—
Total revenue	26,900	22,891	18,484
Costs and expenses:			
Costs of product sales	7,768	6,958	6,303
Research and development	2,342	2,290	2,359
Sales	7,671	7,550	5,792
Marketing	5,290	3,699	2,473
General, administrative and patent	6,439	5,561	4,219
Total costs and expenses	29,510	26,058	21,146
Loss from operations	(2,610)	(3,167)	(2,662)
Interest income	1,017	938	225
Interest expense	(17)	(15)	(15)
Foreign exchange loss, net	(239)	(102)	(444)
Other (expense) income, net	(5)	22	2
Loss before income tax benefit	(1,854)	(2,324)	(2,894)
Income tax benefit	—	—	93
Net loss	(1,854)	(2,324)	(2,801)
Preferred stock dividends	(557)	(525)	(495)
Net loss applicable to common stockholders	$(2,411)	$(2,849)	$(3,296)
Net loss per common share applicable to common stockholders			
Basic and diluted	$ (0.14)	$ (0.17)	$ (0.22)
Weighted average number of common shares outstanding			
Basic and diluted	17,647	17,027	14,653

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, 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
Comprehensive loss:								
Net loss	—	—	—	—	—	(1,854)	—	(1,854)
Unrealized gain on marketable securities	—	—	—	—	—	—	10	10
Translation adjustment	—	—	—	—	—	—	511	511
Total Comprehensive loss								(1,333)
Dividends on convertible preferred stock	557	—	—	—	—	(557)	—	—
Dividends paid in cash in lieu of partial shares	(4)	—	—	—	—	—	—	(4)
Issuance of common stock under employee benefit and incentive plans	—	412	4	1,642	—	—	—	1,646
Issuance of restricted stock	—	17	—	—	—	—	—	—
Forfeiture of restricted stock	—	(100)	(1)	—	—	—	—	(1)
Non-cash stock-based compensation	—	—	—	1,836	—	—	—	1,836
Balance at December 31, 2007	$8,523	18,287	$183	$103,753	$ —	$(84,059)	$ 709	$29,109

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, 2007	2006	2005
Cash flows from operating activities:			
Net loss	$ (1,854)	$ (2,324)	$(2,801)
Adjustments to reconcile net loss to net cash used in operating activities:			
(Recovery of) provision for doubtful accounts	(38)	(8)	66
Provision for inventory obsolescence	328	231	54
Provision for sales returns and allowances	9	—	—
Depreciation	438	445	509
Non-cash stock compensation	1,836	1,425	18
Foreign currency loss, net	239	102	444
Realized loss on available-for-sale investments	13	—	5
Loss on disposal of property and equipment	1	—	—
Changes in operating assets and liabilities:			
Accounts receivable	192	(437)	(725)
Inventories	(1,128)	(449)	593
Prepaid and other current assets	43	(169)	(213)
Accounts payable	513	144	149
Accrued compensation	(334)	39	(3)
Other accrued expenses	69	399	89
Net cash provided by (used in) operating activities	327	(602)	(1,815)
Cash flows from investing activities:			
Purchase of property and equipment	(565)	(464)	(325)
Purchase of marketable securities	(11,162)	(16,575)	—
Proceeds from the sale and maturity of marketable securities	16,395	3,364	764
Net cash provided by (used in) investing activities	4,668	(13,675)	439
Cash flows from financing activities:			
Payment of issuance cost of convertible preferred stock and warrants	—	—	(59)
Proceeds from issuance of common stock, net	—	13,498	—
Proceeds from issuance of common stock under employee benefit and incentive plans	1,645	952	981
Proceeds from capital lease obligations	—	—	43
Payment of cash dividends in lieu of partial shares	(4)	(4)	—
Principal payments under long-term debt and capital lease obligations	(57)	(124)	(163)
Net cash provided by financing activities	1,584	14,322	802
Effect of exchange rate changes on cash and cash equivalents	116	94	(112)
Net increase (decrease) in cash and cash equivalents	6,695	139	(686)
Cash and cash equivalents at beginning of year	8,913	8,774	9,460
Cash and cash equivalents at end of year	$ 15,608	$ 8,913	$ 8,774

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

1. Nature of the Business

BioSphere Medical, Inc. (the "Company") develops, manufactures and markets products for medical procedures that use embolotherapy. 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 or destroy the structure or organ by occluding its blood supply. The Company's core technologies consist of patented bioengineered polymers. These core technologies are used to produce miniature spherical embolic particles, or microspheres, which are designed to have uniquely beneficial properties for a variety of applications. The Company's principal focus is the application of its Embosphere® Microspheres for the treatment of symptomatic uterine fibroids using a procedure called uterine fibroid embolization ("UFE"). The Company's wholly owned subsidiary, BioSphere Medical SA ("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, 2007, 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 2008. 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 UFE marketing programs, the outcome of product liability challenges, including the current product liability lawsuit described under the heading "Part 1, Item 3—Legal Proceedings," for which an adverse judgment against the Company may not be adequately covered by product liability insurance, unanticipated research and development expenses, the scope and results of preclinical 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, delays or failures in the market's acceptance of any approved products, including Embosphere Microspheres for UFE, HepaSphere™ Microspheres and QuadraSphere® Microspheres and the need for additional funds for possible strategic acquisitions of synergistic businesses, products and/or technologies.

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 its 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 revenue 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 90 days or less, as of the date of purchase, to be cash equivalents. As of December 31, 2007 and 2006, approximately $14.84 million and $8.39 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 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, 2007 or 2006, and no single customer accounted for greater than 10% of revenue in 2007, 2006 or 2005.

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, 2007, all marketable securities were classified as available-for-sale, since the Company had the intent and ability 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 creditworthiness 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 step acquisition 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, No. 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, 2007, 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 or distributor), 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 credit returns could have a material adverse impact on the Company's revenue 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 $417,000 and $104,000, respectively, as licensing revenue during the years ending December 31, 2007 and 2006.

Research and Development

Research and development costs include payroll, facility costs, administrative expenses, and third-party costs related to: developing new products, making technological improvements to existing products and production methods. Research and development costs 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.

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 carryforward 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, if any, 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.

Effective January 1, 2007, the Company adopted FASB Interpretation No. 48 ("FIN 48"), "*Accounting for Uncertainty in Income Taxes—an Interpretation of FASB 109*" (the "Interpretation"). The Interpretation clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS No. 109. The Interpretation proscribes a recognition threshold and measurement attribute for financial statement recognition of an income tax position taken or expected to be taken in a tax return. This Interpretation also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company's adoption did not have a material impact on its results of operations or financial position as it did not recognize any assets or liabilities for unrecognized tax benefits relative to uncertain tax positions upon adoption of the Interpretation.

Comprehensive Income

Other comprehensive income 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. The components of accumulated other comprehensive income are as follows:

(in thousands)	December 31, 2007	2006
Foreign exchange currency translation	$703	$192
Unrealized gains (losses) on investments	6	(4)
Total accumulated other comprehensive income	$709	$188

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)	As of December 31, 2007	2006	2005
Shares issuable upon exercise of stock options	2,220	2,627	2,623
Shares issuable upon conversion of convertible securities	2,409	2,271	2,140
Shares issuable upon exercise of outstanding warrants	400	400	400
Unvested restricted stock awards	333	430	15
	5,362	5,728	5,178

Stock Options

The Company adopted the provisions of SFAS 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 vesting period of such awards.

Prior to January 1, 2006, the Company used the intrinsic value method to account for stock-based employee compensation under Accounting Principles Board Opinion ("APB") 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.

SFAS 123R requires the presentation of pro forma information for periods prior to adoption as if the Company had accounted for all stock-based compensation expense under the fair value method of those statements. 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 2005:

(in thousands, except per share amounts)	For the Year Ended December 31, 2005
Net loss applicable to common stockholders	
As reported	$(3,296)
Pro forma compensation expense	(872)
Pro forma net loss	$(4,168)
Basic and diluted loss per share	
As reported	$ (0.22)
Pro forma	$ (0.28)

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 its support of certain international trade shows initiated by the international sales force as marketing expenses. Previously, such trade show costs were classified as selling expenses. This revision in classification does not affect total operating costs and expenses. In connection with preparation of the accompanying consolidated statements of cash flows, the Company concluded that it was appropriate to classify the foreign currency loss on intercompany transactions within operating activities. This revision in classification does not affect the net change in cash and cash equivalents.

New Accounting Pronouncements

In September 2006, the FASB issued SFAS 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.

In February 2007, the FASB issued SFAS No. 159, "*The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment of FASB Statement No. 115,*" or SFAS 159. SFAS 159 permits entities to choose to measure eligible financial assets or liabilities, which include marketable securities available-for-sale and equity method investments, at fair value at specified election dates and report unrealized gains and losses on items for which the fair value option has been elected in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company has not completed its evaluation of the Interpretation, but does not currently believe the adoption of SFAS 159 will have a material impact on its results of operations, financial position or cash flows.

In June 2007, the FASB ratified Emerging Issue Task Force ("EITF") No. 07-3, "*Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities,*" or EITF 07-3. The EITF concluded that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred

and capitalized. The capitalized amounts should be expensed as the related goods are delivered or the services are performed. If an entity's expectations change such that it does not expect it will need the goods to be delivered or the services to be rendered, capitalized nonrefundable advance payments should be charged to expense. EITF 07-3 is effective for fiscal years beginning after December 15, 2007, including interim periods within those years. The Company has not completed its evaluation of the EITF, but does not currently believe the adoption will have a material impact on its results of operations, financial position or cash flows.

In December 2007, the FASB issued Statement of Financial Accounting Standards No. 141(R), *"Business Combinations,"* or SFAS 141R, a replacement of Statement of Financial Accounting Standards No. 141, *"Business Combinations,"* or SFAS 141. SFAS 141R applies to all transactions and other events in which an entity obtains control over one or more other businesses. The statement changes the principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. The statement also provides guidance for recognizing and measuring goodwill acquired in the business combination and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. This statement is effective prospectively, except for certain retrospective adjustments to deferred tax balances, for fiscal years beginning after December 15, 2008. The Company does not believe the adoption of SFAS 141R will have a material impact on its results of operations, financial position or cash flows.

In December 2007, the FASB issued Statement of Financial Accounting Standards No. 160, *"Noncontrolling Interests in Consolidated Financial Statements: an amendment of Accounting Research Bulletin No. 51,"* or SFAS 160. SFAS 160 establishes new accounting and reporting standards for noncontrolling interest (formally referred to as "minority interests") in a subsidiary and for the deconsolidation of a subsidiary. Specifically the statement requires the recognition of a noncontrolling interest as equity in the consolidated financial statements and separate from the parent's equity. The amount of net income attributable to a noncontrolling interest will be included in consolidated net income on the face of the income statement. SFAS 160 clarifies that changes in a parent's ownership interest in a subsidiary that do not result in deconsolidation are equity transactions if the parent retains its controlling financial interest. In addition, SFAS 160 requires that a parent recognize a gain or loss in net income when a subsidiary is deconsolidated. Such gains or losses will be measured using the fair value of the noncontrolling equity investment on the deconsolidation date. SFAS 160 also includes expanded disclosure requirements regarding the interests of the parent and its noncontrolling interest. SFAS 160 is effective for fiscal years and interim periods within those fiscal years, beginning on or after December 15, 2008, with early adoption prohibited. The Company does not believe the adoption of SFAS 160 will have a material impact on its results of operations, financial position or cash flows.

3. Goodwill

Goodwill equaled $1.44 million as of December 31, 2007 and 2006 and was comprised entirely of the unamortized purchase price paid in excess of the net BMSA assets acquired.

4. Marketable Securities and Cash Equivalents

All current fixed maturity securities are classified as "available-for-sale" and are reported at fair value. The Company has determined that 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 and cash equivalents, including accrued interest receivable, as of December 31, 2007 are as follows:

(in thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Marketable securities:				
Corporate obligations	$ 1,368	$ 1	$ (3)	$ 1,366
Bank obligations	1,162	6	(1)	1,167
Asset-backed obligations	2,981	10	—	2.991
Federal agency obligations	1,879	4	—	1,883
Mortgage-backed obligations	324	—	(12)	312
Tax-exempt obligations	252	—	—	252
Total marketable securities	7,966	21	(16)	7,971
Cash Equivalents:				
Bank obligations	1,449	1	—	1,450
Treasury obligations	12,100	—	—	12,100
Total marketable securities and cash equivalents	$21,515	$22	$(16)	$21,521

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

(in thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Marketable securities:				
U.S. Treasury securities	$ 2,014	$—	$(12)	$ 2,002
Corporate obligations	2,059	—	—	2,059
Bank obligations	4,600	—	—	4,600
Asset-backed obligations	4,127	8	—	4,135
Mortgage-backed obligations	411	—	—	411
Total marketable securities	13,211	8	(12)	13,207
Cash Equivalents:				
Bank obligations	1,043	—	—	1,043
Treasury obligations	6,803	—	—	6,803
Total marketable securities and cash equivalents	$21,057	$ 8	$(12)	$21,053

As of December 31, 2007, the contractual maturities of marketable securities are as follows:

(in thousands)	Estimated Fair Market Value
Due within one year:	
Corporate obligations	$1,193
Bank obligations	1,167
Federal agency obligations	1,883
Asset-backed securities	134
Due between one and five years:	
Corporate obligations	173
Asset-backed securities	2,857
Due after ten years:	
Mortgage-backed obligations	312
Tax-exempt obligations	252
Total marketable securities	$7,971

No material realized gains or losses on the Company's marketable securities were recognized during the years ended December 31, 2007 and 2006.

5. Inventories

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

	December 31,	
(in thousands)	2007	2006
Finished goods	$2,387	$1,793
Work in progress	1,319	793
Raw material	130	244
Total inventory	$3,836	$2,830

6. Property and Equipment

Property and equipment consists of the following:

	December 31,	
(in thousands)	2007	2006
Office equipment	$ 1,116	$ 1,080
Laboratory and manufacturing equipment	3,205	2,608
Leasehold improvements	223	211
Total property and equipment	4,544	3,899
Less: accumulated depreciation	(3,420)	(2,970)
Net property and equipment	$ 1,124	$ 929

Property and equipment under capital lease agreements, net of accumulated depreciation, which are included in the table above, were $30,000 and $87,000, respectively, at December 31, 2007 and 2006.

Depreciation expense, including amortization on capital leases, was $439,000, $445,000 and $509,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

7. Accrued Compensation

Accrued compensation consists of the following:

(in thousands)	December 31, 2007	2006
Accrued payroll, vacation and incentive compensation	$1,674	$1,840
Accrued relocation	—	95
Total accrued compensation	$1,674	$1,935

8. Accrued Expenses

Accrued expenses consist of the following:

(in thousands)	December 31, 2007	2006
Accrued royalties	$1,185	$1,016
Accrued other	631	467
Total accrued expenses	$1,816	$1,483

9. Debt and Lease Obligations

Debt consists of the following:

(in thousands)	December 31, 2007	2006
Capital lease obligations	$ 44	$101
Less: current portion	(27)	(57)
Total long-term debt and capital lease obligations	$ 17	$ 44

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 2009. There were no borrowings outstanding under this agreement as of December 31, 2007 or 2006. 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 (5.02% as of December 31, 2007) 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 its equity ownership of its subsidiaries including BMSA, as collateral. Letters of credit issued in the ordinary course of business totaled $447,000 as of December 31, 2007, 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 €270,000 per year (approximately $400,000 as of December 31, 2007). The Company also has several operating leases covering certain pieces of manufacturing and office equipment through 2010.

The Company has 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, 2007, are as follows:

(in thousands)	Operating	Capital
2008	$ 725	$29
2009	474	11
2010	177	8
2011	—	—
Thereafter	—	—
Total lease commitments	$1,376	$48
Less amount representing interest		(3)
Present value of net minimum capital lease payments		$45

Total facility rental expense for the years ended December 31, 2007, 2006 and 2005 was approximately $650,000, $540,000 and $431,000, respectively.

10. Income Taxes

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)	2007	2006	2005
United States	$(2,875)	$(2,815)	$(3,100)
France	1,021	491	206
Pretax loss	$(1,854)	$(2,324)	$(2,894)

For the years ended December 31, 2007, 2006, and 2005, 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. During the years presented, the profit earned in France was fully offset by previous net operating loss carryforwards. 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.

As of December 31, 2007, the Company had federal net operating loss ("NOL") carryforwards of approximately $73.01 million, which will expire through the year 2027, state NOL carryforwards of approximately $24.00 million, which will expire through the year 2017, and foreign NOL carryforwards of approximately $3.76 million, which do not expire. During the year ended December 31, 2007 approximately $6.00 million of state NOLs expired. The Company has $185,000 of research and development credit carryforwards 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, 2007 and 2006 are as follows:

(in thousands)	December31, 2007	2006
Assets derived from the following:		
NOL carryforwards	$ 26,513	$ 26,981
Tax credit carryforwards	185	186
Other	702	374
Subtotal	27,400	27,541
Valuation allowance	(27,400)	(27,541)
Net deferred tax asset	$ —	$ —

Utilization of the NOL carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. The Company has not completed a study to assess whether an ownership change has occurred, or whether there have been multiple ownership changes since its formation, due to the significant complexity and related cost associated with such study. There also could be additional ownership changes in the future which may result in additional limitations in the utilization of the carryforward NOLs and credits.

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 carryforwards that included deductions for excess tax benefits from stock-based compensation. Included in the net operating loss carryforward stated above is approximately $7.64 million of unrealized excess tax benefit. In addition, the Company also has $2.38 million of additional net operating losses resulting from excess tax benefits that were recognized after the adoption of FAS 123R.

The Company has established a full valuation allowance against its deferred tax assets as of December 31, 2007, 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, 2006 to December 31, 2007 is a result of the increase in NOL carryforwards from the inclusion of the current period loss offset by a decrease in state NOL carryforwards due to expiration and the utilization of foreign net operating loss carryforwards.

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.

In June 2006, the FASB issued Interpretation No. 48, "*Accounting for Uncertainty in Income Taxes, an interpretation of FAS 109*" ("FIN 48"). This statement clarifies the criteria that an individual tax position must satisfy for some or all of the benefits of that position to be recognized in a company's financial statements. The Company adopted FIN No. 48 on January 1, 2007. The implementation of FIN No. 48 did not have a material impact on the Company's consolidated financial statements, results of operations or cash flows. At the adoption date of January 1, 2007, and also at December 30, 2007, the Company had no unrecognized tax benefits. The Company has not, as yet, conducted a study of its

research and development credit carryforwards; This study may result in an adjustment to the Company's research and development credit carryforwards, however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position under FIN 48. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheet or statement of operations if an adjustment were required.

11. Segment Information

The Company develops microspheres and other ancillary embolotherapy products for use in the treatment of uterine fibroids, other 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, attributable to countries according to the location of customers and equipment, is as follows:

	For the years ended December 31,		
(in thousands)	2007	2006	2005
Revenue:			
United States	$19,395	$16,458	$12,663
France	4,074	3,516	3,382
Other European Union countries	2,183	1,855	1,658
Other foreign countries	1,248	1,062	781
Total revenue	$26,900	$22,891	$18,484
Long-lived assets:			
United States	$ 340	$ 385	$ 297
France	784	544	561
Total long-lived assets	$ 1,124	$ 929	$ 858

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 accredited investors in a private placement. Upon payment of all offering expenses, the Company received net proceeds of approximately $13.50 million. 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, 2007, the Company issued 1,495 shares of series A preferred stock in payment of series A preferred stock dividends requirements.

13. Stock Plans

Stock Incentive Plans

As of December 31, 2007, the Company has granted options and/or restricted stock awards under the following three 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 expired March 2007 and, accordingly, has no shares available for future grant; (iii) 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 and 1997 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, 2007 there were 1,285,000 shares available for future grant under the 2006 Plan.

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, which 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 existing executive officers under the 2006 Plan. These 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 gains in the market price of 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 at the date of grant 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 method 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. In connection with the resignation of one of the Company's executive officers on July 27, 2007, the Company exercised its right to repurchase all 100,000 shares of the common stock issued to this executive at the price per share originally paid by the executive.

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.

As discussed in Note 2, the Company adopted SFAS 123R beginning January 1, 2006. Stock-based compensation expense relates to stock options, restricted stock and stock issued under the Company's employee stock purchase plan. 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. The Company recognizes compensation expense on fixed awards with pro rata vesting on a straight-line basis over the vesting period of such awards.

The fair value of stock options granted during the years ended December 31, 2007, 2006 and 2005 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,		
	2007	2006	2005
Options granted (in thousands)	441	620	483
Weighted average exercise price	$7.05	$7.01	$4.49
Weighted average grant date fair value	$4.48	$5.21	$3.19
Assumptions:			
Dividend yield	0%	0%	0%
Expected volatility	68%	83%	84%
Risk-free interest rate	4.41%	4.85%	3.77%
Expected term (years)	5.79	6.25	5.71

Historical Company information was the primary basis for the expected volatility and the expected term assumptions. SFAS 123R requires the application of an estimated forfeiture rate to current period expense to recognize stock-based compensation expense only for those awards expected to vest. The Company estimates forfeitures based upon historical data, adjusted for known trends, and will adjust its estimate of forfeitures if actual forfeitures differ, or are expected to differ from such estimates. Subsequent changes in estimated forfeitures will be recognized through a cumulative adjustment in the period of change and will also impact the amount of stock-based compensation expense in future periods.

Changes in outstanding stock options for the year ended December 31, 2007, were as follows:

(in thousands, except exercise price and term)	Number of Stock Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)
Outstanding at December 31, 2006	2,627	$5.04	
Granted	441	$7.05	
Exercised	(394)	$3.93	
Forfeited and expired	(454)	$6.73	
Outstanding at December 31, 2007	2,220	$5.29	7.20
Exercisable at December 31, 2007	947	$5.30	6.17
Vested or expected to vest at December 31, 2007	1,963	$5.29	7.10

The aggregate intrinsic value of stock options outstanding at December 31, 2007 of $2.38 million is calculated as the difference between the exercise price of the underlying stock options and the market price of the Company's common stock for the 1,272,550 shares of common stock underlying stock options that had exercise prices that were lower than the $5.13 closing market price of the Company's common stock at December 31, 2007. The aggregate intrinsic value of stock options vested or expected to vest at December 31, 2007 is $1.34 million. The aggregate intrinsic value of stock options exercisable at December 31, 2007 is $2.18 million. The total intrinsic value of stock options exercised was $338,000, $2.30 million and $2.56 million during the years ended December 31, 2007, 2006 and 2005, respectively, determined as of the date of exercise.

Changes in non-vested restricted stock awards for the year ended December 31, 2007, were as follows:

(in thousands, except fair value)	Number of Restricted Shares	Weighted Average Grant Date Fair Value
Non-vested at December 31, 2006	430	$1.73
Awarded	18	$6.84
Vested	(15)	$3.90
Forfeited	(100)	$1.45
Non-vested at December 31, 2007	333	$1.99

The aggregate intrinsic value of restricted shares outstanding at December 31, 2007 is $1.70 million.

At December 31, 2007, there was $4.17 million and $363,000 of unrecognized compensation cost, net of estimated forfeitures, related to non-vested stock options and restricted stock awards, respectively, which the Company expects to recognize over weighted-average periods of 2.98 years and 2.27 years, respectively. At December 31, 2006, there was $3.15 million and $579,000 of unrecognized compensation cost, net of estimated forfeitures, related to non-vested stock 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.

Employee Stock Purchase Plan

Under the 2000 Employee Stock Purchase Plan (the "2000 ESPP"), an aggregate of 100,000 shares of common stock may be purchased by employees at 85% of the fair market value on the first or last day of each six-month offering period, whichever is lower. During each offering period, the maximum number of shares that may be purchased by a participating employee is determined on the first day of the offering period and is equal to the number of shares of common stock determined by dividing $12,500 by the last reported sale price of the common stock on the NASDAQ Global Market on the first day of the offering. An eligible employee may elect to have up to a maximum of 10% deducted through payroll deductions from his or her regular salary. During 2007, 2006 and 2005, respectively, 18,370, 21,801 and 7,836 shares of the Company's common stock were issued under the 2000 ESPP. During the years ended December 31, 2007 and 2006, the Company recognized $17,000 and $43,000, respectively, of equity compensation related to the issuance of shares under the 2000 ESPP.

The following table presents the stock-based compensation expense relating to stock options, restricted stock and stock issued under the Company's employee stock purchase plan, for the years ended December 31, 2007 and 2006:

	For the Years Ended December 31,	
(in thousands)	2007	2006
Cost of product sales	$ 274	$195
Research and development	$ 93	$ 72
Sales	$ 237	$ 46
Marketing	$ 54	$ 18
General, administrative and patent	$1,178	$794

14. Employee Savings Plan

The Company has a 401(k) savings plan for all domestic employees pursuant to which eligible employees may voluntarily contribute up to $15,500 subject to statutory limitations. In addition, the Company matches in cash 50% of the first $3,000 contributed by employees up to a $1,500 maximum per employee per year. Employer cash matching contributions amounted to approximately $46,000, $43,000, and $36,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

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, 2007, 2006 and 2005 is as follows:

(in thousands)	Balance, Beginning of Period	Charged to Costs and Expenses	Deductions	Balance, End of Period
Year ended December 31, 2007	$218	$(38)	$(20)	$160
Year ended December 31, 2006	$233	$ (8)	$ (7)	$218
Year ended December 31, 2005	$184	$ 66	$(17)	$233

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 EmboGold 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. 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. Some pretrial discovery has been completed, but no party has disclosed any expert opinions. The case is presently set for trial on October 27, 2008. The Company intends to defend against the claims vigorously. However, the Company cannot give any assurance that it will prevail or that all or any part of its liability, if any, would be covered by its product liability insurance. Accordingly, the Company 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 revenue				
2007	$ 6,585	$ 6,974	$6,637	$6,704
2006	$ 5,269	$ 5,637	$5,644	$6,341
Gross profit				
2007	$ 4,490	$ 5,052	$4,740	$4,850
2006	$ 3,578	$ 3,968	$3,936	$4,451
Net loss applicable to common stockholders				
2007	$(1,172)	$ (405)	$ (453)	$ (381)
2006	$ (901)	$(1,115)	$ (500)	$ (333)
Basic and diluted net loss per share				
2007	$ (0.07)	$ (0.02)	$(0.03)	$(0.02)
2006	$ (0.06)	$ (0.06)	$(0.03)	$(0.02)

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

None.

Item 9A. CONTROLS AND PROCEDURES

1. Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2007. 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, 2007, our 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.

2. Internal Control Over Financial Reporting

a) Management's Annual Report on Internal Control Over Financial Reporting

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting for the Company. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of, the Company's principal executive and principal financial officers and effected by the Company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2007. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework.

Based on our assessment, management concluded that, as of as of December 31, 2007, the Company's internal control over financial reporting is effective based on those criteria.

b) Attestation Report of the Independent Registered Public Accounting Firm

We are a "non-accelerated filer," as defined in rules promulgated by the Securities and Exchange Commission. As such, our independent auditors are not currently required to issue, and have not issued, an audit report on our assessment of our internal control over financial reporting for the year ended December 31, 2007.

c) Changes in Control Over Financial Reporting

No change in our internal control over financial reporting occurred during the fiscal quarter ended December 31, 2007 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 2008 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 2008 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 2008 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 web site at *www.biospheremed.com*.

Item 11. EXECUTIVE COMPENSATION

The response to this item will be included in the definitive proxy statement for the 2008 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 2008 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 2008 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 2008 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, 2007 and 2006
Consolidated Statements of Operations—Years ended December 31, 2007, 2006 and 2005
Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss)—Years ended December 31, 2007, 2006 and 2005
Consolidated Statements of Cash Flows—Years ended December 31, 2007, 2006 and 2005
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 Index

Exhibit No.	Description	Incorporated by Reference			Filed with this 10-K
		Form	SEC Filing Date	Exhibit No.	
	Articles of Incorporation and Bylaws				
3.1	Certificate of Incorporation, as amended, of the Company	S-8	07/23/1999	4.1	
3.2	Certificate of Amendment of Certificate of Incorporation of the Company	10-K	03/24/2007	4.4	
3.2	Bylaws of the Company	S-8	06/10/1999	4.2	
3.3	Amendment to Bylaws of the Company	8-K	12/11/2007	3.1	
	Instruments defining the rights of security holders				
4.1	Specimen Certificate for shares of Common Stock, $.01 par value, of the Company	10-K	03/30/2000	4	
4.2	Certificate of Designations, Preferences and Rights of Series A Preferred Stock of the Company	8-K	11/15/2004	4.1	
4.3	Amendment No. 1 to Certificate of Designation, Preferences and Right of Series A Preferred Stock of the Company	8-K	05/23/2005	4.1	
	Material Contracts—financing agreements				
10.1	Share Purchase Agreement by and between Marie-Paule Leroy-Landercy and the Company dated December 31, 1998	10-K	03/30/2000	10.4	
10.2	Credit Agreement between the Company and Brown Brothers Harriman & Co. dated May 17, 2002	10-Q	08/14/2002	10.1	
10.3	Second Modification, dated as of June 30, 2004, to the Credit Agreement and Promissory Note by and between the Company and Brown Brothers Harriman & Co. dated May 17, 2002	10-Q	11/12/2004	10.1	
10.4	Third Modification, dated as of June 29, 2005, to the Credit Agreement and Promissory Note by and between the Company and Brown Brothers Harriman & Co. dated May 17, 2002	8-K	07/05/2005	10.1	

Exhibit No.	Description	Incorporated by Reference			Filed with this 10-K
		Form	SEC Filing Date	Exhibit No.	
10.5	Fourth Modification, dated as of June 29, 2007, to the Credit Agreement and Promissory Note by and between the Company and Brown Brothers Harriman & Co. dated May 17, 2002	8-K	07/03/2007	10.1	
10.6	Security Agreement between the Company and Brown Brothers Harriman & Co. dated May 17, 2002	10-Q	08/14/2002	10.2	
10.7	Securities Purchase Agreement, dated as of November 10, 2004, by and among the Company and the investors named therein	8-K	11/15/2004	10.1	
10.8	Investor Rights Agreement, dated as of November 10, 2004, by and among the Company and the investors named therein	8-K	11/15/2004	10.2	
10.9	Warrant No. 2004-1, dated as of November 10, 2004, issued to Cerberus Partners, L.P.	8-K	11/15/2004	10.3	
10.10	Amendment No. 1 to Warrant No. 2004-1, dated December 23, 2004, issued to Cerberus Partners, L.P.	8-K	12/30/2004	10.2	
10.11	Warrant No. 2004-2, dated as of November 10, 2004, issued to Sepracor Inc.	8-K	11/15/2004	10.4	
10.12	Amendment No. 1 to Warrant No. 2004-2, dated December 23, 2004, issued to Sepracor Inc.	8-K	12/30/2004	10.3	
10.13	Restrictive Covenants Agreement, dated as of December 23, 2004, by and among the Company, Cerberus Partners, L.P. and Sepracor Inc.	8-K	12/30/2004	10.1	
10.14	Securities Purchase Agreement, dated as of February 17, 2006, by and among the Company and the investors named therein	8-K	2/21/2006	10.1	
10.15	Registration Rights Agreement, dated as of February 17, 2006, by and among the Company and the investors named therein	8-K	2/21/2006	10.2	

Exhibit No.	Description	Incorporated by Reference			Filed with this 10-K
		Form	SEC Filing Date	Exhibit No.	
	Material Contracts—leases				
10.16	Lease Agreement dated January 7, 2000 by and between 1050 Hingham Street Realty Trust and the Company	10-K	03/30/2000	10.16	
10.17	First Amendment to Lease Agreement dated June 27, 2000 by and between 1050 Hingham Street realty Trust and the Company	10-K	03/29/2001	10.15	
10.18	Third Amendment to Lease between the Company and Thomas J. Teuten and John H. Spurr, Jr., Trustees of 1050 Hingham Street Realty Trust, dated February 24, 2006	8-K	2/28/2006	10.1	
10.19	Second Amendment to Lease between the Company and Thomas J. Teuten and John H. Spurr, Jr., Trustees of 1050 Hingham Street Realty Trust, dated January 24, 2005	8-K	01/27/2005	10.1	
10.20	Lease Agreement dated October 19, 2000 by and between the Company and Salamandre S.A. (translated from French to English)	10-K	03/29/2001	10.20	
	Material Contracts—collaboration agreements and licenses				
10.21	Form of Technology Transfer and License Agreement dated as of January 1, 1994 between the Company and Sepracor Inc.	S-1	02/14/1994	10.3	
10.22+	Joint Ownership Contract between the Company and L'Assistance Publique Hôpitaux de Paris dated January 5, 2998, together with amendment dated February 10, 2001 (translated from French)	10-K	03/30/2000	10.5	
10.23	Rider No. 2 dated June 20, 2000 to the Joint Ownership Contract between the Company and L'Assistance Publique Hôpitaux de paris dated January 5, 1998 (translated from French)	10-K	04/01/2002	10.5	
10.24+	Exclusive License Agreement between Dr. Shin-ichi Hori and the Company dated May 8, 2000	10-K	04/01/2002	10.6	

Exhibit No.	Description	Incorporated by Reference			Filed with this 10-K
		Form	SEC Filing Date	Exhibit No.	
10.25+	Exclusive License and Know-How Agreement No. L99037 by and between Le Centre National de la Recherche Scientifique, L'Universite Louis Pasteur Strasbourg and the Company dated July 15, 1999 (translated from French)	10-K	03/30/2000	10.10	
10.26+	Microspheres Yield Improvement Agreement with E.I. du Pont de Nemours and Company				X
	Material Contracts—management contracts and compensatory plans				
10.27(1)	1994 Director Option Plan	S-1	02/14/1994	10.2	
10.28(1)	1994 Stock Option Plan	S-1	02/14/1994	10.1	
10.29(1)	1997 Stock Incentive Plan	10-Q	08/08/1997	10.2	
10.30(1)	2006 Stock Incentive Plan	8-K	05/16/2006	10.1	
10.31(1)	Amendment No. 1 to 2006 Stock Incentive Plan	8-K	08/09/2006	10.1	
10.32(1)	Form of Nonstatutory Stock Option Agreement granted under 1994 Stock Option Plan	10-K	03/29/2005	10.4	
10.33(1)	Form of Incentive Stock Option Agreement granted under 1997 Stock Incentive Plan	10-K	03/29/2005	10.5	
10.34(1)	Form of Nonstatutory Stock Option Agreement granted under 1997 Stock Incentive Plan	10-K	03/29/2005	10.6	
10.35(1)	Form of Restricted Stock Agreement granted under 1997 Stock Incentive Plan	10-K	03/29/2005	10.7	
10.36(1)	Form of Incentive Stock Option Agreement granted under 2006 Stock Incentive Plan	8-K	05/16/2006	10.2	
10.37(1)	Form of Nonstatutory Stock Option Agreement granted under 2006 Stock Incentive Plan	8-K	05/16/2006	10.3	
10.38(1)	Form of Restricted Stock Agreement granted under 2006 Stock Incentive Plan	8-K	05/16/2006	10.4	
10.39(1)	Employment Agreement between the Company and Richard J. Faleschini, dated November 2, 2004	8-K	11/08/2004	10.2	

Exhibit No.	Description	Incorporated by Reference			Filed with this 10-K
		Form	SEC Filing Date	Exhibit No.	
10.40(1)	Executive Retention Agreement between the Company and Richard J. Faleschini, dated November 2, 2004	8-K	11/08/2004	10.3	
10.41(1)	Second Acknowledgement and Amendment Agreement between the Company and Richard J. Faleschini, dated April 5, 2007	10-Q	05/14/2007	10.2	
10.42(1)	Third Acknowledgement and Amendment Agreement between the Company and Richard J. Faleschini, dated October 10, 2007	8-K	10/12/2007	10.3	
10.43(1)	Letter Agreement between the Company and Martin J. Joyce, dated June 14, 2005	8-K	06/17/2005	10.2	
10.44(1)	Acknowledgement and Amendment Agreement between the Company and Martin J. Joyce, dated October 10, 2007	8-K	10/12/2007	10.1	
10.45(1)	Letter Agreement between the Company and Peter C. Sutcliffe, dated June 14, 2005	8-K	06/17/2005	10.3	
10.46(1)	Acknowledgement and Amendment Agreement between the Company and Peter C. Sutcliffe, dated October 10, 2007	8-K	10/12/2007	10.2	
10.47(1)	Letter Agreement between the Company and Gary M. Saxton, dated November 18, 2004	10-K	03/29/2005	10.28	
10.48(1)	Acknowledgement and Amendment Agreement Gary M. Saxton, dated April 8, 2007	10-Q	05/14/2007	10.1	
	Additional Exhibits				
14.1	Code of Business Conduct and Ethics of the Company	10-K	03/29/2005	14.1	
21.1	Subsidiaries of the Company	10-K	03/29/2001	21	
23.1	Consent of Ernst & Young LLP				X

Exhibit No.	Description	Incorporated by Reference			Filed with this 10-K
		Form	SEC Filing Date	Exhibit No.	
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, 2008				X
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 26, 2008				X
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, 2008				X
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 26, 2008				X

(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.

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, 2008

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, 2008
/s/ MARTIN J. JOYCE **Martin J. Joyce**	Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 26, 2008
/s/ TIMOTHY J. BARBERICH **Timothy J. Barberich**	Director	March 26, 2008
/s/ WILLIAM M. COUSINS, JR. **William M. Cousins, Jr.**	Director	March 26, 2008
/s/ MARIAN L. HEARD **Marian L. Heard**	Director	March 26, 2008
/s/ ALEXANDER M. KLIBANOV, Ph.D. **Alexander M. Klibanov, Ph.D.**	Director	March 26, 2008
/s/ JOHN H. MACKINNON **John H. MacKinnon, CPA**	Director	March 26, 2008
/s/ RICCARDO PIGLIUCCI **Riccardo Pigliucci**	Director	March 26, 2008
/s/ DAVID P. SOUTHWELL **David P. Southwell**	Director and Chairman of the Board	March 26, 2008

Officers

Richard J. Faleschini
President and Chief Executive Officer

Martin J. Joyce
Executive Vice President
and Chief Financial Officer

Melodie R. Domurad, Ph.D.
Vice President of Regulatory,
Medical Affairs, and Quality Systems

Willard W. Hennemann, Ph.D.
Vice President of New Product
and Business Development

Peter C. Sutcliffe
Vice President of Manufacturing

Joel B. Weinstein
Vice President of Global Marketing
and Sales

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 of the Board,
Sepracor Inc.

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

Marian L. Heard
President and Chief Executive Officer,
Oxen Hill Partners

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

John H. MacKinnon
Retired Partner,
Pricewaterhouse-
Coopers LLP

Riccardo Pigliucci
Managing Director,
Aldwych Associates, LLP

Market for Common Stock

The Common Stock of
BioSphere Medical, Inc.
is traded on the Nasdaq
Stock 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

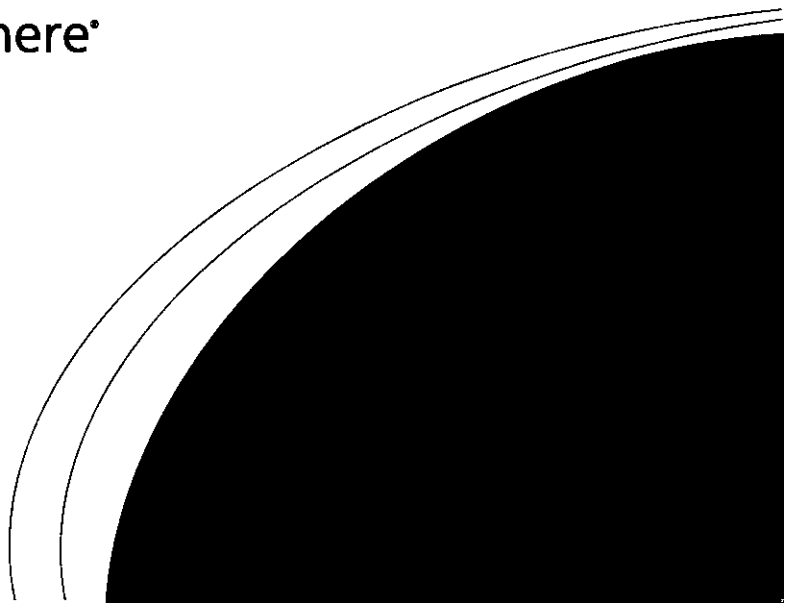
Ernst & Young LLP
200 Clarendon Street
Boston, MA 02116
617-266-2000

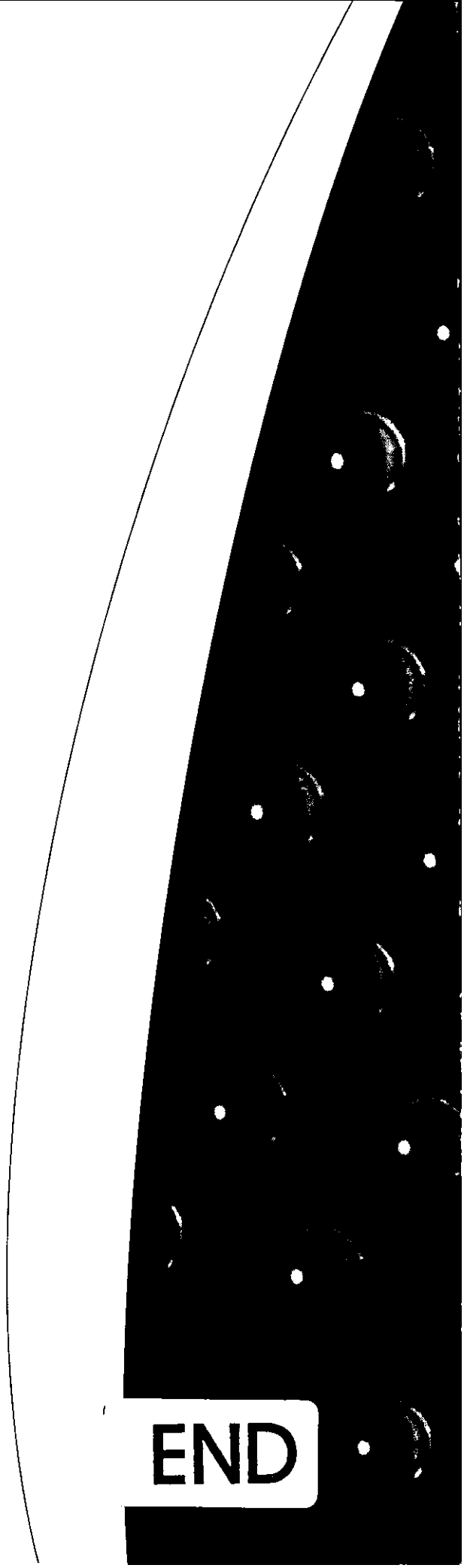
Annual Meeting

The Annual Meeting of Stockholders will be held at 9:00 AM on May 14, 2008, at Wilmer Cutler Pickering Hale and Dorr LLP, 60 State Street, Boston, MA 02109.

There are a number of important factors that could cause BioSphere's actual results to differ materially from those indicated by forward-looking statements in this annual report, including those risk factors identified in the filings that BioSphere makes from time to time with the SEC.

BioSphere® Medical





BioSphere® Medical

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www.ask4ufe.com

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